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In re: Power of Attorney of GUY D. FERRAIOLO, Principal	:	COURT OF COMMON PLEAS LEHIGH COUNTY – ORPHAN'S COURT
	:	NO. 2024-OC-0680

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFF'S EMERGENCY PETITION (ENTITLED COMPLAINT FOR EMERGENCY MEDICAL DECLARATORY JUDGMENT AND EMERGENCY INJUNCTIVE RELIEF)

Defendants, St. Luke's University Health Network and St. Luke's University Hospital – Bethlehem (hereinafter St. Luke's), by and through their undersigned counsel, hereby submit the Memorandum of Law in support of their Opposition to Plaintiff's Complaint for Emergency Medical Declaratory Judgment and Emergency Relief (entitled "Emergency Petition" by Court Order dated April 16, 2024).

I. INTRODUCTION

In this Declaratory Judgment action, Plaintiff (Ms. Moy) is asking this Honorable Court to intervene in the care of Mr. Ferraiolo ("the patient") through the extraordinary exercise of a mandatory injunction that would compel St. Luke's to administer or facilitate the administration of an experimental, unproven and inadvisable regimen of medications, including Ivermectin,

Mebendazole, Vitamin D, Itraconazole, EGCG, Melatonin, Curcumin, Omega 3 fatty acids, Doxycycline, Disulfiram and Vitamin C (hereinafter "experimental regimen"), to a cancer patient against the standard of care. St. Luke's Hospital and its physicians, pursuant to their duties to provide ethical, appropriate, and safe medical care, are unwilling to participate in the requested experimental regimen, as it is unproven and not standard of care.

The issue in this action is whether St. Luke's Hospital and its healthcare providers can be forced to administer an experimental treatment regimen, which they do not endorse, is unproven and not standard of care. The Superior Court has already answered this question in the negative, ruling that there is no legal right to compel a healthcare provider to administer a treatment contrary to the provider's professional judgment and outside the standard of care or to compel a hospital to grant privileges to an unvetted physician to administer the treatment. *Shoemaker v. UPMC Pinnacle Hospitals*, 283 A.3d 885, 896 (Pa. Super. 2022). In so ruling and reversing the trial court, the Superior Court further instructed:

> …judges are not doctors and cannot practice medicine from the bench. The judiciary is called upon to serve in black robes, not white coats. And it must be vigilant to stay in its lane and remember its role. Even if we disagree with a hospital's decision, we cannot interfere with its lawful exercise of discretion without a valid legal basis.

Id. at 897.

St. Luke's respectfully requests this Honorable Court to apply the Superior Court's clear holding in *Shoemaker* and deny Plaintiff's efforts to force St. Luke's to participate in and/or facilitate the administration of an unapproved experimental treatment regimen to a patient of its hospital.

II. STATEMENT OF FACTS AND PROCEDURAL HISTORY

Guy Ferraiolo was diagnosed with metastatic stage IV gastric carcinoma in January of 2024. Mr. Ferraiolo was advised in February that his condition was incurable. He was offered chemotherapy (FOLFOX) in an effort to prevent progression of the cancer. In February of 2024, Mr. Ferraiolo presented to the Emergency Department of St. Luke's Hospital – Bethlehem Campus due to symptomatic anemia and was admitted for treatment ("the current admission"). His medical history included essential hypertension, history of atrial fibrillation, uncontrolled type 2 diabetes, morbid obesity and sleep apnea. He remains in the hospital as of the time of this filing.

During the course of the current admission, Mr. Ferraiolo was found to have bleeding from his gastric tumors, requiring paracentesis (removal of fluid from the abdomen and peritoneal cavity), and was anemic. According to St. Luke's established blood transfusion protocols, Mr. Ferraiolo was given blood transfusions when his hemoglobin decreased below 7.0 g/dL. After Mr. Ferraiolo was properly stabilized, chemotherapy was started on February 29, 2024.[1] Unfortunately, Mr. Ferraiolo developed tumor lysis syndrome (TLS) in response to the chemotherapy, causing an acute kidney injury, worsening the patient's kidney function. Due to TLS, further palliative chemotherapy is not currently possible. The treatment team at St. Luke's recommended palliative/comfort care, which has been rejected by Plaintiff.

Plaintiff and Dr. Messina, Mr. Ferraiolo's healthcare proxy, have requested alternative therapies, which St. Luke's has reviewed and determined to be experimental and not within the standard of care. As recent as April 3, 2024, the hematology/oncology consultants advised the patient's POA that the requested medications, including Ivermectin, "are not FDA approved and

[1] On or about this same date, Ms. Moy inquired about administering IV Ozone therapy, and was advised that it was not FDA approved, and not recommended by the team treating him at St. Luke's.

not NCCN guidelines, and we do not recommend these treatments."[2] *See* April 3, 2024 note attached as Hospital #1. Mr. Ferraiolo signed a consent to enter the "Frontline Covid Critical Care Alliance observational cancer study using repurposed drugs (the "Care Study")." *See* Cmplt. at ¶ 18 and Research Participant Informed Consent Form "Investigational Use of Ivermectin and/or Other Repurposed Drugs for the Treatment of Cancer" Executed by Guy Ferraiolo (hereinafter "Consent"), Hospital #2. The consent form specifically admits that "ivermectin and/or other repurposed drugs…are not approved for the treatment of cancer by the FDA, they are considered investigational, not considered proven or established therapies and ***are not the current standard of care***." Consent at p. 1-2 (emphasis added).

St. Luke's has offered to transfer Mr. Ferraiolo to an institution willing to administer the "experimental regimen" should his condition allow such transfer. Instead, Plaintiff has chosen to file the instant Declaratory Judgment action seeking a mandatory injunction that would compel St. Luke's physicians to administer or facilitate the administration of an experimental and unproven regimen of medications to Mr. Ferraiolo against their medical judgment. Plaintiff seeks to compel St. Luke's to allow for the administration of an experimental and unproven regimen of medications, including Ivermectin, Mebendazole, Vitamin D, Itraconazole, EGCG, Melatonin, Curcumin, Omega 3 fatty acids, Doxycycline, Disulfiram and Vitamin C (hereinafter "experimental regimen"), to be overseen by Dr. Pierre Kory. *Cmplt.* at ¶ 3. Plaintiff, Mr. Ferraiolo, and Dr. Anthony Messina (noted to be Mr. Ferraiolo's health care proxy) have been

[2] NCCN is the National Comprehensive Care Network, "a not for profit alliance of 33 leading cancer centers devoted to patient care, research, and education. NCCN is dedicated to improving and facilitating quality, effective, equitable, and accessible cancer care so all patients can live better lives. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. By defining and advancing high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers around the world." See About (nccn.org) . Webpage attached as Hospital #3.

advised that the "experimental regimen" is unproven, not standard of care and would not be administered at St. Luke's.

At no point has Plaintiff submitted the proposed "Care Study" to the St. Luke's Clinical Trials and Research Department, which would be necessary for an experimental treatment to be approved at St. Luke's. Furthermore, the "Care Study" has not been submitted to St. Luke's Institution Review Board, a requirement for any experimental clinical trial to be administered at St. Luke's. *See* Affidavit of William A. Peters, D.O., Hospital #4.

The proposed regimen of "repurposed drugs" is based, in part, on a monograph authored by Paul Marik, M.D., entitled "Cancer Care" from the Frontline Covid Critical Care Alliance. This monograph specifically states in its "Caution to Patients" that:

> a. A repurposed drug is one that is used "off-label", a common basis for prescribing but which means that ***it has not been reviewed and approved by the U.S. Food and Drug Administration for that indication***. (emphasis added);
>
> b. This document represents the author's effort to provide educational materials and ***is not a peer reviewed publication***. (emphasis added); and
>
> c. No guarantees of benefit or the absence of harm can be offered, and reliance on any information provided is solely at your own risk.

See Cancer Care, pages 1-5, attached as Hospital #5. As acknowledged by the monograph itself, Ivermectin, Mebendazole, Atorvastatin, Itraconazole, Melatonin, Doxycycline, Disulfiram have not been approved by the FDA for use in cancer treatment. The experimental regimen has not been tested in clinical trials and has not been published in peer reviewed literature. [3]

[3] A search of the entire website of the NCCN notes "no search results for Ivermectin". *See* Search Result (nccn.org), Hospital #6.

Plaintiff, Denise Moy, as attorney in fact for Guy D. Ferraiolo, filed her Complaint in this Declaratory Judgment action on April 11, 2024, which was transferred to Lehigh County Court of Common Pleas Orphans' Court Division. On April 16, 2024, St. Luke's was served via electronic mail by the Clerk of the Orphans' Court with copies of the Plaintiff's Complaint, April 15, 2024 Order transferring the Emergency Petition to the Orphan's Court Division, Plaintiff's Motion for Pro Hac Vice admission of Ralph C. Lorigo, Esquire, April 15, 2024 Scheduling Order, and April 16, 2024 Revised Scheduling Order. Thereafter, St. Luke's filed its Answer with New Matter to Plaintiff's Complaint.

Now, St. Luke's files this Memorandum of Law in opposition to Plaintiff's requested injunctive relief. St. Luke's opposes Plaintiff's request for mandatory injunctive relief on the basis that Plaintiff does not have a legal right to injunctive relief pursuant to authoritative appellate case law, the experimental regimen is outside the standard of care, and Plaintiff cannot meet her burden to demonstrate that she is entitled to a mandatory injunction.

III. ISSUES PRESENTED

Whether St. Luke's Hospital and its healthcare providers can be compelled to administer medications that are experimental, not approved by the FDA and not standard of care?

Suggested Answer: No.

IV. ARGUMENT

"An injunction that commands the performance of an affirmative act," like requested here, is a mandatory injunction, "the rarest form of injunctive relief' and an "extreme remedy." *Wyland v. W. Shore Sch. Dist.*, 52 A.3d 572,582 (Pa. Commw. 2012); *Kesslerv. Broder*, 851 A.2d 944,946 (Pa. Super. 2004). The act of commanding the performance of some positive acts requires a "much stronger case" than those injunctions which seek to prohibit an act and that standard is already high. *See, e.g.*, *Roberts v. Bd. ofDirs. of Sch. Dist.*, 341 A.2d 475,478 (Pa.

1975). When a court considers whether to grant a mandatory injunction, it must examine the merits of the controversy and be satisfied that the petitioner has established a "clear right to relief." *Kessler*, 851 A.2d at 947 (*citing Mazzie v. Commonwealth*, 432 A.2d 985, 988 (Pa. 1981)). Furthermore, the petitioner **must establish each of the following prerequisites** for the injunction to issue:

1. An injunction is necessary to prevent immediate and irreparable harm that cannot be adequately compensated by damages.

2. Greater injury would result from refusing an injunction than from granting it, and, concomitantly, that issuance of an injunction will not substantially harm other interested parties in the proceedings.

3. The injunction will properly restore the parties to their status as it existed immediately prior to the alleged wrongful conduct.

4. The activity the injunction seeks to restrain is actionable, that its right to relief is clear, and that the wrong is manifest, or, in other words, the petitioner must show that it is likely to prevail on the merits.

5. The injunction it seeks is reasonably suited to abate the offending activity.

6. The preliminary injunction will not adversely affect the public interest.

Id. (*citing Summit Towne Centre, Inc. v. Shoe Show of Rocky Mt., Inc.*, 828 A. 2d 995, 1001 (Pa. 2003).

In this case, the Plaintiff cannot satisfy this extraordinarily high evidentiary burden. As stated above and with respect to the fourth prerequisite, a clear right to relief, the Superior Court has already held that there is no legal right to compel a healthcare provider to administer a treatment contrary to the provider's professional judgment and outside the standard of care or to compel a hospital to grant privileges to an unvetted physician to administer the treatment.

Shoemaker v. UPMC Pinnacle Hospitals, 283 A.3d 885, 896 (Pa. Super. 2022). The plaintiff's inability to satisfy this requirement requires denial of their injunction, but as noted below, other factors also require finding in favor of St. Luke's.

A. Under *Shoemaker v. UPMC Pinnacle Hospitals*, Plaintiff has no Legal Basis to Compel St. Luke's to Administer a Treatment Contrary to Medical Judgment and Outside the Standard of Care

In *Shoemaker*, a critically ill patient was admitted to the UPMC Harrisburg intensive care unit for treatment of his COVID-19 infection. During the admission, plaintiff, with power of attorney for the patient, filed a complaint seeking a declaratory judgment seeking to compel the hospital to follow a primary care physician's prescription to administer ivermectin to the patient. The Perry County Court of Common Pleas granted plaintiff's motion for a preliminary injunction and specifically directed hospital to allow two physicians, who were not credentialed at UPMC Harrisburg, or a nurse acting at their direction, to administer ivermectin to the patient at UPMC Harrisburg. UPMC appealed the trial court's decision.

Even though the patient's death rendered the appeal technically moot, the Superior Court chose to reach the merits of the appeal noting that the issues raised by the appeal were questions of public importance capable of repetition. *Id.* at 892. The Superior Court also stated that the appeal involved "a broad range of public policy issues involving the standard of care, ethical concerns of healthcare providers, and whether a court may direct a hospital to administer a certain treatment or to allow the administration of a certain treatment against hospital protocol, overriding the advice of medical professionals and hospital accreditation standards." *Id.*

The Superior Court exercised its discretion to address the merits of a technically moot appeal in order to establish a bright line rule that a patient does not have the legal right to either force a hospital to administer experimental medication regimens against the advice of the

patient's treating physicians and hospital protocol or to grant privileges to unvetted physicians to administer the experimental medication regimens on the hospital premises. By exercising its discretion to address the merits, the Superior Court provided the trial courts of Pennsylvania with clear appellate court precedent to rely upon when they are placed in the unenviable position of addressing these issues in the context of an emergency petition for a mandatory injunction seeking to compel hospitals and physicians to administer treatment outside the standard of care.

In reversing the trial court's decision to grant the mandatory injunction, the Superior Court noted that the trial court focused its attention on the wrong issue, i.e. whether ivermectin has potential benefits in treating COVID-19 patients. *Id.* at 894. The Superior Court instructed that the trial court should have focused its inquiry on whether the plaintiff had identified a *legal right* in need of protection through a mandatory injunction. *Id.* "More specifically, the trial court failed to evaluate whether Ms. Shoemaker established that Mr. Cauffman had the legal right to compel UPMC to administer a certain treatment that contravened its own hospital policy or to allow an uncredentialed physician to practice on its premises in violation of the hospital's protocols." *Id.* The Superior Court found that a patient has no such legal right.

"There is no precedent or applicable law to support the proposition that a patient has a legal right to demand a particular medical treatment against the advice of their treating physicians, to compel a hospital to allow the administration of a medical treatment that contravenes its own hospital policy, or to force a hospital to issue credentials to a physician to administer such a treatment." *Id.* The Superior Court observed that notably absent from the regulation that requires hospitals to establish a Patient's Bill of Rights, which, in part, provides that a "patient has the right to full information about his diagnosis, treatment, and prognosis as well as the right to refuse treatment," is "any language granting a patient the right to demand a

particular treatment or therapy, especially one against hospital protocol and outside the standard of care." *Id.* at 895.

As in *Shoemaker*, Plaintiff is unable to identify any legal right to demand treatment that is outside the standard of care. The position of the treating physicians at St. Luke's is that the requested treatment are not approved or standard. See Hospital #2. The consent executed by the patient admits that the experimental regimen is not approved for treatment of cancer by the FDA, not considered proven or established therapies for cancer, and are not the current standard of care. Consent at p. 1-2, Hospital #2. Accordingly, her request for a mandatory injunction must be denied.

B. Plaintiff cannot compel St. Luke's to allow Dr. Kory to practice medicine in its institutions

Plaintiff has also requested that their outside physician, Dr. Pierre Kory, be allowed to prescribe, administer, and monitor the effects of the experimental regimen. Dr. Kory does not have a license to practice medicine in Pennsylvania and is not approved or credentialed to practice medicine at St. Luke's.

The *Shoemaker* court also reviewed the trial court's order to allow an outside physician to practice within the walls of UPMC. The *Shoemaker* Court reviewed the purpose and importance of the peer review credentialing process. *Id.* at 896. Pennsylvania law places a legal duty on a hospital to select and retain only competent physicians as well as a duty to oversee all who practice medicine on its premises. *Id.* (*citing Thompson v. Nason Hosp.*, 591 A.2d 703 (Pa. 1991); *Whittington v. Episcopal Hosp.*, 768 A.2d 1144 (Pa. Super. 2001). Peer review is the common method by which hospitals exercise self-regulatory competence and evaluate physicians for privileges. *Id.* at 896. "The purpose of this privilege system is to improve the quality of health care, and reflects a widespread belief that the medical profession is best qualified to police

its own. Thus, it is beyond question that peer review committees play a critical role in the effort to maintain high professional standards in the medical practice." *Id.* The Superior Court held that "the trial court improperly interfered with the Hospital's discretion to select, retain, and supervise the physicians who practiced on its premises when it ordered the Hospital to allow uncredentialed physicians to administer ivermectin within the hospital's ICU." *Id.* Further, "[h]ospitals, not courts, have the resources and authority to determine whether a physician has the appropriate medical training, experience, and personal fitness to be eligible for medical staff privileges, especially within an intensive care unit." *Id.*

Dr. Kory does not have privileges with St. Luke's, and therefore is unable to practice within its walls, and under established precedent, St. Luke's cannot be compelled to credential him. *Shoemaker,* supra.[4]

C. The Care Study has not been approved for use at St. Luke's

In this case, Plaintiff is requesting an experimental treatment regimen that is outside the standard of care, contrary to the clinical judgment of Mr. Ferraiolo's treating physicians and against hospital protocol. The experimental regimen is not approved by the FDA for treatment of cancer, has not been tested in clinical trials, has not been published in peer reviewed literature, and is not the standard of care. For such treatment to be administered at St. Luke's, Dr. Kory or

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[4] In addition to *Shoemaker*, it should also be noted that "[e]very published appellate decision involving a request by a patient to force a hospital or doctor to administer ivermectin to treat COVID-19 has rejected that request." *Abbinanti v. Presence Cent. & Suburban Hosps. Network*, 2021 IL App (2d) 210763, ¶ 20 (App. Ct. Ill. Dec. 29, 2021); *see also Pisano v. Mayo Clinic Fla.*, No. 1D22-43, 2022 Fla. App. LEXIS 647 (Fla. App. Jan. 27, 2022); *Huguley, Inc. v. Jones*, No. 02-21-00364-cv, 2021 Tex. App. LEXIS 9432, 2021 WL 5405794 (Tex. App. Nov. 18, 2021); *DeMarco v. Christiana Care Health Services, Inc.*, No. 2021-0904-MTZ, 2021 Del. Ch. LEXIS 221, 2021 WL 4343661 (Del. Ch. Sept. 21, 2021)); *Frey v. Trinity Health-Michigan*, No. 359446, 2021 Mich. App. LEXIS 6988 (Mich. Ct. App. Dec. 10, 2021); *Smith v. W. Chester Hosp.*, LLC, No. CV 2021 08 1206, 2021 Ohio Misc. LEXIS 103 (Ohio Ct. Com. Pl. Sept. 6, 2021); *Cammarano v. Staten Island Univ. Hosp.*, 2021 NYLJ LEXIS 987 (N.Y. Sup. Ct. Sept. 20, 2021); *Marik v. Sentara Healthcare*, No. CL21-13852, 2021 Va. Cir. LEXIS 219 (Va. Cir. Ct. Nov. 23, 2021). Reported decisions, thus, have overwhelmingly denied or vacated injunctions to compel a healthcare provider to administer ivermectin for the treatment of patients with COVID-19.

another physician would be required to submit their research proposal to the St. Luke's Institutional Review Board.[5] *See* Affidavit of William A. Peters, D.O., Hospital #4.

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[5] The Institutional Review Board (IRB) of St. Luke's University Health Network (SLUHN) is a standing committee empowered to protect the rights and welfare of individuals recruited to participate in human research activities conducted under the auspices of the Institution. Except when an expedited or exempt review procedure is used, the IRB will review proposed research at a convened meeting at which a quorum is present. The IRB meets monthly, with an additional "back-up" meeting per month if necessary based on the number of items to be reviewed (45 CFR.103 (b) (4); 46.108).

The SLUHN IRB has been established in accordance with the laws of the State of Pennsylvania and New Jersey; the regulations of the Department of Health, the Department of Health and Human Services, and the U.S. Food and Drug Administration; the Medical Staff Bylaws; and in accordance with the guidelines of ICH-GCP (Good Clinical Practices); the Belmont Report, and the Declaration of Helsinki. The IRB is under the authority of the SLUHN General Council and the SLUHN Federal Wide Assurance (FWA) with the Department of Health and Human Services.

The purpose of the IRB is to protect the rights and welfare of human participants in biomedical and behavioral research conducted at SLUHN. The IRB is responsible for the review, approval and oversight of such research to assure that it meets the ethical principles established for research involving human participants, and that it complies with federal regulations that pertain to human research participant protection at 45 CFR, Part 46 and 21 CFR, Part 56 and any other pertinent regulations and guidance.

The function of the IRBs is to review and approve biomedical and behavioral research involving human participants that is conducted by SLUHN employees, utilizing SLUHN patients, or utilizing SLUHN facilities regardless of the source of funding and the location at which the research is performed. The authority to carry out this mandate is stated in 21 CFR 56.108(a(1); 108(b)(3); 109(a) (f); 113 and 45 CFR 160, 164. Consequently, the IRBs will review all research that:

- is sponsored by St. Luke's University Health Network
- is conducted by or under the direction of any faculty of SLUHN in connection with his/her institutional responsibilities
- is conducted by or under the direction of faculty of SLUHN using any property or facility of the St. Luke's University Health Network
- involves the use of the SLUHN nonpublic information to identify and contact human research participants
- involves the use or disclosure of protected health information

The SLUHN IRB may approve, require modifications to secure approval, or disapprove all human participants in research activities overseen and conducted by the organization (45CFR46.109(b)). In addition, the IRB has the authority to place restrictions on a study or require progress reports from the investigators and observe, or have a third party observe, the consent process (21CFR56.109(f)) and/or the conduct of the research (21CFR56.109(f)). They may also suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants (45CFR46.113).

SLUHN requires that all research involving human participants, or material or personal information from living humans, be reviewed and approved by the SLUHN IRB prior to initiation of any research activities. No intervention or interaction with human participants in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol.

Information on how to submit a request to the Institutional Review Board is readily obtained on the St. Luke's Health Network website. *See* https://slhn.org/research/institutional-review-board.

St. Luke's requires that all research involving human participants, or material or personal information from living humans, be reviewed and approved by the SLUHN IRB prior to initiation of any research activities. No intervention or interaction with human participants in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol. *See* Affidavit of William A. Peters, D.O., Exhibit "C". "Human subjects research" is any activity that either 1) meets the HHS definition of "research" involving "human subjects" as defined at 45 CFR 46.102(d)(e)(f) or 2) meets the FDA definition of "clinical investigation" involving "human subjects" as defined at 21 CFR 56.102(c)(e).

The function of the IRB is to review and approve biomedical and behavioral research involving human participants that is conducted by SLUHN employees, utilizing SLUHN patients, or utilizing SLUHN facilities regardless of the source of funding and the location at which the research is performed. The authority to carry out this mandate is stated in 21 CFR § 56.108(a)(1); 108(b)(3); 109(a) (f); 113 and 45 CFR 160, 164. 21 CFR 56.102(g) defines an IRB as "any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The term has the same meaning as the phrase institutional review committee as used in section 520(g) of the act." "An IRB shall review and have authority to

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See https://slhn.org/research/institutional-review-board.

approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations." 21 CFR §56.109(a). "IRB approval means the determination of the IRB that the clinical investigation has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements." 21 CFR §56.102(m). The regulation further provides that research "may be subject to further appropriate review and approval or disapproval by officials of the institution." 21 CFR §56.112.

It is undisputed that this Care Study has not been submitted for review or approved, as required by the policies of St. Luke's and, as such, the experimental regimen cannot be administered to Mr. Ferraiolo at St. Luke's.

D. Plaintiff's Willingness to Sign a Release is Irrelevant

It is anticipated that Plaintiff will argue that, because Plaintiff is willing to sign a release to relieve St. Luke's, its agents, assigns, any third parties acting on its behalf, and any doctors acting on its behalf, from any and all liability in complying with the Care Study and its treatment plan, the court should compel St. Luke's to administer the experimental regimen. *See* Cmplt. at ¶ 22. The Superior Court rejected this argument in *Shoemaker.* In The *Shoemaker* plaintiff made the same argument. The Superior Court rejected the argument explaining that the hospital could not be compelled to enter a waiver of liability agreement and was free to accept or reject the plaintiff's offer to release the hospital from liability associated with the experimental treatment. *Shoemaker,* at N. 6. Here, St. Luke's is not willing to execute a release because it is not willing to administer the experimental regimen to Mr. Ferraiolo.

E. Plaintiff Cannot meet the Extraordinarily High Evidentiary Burden to Demonstrate to this Court that she is Entitled to a Mandatory Injunction.

In an abundance of caution, and despite the clear appellate precedent precluding Plaintiff's legal right to a mandatory injunction, which relates primarily to the fourth prerequisite

factor, St. Luke's also argues that Plaintiff cannot satisfy her burden under the remaining factors. Specifically, Plaintiff's requested mandatory injunction would (1) alter rather than maintain the status quo, (2) cause substantial harm to St. Luke's, (3) not prevent immediate and irreparable harm because the experimental regimen is not an effective cancer treatment, (4) not abate an offending activity, and (5) cause substantial harm to the public interest.

1. The mandatory injunction would alter rather than maintain the status quo

"A preliminary injunction is to put and keep matters in the position in which they were before the improper conduct of the defendant commenced." *Chipman v. Avon Grove Sch. Dist.*, 841 A.2d 1098, 1101 (Pa. Commw. 2004). "The sole object of a preliminary injunction is to preserve the subject of the controversy in the condition in which it is when the order is made, it is not to subvert, but to maintain the existing status until the merits of the controversy can be fully heard and determined." *Id.* A "mandatory preliminary injunction is designed to restore the status quo to the last actual, peaceable and noncontested status which preceded the pending controversy." *Shanaman v. Yellow Cab Co.*, 421 A.2d 664, 666 (Pa. 1980). "While the purpose of all injunctions is to preserve the status quo, prohibitory injunctions do this by forbidding an act or acts while mandatory injunctions command the performance of some specific act that will maintain the relationship between the parties." *Ambrogi v. Reber*, 932 A.2d 969, 974 (Pa. Super. 2007).

Plaintiff does not plead that Mr. Ferraiolo was ever treated with the experimental regimen while admitted in St. Luke's Hospital. As such, Plaintiff's action seeking a mandatory injunction seeks to alter the status quo between the parties rather than maintain it. As argued above, Plaintiff seeks to force St. Luke's to administer an experimental medication regimen to a cancer patient in its hospital contrary to the standard of care, medical judgment of its physicians, and

hospital protocol. Plaintiff's action does not seek to preserve the status quo until such time as the merits of the controversy can be fully heard and determined, rather it seeks to obtain improper affirmative relief that is not countenanced under the preliminary injunction procedure.

2. Granting the mandatory injunction will cause substantial harm to St. Luke's

St. Luke's will be substantially harmed if this Honorable Court were to grant Plaintiff's mandatory injunction. If this Honorable Court were to award injunctive relief to the Plaintiff, it would represent an extraordinary intrusion into the medical profession and compel St. Luke's and its physicians to act contrary to the standard of care, the ethical and professional duties of the medical profession, and potentially expose St. Luke's and its providers to legal liability.

While Pennsylvania law supports an individual's right to make decisions relating to their own healthcare, the right is a qualified right, not an absolute one. 20 Pa. C.S.A. § 5423(c)(I). The right to make healthcare decisions for oneself is subject to certain interests of society, such as the maintenance of ethical standards in the medical profession. 20 Pa. C.S.A. § 5423. Under Pennsylvania law, if a physician cannot in good conscience comply with a health care decision of a health care agent or health care representative or if the policies of a health care provider preclude compliance, the provider has a right to decline. 20 Pa. C.S.A. § 5424. Likewise, a healthcare provider is not subject to liability when acting in good faith and in accordance with acceptable medical standards of care when the provider declines to "comply with a direction or decision of an individual based on a good faith belief that compliance with the direction or decision would be unethical or, to a reasonable degree of medical certainty, would result in medical care having no medical basis in addressing any medical need or condition of the individual." 20 Pa. C.S. A. § 5431.

A patient's rights do not include the right to dictate treatment or demand medication. The fact that a patient always has the legal right to refuse a particular treatment does not imply that the patient enjoys a corresponding right to extort a hospital into providing whatever purported treatment the patient desires. A patient cannot simply appear at a hospital, demand a heart transplant or pain medication, and then seek judicial intervention to force the hospital's hand. Acceding to such demands would subvert the entire healthcare delivery system.

Instead, treatment decisions must be made according to the standard of care as determined by the treating practitioner's knowledge and experience. If this Honorable Court were to accede to Plaintiff's request for injunctive relief based on the rationale that the urgency of a terminal diagnosis enables a patient or their healthcare proxy to demand any form of treatment completely disregarding their physician's medical judgment, hospital governance and protocol and the established standard of care, it would substantially harm St. Luke's by undermining its ability and the ability of its physicians to practice medicine based on their medical judgment and the standard of care.

Because a medical provider is responsible for knowing and implementing the standard of care in the treatment of a patient, Pennsylvania law does not recognize the assumption-of- the-risk defense for medical providers who fail to meet the standard of care at the patient's request. *Mitchell v. Shikora*, 209 A.3d 307, 317 (Pa. 2019). While Plaintiff's Complaint alleges that Plaintiff has offered to sign a release purporting to relieve St. Luke's from liability concerning the administration of the experimental regimen, a pre-injury exculpatory release cannot generally absolve a party from gross negligence or recklessness. *Feleccia v. Lackawanna Coll.*, 215 A.3d 3, 19 (Pa. 2019).

Moreover, Pennsylvania law is not alone in this regard. For example, as noted by the Delaware Superior Court, "there is virtually no scenario in which a patient can consent to allow a healthcare provider to exercise less than ordinary care. Even if given a patient's consent to allow a healthcare provider to exercise less than ordinary care would be specious when considered against the strict legal, ethical and professional standards that regulate the healthcare profession." *Storm v. NSL Rockland Place, LLC,* 898 A.2d 874, 883 (Del. Super. Dec. 29, 2005). As a result, a healthcare provider owes its patients a generally accepted standard of care, and a patient can neither consent to, nor release a healthcare provider from, care that falls below that standard. If Plaintiff were to succeed in forcing St. Luke's to knowingly provide treatment outside the standard of care, St. Luke's and its physicians would be subject to substantial harm in the form of legal liability.

3. An injunction is not necessary to prevent immediate and irreparable harm because the experimental regimen is not an effective cancer treatment

With respect to the prerequisite requiring Plaintiff to prove that an injunction is necessary to prevent immediate and irreparable harm, Plaintiff cannot meet this burden because the experimental regimen is not an effective treatment for cancer. *See* Consent (admitting that Ivermectin and the other "repurposed drugs" are not approved for the treatment of cancer by the FDA, they are considered investigational, not considered proven or established therapies and are not the current standard of care.), Exhibit "B". Plaintiff and Mr. Ferraiolo were advised by his hematology/oncology consultants that the requested medications, including Ivermectin, are not FDA approved, do not comply with NCCN guidelines and are not recommended. 4/3/2024 Progress Note, Hospital #1. The experimental regimen has not been tested in clinical trials and has not been published in peer reviewed literature.

This is all to say that the experimental regimen being promoted by the FLCCC, to this point, has not been tested in clinical trials for safety and efficacy, has not been vetted through the process of peer reviewed publication, is not approved for treatment of cancer by the FDA, and has not gained recognition from the larger medical community as an effective treatment for cancer. Because the FLCCC experimental treatment regimen remains fringe medicine and is not recognized as an effective treatment of cancer, it cannot be said that denying Plaintiff's request to compel administration of this experimental treatment regimen will result in immediate and irreparable harm.

4. The injunctive relief sought by Plaintiff would not abate an offending activity

One of the prerequisites the Plaintiff must prove is that the injunction sought is reasonably suited to abate the offending activity. As argued above, the *Shoemaker* Opinion makes clear that a hospital being unwilling to administer medication to a patient outside the standard of care or grant privileges to an unvetted physician to administer medication to a patient outside the standard of care is not an offending activity or one that results in a cause of action accruing to the patient or his power of attorney. In this case, St. Luke's has not engaged in an "offending activity."

5. Granting injunctive relief to the Plaintiff will cause substantial harm to the public.

It would be harmful to the public for a court to compel a hospital to violate its standard of care, to mandate that medical professionals provide care that they believe is medically unnecessary, to dissolve the fiduciary duty between patient and provider, and to medicate from the bench. Public policy does not support the use of "any" type of treatment on its patients. Rather, public policy supports the safe and effective development of medications and medical practices. The advocacy for ivermectin as a COVID-19 therapeutic or cancer treatment should be carried out

by approved clinical trials, not by forcing hospitals to conduct experiments on their patients in violation of their professional, ethical and legal duties. Granting Plaintiff's mandatory injunction would create a dangerous precedent that patients who have incurable diseases may obtain judicial substitution for medical judgment and the established standard of care. The Superior Court made it clear that trial courts must exercise appropriate judicial restraint when addressing these types of legal challenges.

If this Honorable Court were to grant Plaintiff's requested injunctive relief, it would only serve to incentivize groups like the FLCCC to continue to attempt to leverage the urgency created by terminal diagnoses into court orders that compel health care providers and hospitals to administer unapproved cocktails of medication against their own qualified medical judgment and outside the standard of care. If FLCCC wants to prove that its experimental treatment regimen is an effective cancer treatment it must do so through a scientific process not a judicial one. The scientific validity of an experimental treatment regimen must be proven through objective, validated data and analysis not through the anecdotal testimony of a single physician in an emergency hearing in a court of law.

Furthermore, if this Honorable Court were to issue a public opinion granting the requested injunctive relief it would erode the concept of a standard of care and undermine the public's faith in the medical profession and would open the proverbial flood gates for lawsuits seeking to compel a physician or hospital to provide treatment that contravenes medical judgment, is medically unnecessary, or outside the standard of care. As stated wisely stated by the Superior Court when it instructed Pennsylvania courts to exercise judicial restraint, "...judges are not doctors and cannot practice medicine from the bench. The judiciary is called upon to serve in black robes, not white coats. And it must be vigilant to stay in its lane and remember its role. Even if we disagree with

a hospital's decision, we cannot interfere with its lawful exercise of discretion without a valid legal basis." It is respectfully requested that this Court uphold these principles of judicial restraining and deny Plaintiff's request for mandatory injunctive relief.

V. CONCLUSION

WHEREFORE, St. Luke's University Health Network and St. Luke's University Hospital – Bethlehem respectfully request this Honorable Court to deny Plaintiff's request for mandatory injunctive relief.

Respectfully submitted,

Date: 4/18/2024

/s/ Mark R. Zolfaghari
Mark R. Zolfaghari
Attorney for Defendants
St. Luke's University Health Network and
St. Luke's University Hospital – Bethlehem

CERTIFICATE OF COMPLIANCE

I certify that this filing complies with the provisions of the *Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts* that requires filing confidential information and documents differently than non-confidential information and documents.

Dated: April 18, 2024

/s/ Mark R. Zolfaghari
Mark R. Zolfaghari, Esq.

CERTIFICATE OF SERVICE

I, Mark R. Zolfaghari, Esquire, hereby certify that on April 18, 2024, I served a copy of the Memorandum of Law in support of Defendants' Opposition to Plaintiff's Emergency Petition (Entitled Complaint for Emergency Medical Declaratory Judgment and Emergency Injunctive Relief), via email upon the following:

Robert N. Rust, III, Esquire
Rust Law, LLC
4461 Kohler Drive
Allentown, PA 18103
rnrust@rustlawllc.com

Ralph C. Lorigo, Esquire
101 Slade Avenue
Buffalo, NY 14224
rlorigo@lorigo.com

/s/ Mark R. Zolfaghari
Mark R. Zolfaghari

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Mar 06, 2024

Research Participant Informed Consent Form

Investigational Use of Ivermectin and/or Other Repurposed Drugs for the Treatment of Cancer

TITLE:	A multicenter Observational Study evaluating the impact of repurposed drugs and metabolic therapies on the outcome of patients with cancer.
PROTOCOL NO.:	None WCG IRB Protocol #20240731
SPONSOR:	FLCCC Alliance
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number(s) (24 hours) [24 hour number is required]

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

This form sets forth important information about the nature of this investigation into the safety and clinical value of ivermectin and/or other repurposed drugs as well as dietary interventions for the treatment of cancer, primarily for the remission of malignant tumors. A "repurposed" drug, also known as a prescription for an "off-label" use, is a drug that has been approved for another indication by the US Food and Drug Administration ("FDA") but not for the proposed indication. Off-label prescribing is quite common, accounting for between 20 and 40% of all prescriptions. These drugs are not approved for the treatment of cancer by the FDA, they are

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considered investigational, not considered proven or established therapies and are not the current standard of care.

You are being asked to participate in this research study because you are currently receiving treatment for your cancer with repurposed medications and dietary interventions. If you choose to participate in this research study, you will not receive medication or treatment for your cancer. This is an observational study where only medical record data will be collected. Please read this form carefully, as well as the Informed Consent Form for Complementary and Supportive Therapies for Cancer Patients.

Patient Name: ___Guy Ferraiolo_____

[redacted]

Address: _____

Telephone: _Cell 732-618-0250 GF, Dr Messina POA 385 313 4170_____ Date of Birth_April 26, 1953_____ Age___71_____ Sex_____M___

Diagnosis_gastric cancer stage 4_____ Enrollment Date__3/11/24_____

Human Subject Research Consent

This study is designed to assess the safety and clinical effectiveness of ivermectin and/or other repurposed drugs for cancer treatment, primarily the remission of malignant tumors. This practice is participating in an observational study that is being conducted by a number of health care practitioners at their individual treatment sites. Patients who are already undergoing cancer treatment may be eligible to participate in this study. Your treatment plan will NOT be changed/altered by enrollment into this study.

This research project will follow your care for a five-year period, which will provide the researchers insight into the safety and effectiveness of adding these repurposed drugs to treatment regimens as well as of the other drug and metabolic therapies provided by your

practitioner and others involved in this study. While each practitioner may use a variety of repurposed drugs and functional medicine approaches including dietary interventions, ivermectin will be the core additional medication used in most research subjects. Depending on your circumstances and wishes, you may concurrently receive "conventional" cancer treatments from your healthcare practitioner while participating in this study.

Participation Agreement

Please review the following information and initial your understanding and agreement. Please ask your physician or their staff any questions:

Limitations of Researcher Direction and Responsibility

Except for the addition of the repurposed drug(s), enrollment in this study will not alter the treatment approach that your practitioner follows. Your practitioner will otherwise continue to formulate and treat you using their unique approach.

I understand that other than the addition of any repurposed drugs, the researchers are not directing nor are responsible for any of the treatment choices made by my practitioner.

Patient initial

IRB Participation

This study is being done under the auspice of an Institutional Review Board ("IRB") which will monitor the study and its methods and human subject protections.

Patient initial

Completion of Treatment

Your participation in this research is a valuable contribution that will provide real world data to assist in determining optimal treatment approaches. In order to collect proper data, it is important that you complete the therapy to allow us to understand the impacts of your treatments over the five-year term of the study.

Patient demographic and clinical data will be collected in a standardized data collection form. The data collected will include both retrospective (existing data) as well as prospective data. Patients may be asked to complete forms describing their progress and agree to complete all of

these surveys even if your participation in treatment has concluded. You should fully describe and update any treatment regimen you are currently undergoing elsewhere, including other cancer treatments and dietary supplements such as herbs, to assess any potential interactions and to ensure the accuracy of the study.

I realize that my full and honest responses to these surveys and cooperation are vital to the completion of this research project and the advancement of knowledge about this therapy.

Patient's initials

I agree to complete the data collection of my recommended course of treatments, which has been explained to me, unless there are clinical reasons, such as side effects, that make it inadvisable to continue.

Patient initial

Continuation

Patients' participation in the study is not a guarantee that treatment will be continued. If your physician believes that the use of the repurposed drug or other treatment should be discontinued, the clinical decision should be made in consultation with your physician and other specialists independent of your participation in this study.

Participation in this study is voluntary. No one has to participate in this study; present or future care will not be affected by choice in participation. Patients can change their mind and drop out of this study at any time. Further, physicians in charge of this study may decide either that continued treatment is not appropriate, or indicated, or to end a patient's participation in this study at any time, after explaining the reason(s) for doing so and helping arrange for other appropriate care.

Patient initial

Financial Responsibility /Insurance Issues

Ivermectin as well as the other repurposed drugs and nutraceuticals which will be recommended/prescribed are generally inexpensive drugs but their costs will not be covered by

Medicare or insurance as its use in cancer treatment would be excluded as investigational or experimental. Your treatment otherwise will continue on the same financial terms you have with your practitioner.

You will not be paid for being in this study.

Patient initial

Benefits/No Guarantee

There is no direct benefit for participating in this research study. Your taking part in this study may help people with cancer by giving us a better understanding about the treatment of your disease.

Patient initial

Risks There is a risk of loss of confidentiality for participating in this study.

Patient's initials

Alternatives to Participation

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

Contraindications/Exclusions

It is important that patients accurately provide historical information prior to participation in this study, including other medical conditions, and update it on an ongoing basis. Certain conditions may make it unsafe or otherwise inadvisable to participate.

In order to ensure that I can safely participate in this study, I will provide complete medical information on an ongoing basis.

Patient initial

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Medical Information

In order to help assess the impact of this treatment, it is important for the investigators to have information about other medical treatments that patients undergo prior to and during the study period, including throughout the follow-up self-reporting and follow-up period, such information reported to the principal investigators, who are not on-site will not include any identifying information but coded to allow comparison with reported study data.

I consent to allowing information about other treatments I receive for the indications I am being treated for in this study to be given to principal investigators on–site, or to principal investigators off –site without any identifying information.

Patient's initial

Confidentiality of Patient Records

All participants' names and data will be coded by the physician participating in the study. The key to the code will be kept in a secure, locked location. The research does not involve the collection of identifiable private information or identifiable biospecimens. Only de-identified information will be forwarded to any off-site investigators or researchers. Researchers managing and analyzing the data will not have access to identifying information. No information will be released or published in any manner that would identify an individual without the written informed consent of said individual.

In the event you believe your privacy has been breached, or you have any concerns about your privacy, contact the CENTER's treating physician or the study doctor listed on the first page of this document.

I consent to the principal investigator on location at my treatment location to have access to my medical record for the sole purpose of collecting data and providing research oversight.

Patient initial

Except to the extent described in the optional release I may have signed above, information contained in patients' records may not be given to anyone unaffiliated with this study in a form

that could identify a patient without their written, informed consent, as described in this consent form or except as required by law.

It is possible that patients' medical and research data may be inspected and/or copied by the study sponsor (and /or its agent, the Food and Drug Administration (FDA), WCG IRB or other federal or state government agencies in the course of carrying out their duties. If a patient's record is inspected or copied by any agency, the principal investigators or the study will use reasonable efforts to protect patient privacy and the confidentially of medical research information.

The results of this study may be published in a medical journal or used for teaching purposes. However, any identifying information will not be used in any publication or teaching materials without specific, written permission. In addition, if photographs, audiotapes or videotapes were taken during the study that could identify a patient, then special written permission for use must first be given. In that case, there will be an opportunity to view or to listen, as applicable, to the photographs, audiotapes or videotapes before permission for use is given.

Patient initial

Availability of Additional Information/ Protecting Your Rights
Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to me.

A copy of this consent form will be provided upon request, and further questions about this study may be asked at any time. The investigators' telephone numbers are provided, and any significant new findings discovered during the course of this study that might influence continued participation will be provided.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.

- You have questions about your rights as a research subject.

Further, privacy concerns may be addressed with the treating physician and the principal investigator noted above. Serious breaches not resolved by these contacts can be addressed with the http://www. Hhs.gov/ocr/privacy/hipaa/complaints/index.html

Patient initial

If Problems Develop

I understand that monetary compensation for injury sustained as a result of this investigational research is not routinely available nor can medical treatment rendered as a result of an injury be offered.

Patient *initial*

Treatment and Study Participation Agreement

I wish to enroll in this study and authorize CENTER physicians, practitioners and staff or those associated and working with them on this study, to obtain data regarding the therapy and the care required in order to implement the study design. I confirm that the purpose of the research, the study procedures and the possible risks and discomforts I may experience by participating in this study have been discussed. I have read and understood this consent form. All my questions have been satisfactorily answered and I feel I have sufficient understanding of this subject matter to be able to give my informed consent. I intend to complete the course of therapy and study surveys and other data collection instruments. While I intend to commit for the duration of the study, I understand that I am free to withdraw my consent to participate at any time. Should I choose to do so, I have received assurances that my rights to receive care from my physician for medical care in the future will in no way be prejudiced. My signature below indicates my consent to treatment and willingness to participate in this study.

Subject Signature

Date

GUY FERRAIOLO

Subject Printed Name

Witness(if required) Date 3/11/24

I have explained the nature of and purpose of this research, the study procedures and have answered any questions regarding the study to the best of my ability.

ANTHONY MESSINA MD 3/11/2024

Ordering/Treating Physician obtaining informed consent Date

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****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff. They may also share the research information with an agent for the study doctor, if applicable.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

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Authorization:

I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

Signature of Subject

3/11/2024
Date

About

The National Comprehensive Cancer Network® (NCCN®) is a not-for-profit alliance of 33 leading cancer centers devoted to patient care, research, and education. NCCN is dedicated to improving and facilitating quality, effective, equitable, and accessible cancer care so all patients can live better lives. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. By defining and advancing high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers around the world.

World-renowned experts from NCCN Member Institutions diagnose and treat patients with a broad spectrum of cancers and are recognized for dealing with complex, aggressive, or rare cancers. NCCN Member Institutions pioneered the concept of the multidisciplinary team approach to patient care and conduct innovative research that contributes significantly to understanding, diagnosing, and treating cancer. NCCN programs offer access to expert physicians, superior treatment, and quality and safety initiatives that continuously improve the effectiveness and efficiency of cancer care globally.

Hospital # 3

Who We Are

An alliance of leading cancer centers devoted to patient care, research, and education

Why We Exist (Our Mission)

To improve and facilitate quality, effective, equitable, and accessible cancer care so all patients can live better lives

Our Vision

To define and advance high-quality, high-value, patient-centered cancer care globally

Our Core Values

The NCCN Core Values represent the principles that we, the NCCN team, strive to embrace. As representatives of leading cancer centers, we believe that by exemplifying these ideals within our organization, we can improve and facilitate quality, effective, equitable, and accessible cancer care so all patients can live better lives as outlined in our mission statement and vision statement.

View the NCCN Core Values

View the NCCN Annual Report

View NCCN History

NCCN's Commitment to Diversity, Equity, and Inclusion in Our Content

View NCCN's Guidance on Inclusive Language

Read a Special Feature in JNCCN

- NCCN Member Institutions
- NCCN Leadership
- Advancing Cancer Equity
- NCCN Employment Opportunities
- Permissions Requests
- NCCN Patents
- NCCN News
- NCCN Foundation
- NCCN Supporter Opportunities
- NCCN Corporate Council and Global Corporate Council

NCCN Policies

Safe Vincristine Handling: Just Bag It

3025 Chemical Road, Suite 100, Plymouth Meeting, PA 19462
Phone: 215-690-0300 Fax: 215-690-0280

St. Luke's University Health Network
By: Mark R. Zolfaghari
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Mark.Zolfaghari@sluhn.org
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(484) 526-2642

Attorneys for Defendant,
St. Luke's University Health Network and St. Luke's University Hospital – Bethlehem

	COURT OF COMMON PLEAS LEHIGH COUNTY – ORPHANS' COURT DIVISION
In re: Power of Attorney of GUY D. FERRAIOLO Principal	CIVIL ACTION
	NO. 2024-OC-0680

AFFIDAVIT OF WILLIAM A. PETERS, D.O.

1. I am a licensed physician in the state of Pennsylvania.
2. I am a board certified practicing radiologist at St. Luke's University Health Network.
3. I serve as the Vice Chair of The Institutional Review Board of St. Luke's University Health Network.
4. The Institutional Review Board (IRB) of St. Luke's University Health Network (SLUHN) is a standing committee empowered to protect the rights and welfare of individuals recruited to participate in human research activities conducted under the auspices of the Institution.
5. The SLUHN IRB has been established in accordance with the laws of the State of Pennsylvania and New Jersey; the regulations of the Department of Health, the Department of Health and Human Services, and the U.S. Food and Drug Administration;

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the Medical Staff Bylaws; and in accordance with the guidelines of ICH-GCP (Good Clinical Practices); the Belmont Report, and the Declaration of Helsinki.

6. The purpose of the IRB is to protect the rights and welfare of human participants in biomedical and behavioral research conducted at SLUHN.
7. The IRB is responsible for the review, approval and oversight of such research to assure that it meets the ethical principles established for research involving human participants, and that it complies with federal regulations that pertain to human research participant protection at 45 CFR, Part 46 and 21 CFR, Part 56 and any other pertinent regulations and guidance.
8. The function of the IRB is to review and approve biomedical and behavioral research involving human participants that is conducted by SLUHN employees, utilizing SLUHN patients, or utilizing SLUHN facilities regardless of the source of funding and the location at which the research is performed. The authority to carry out this mandate is stated in 21 CFR 56.108(a(1); 108(b)(3); 109(a) (f); 113 and 45 CFR 160, 164. Consequently, the IRBs will review all research that:
    - is sponsored by St. Luke's University Health Network
    - is conducted by or under the direction of any faculty of SLUHN in connection with his/her institutional responsibilities
    - is conducted by or under the direction of faculty of SLUHN using any property or facility of the St. Luke's University Health Network
    - involves the use of the SLUHN nonpublic information to identify and contact human research participants
    - involves the use or disclosure of protected health information
9. SLUHN requires that all research involving human participants, or material or personal information from living humans, be reviewed and approved by the SLUHN IRB prior to

initiation of any research activities. No intervention or interaction with human participants in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol.

10. "Human subjects research" is any activity that either 1) meets the HHS definition of "research" involving "human subjects" as defined at 45 CFR 46.102(d)(e)(f) or 2) meets the FDA definition of "clinical investigation" involving "human subjects" as defined at 21 CFR 56.102(c)(e).

11. 45 CFR 46.102 defines "research" as follows:

> Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:
>
> (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
>
> (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
>
> (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

> (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

12. 45 CFR 46.102 defines "research" as follows:

> Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
>
> (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
>
> (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

13. 21 CFR 56.102(c) defines "clinical investigation" as follows:

> Clinical investigation means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part.

14. 21 CFR 56.102(c) defines "human subject" as follows:

> Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

15. It is my understanding that Mr. Ferraiolo seeks to participate in the "Frontline Covid Critical Care Alliance observational cancer study" using repurposed drugs.

16. In order to participate in the "Frontline Covid Critical Alliance observational cancer study" at St. Luke's, the study would need to be approved by the SLUHN IRB.

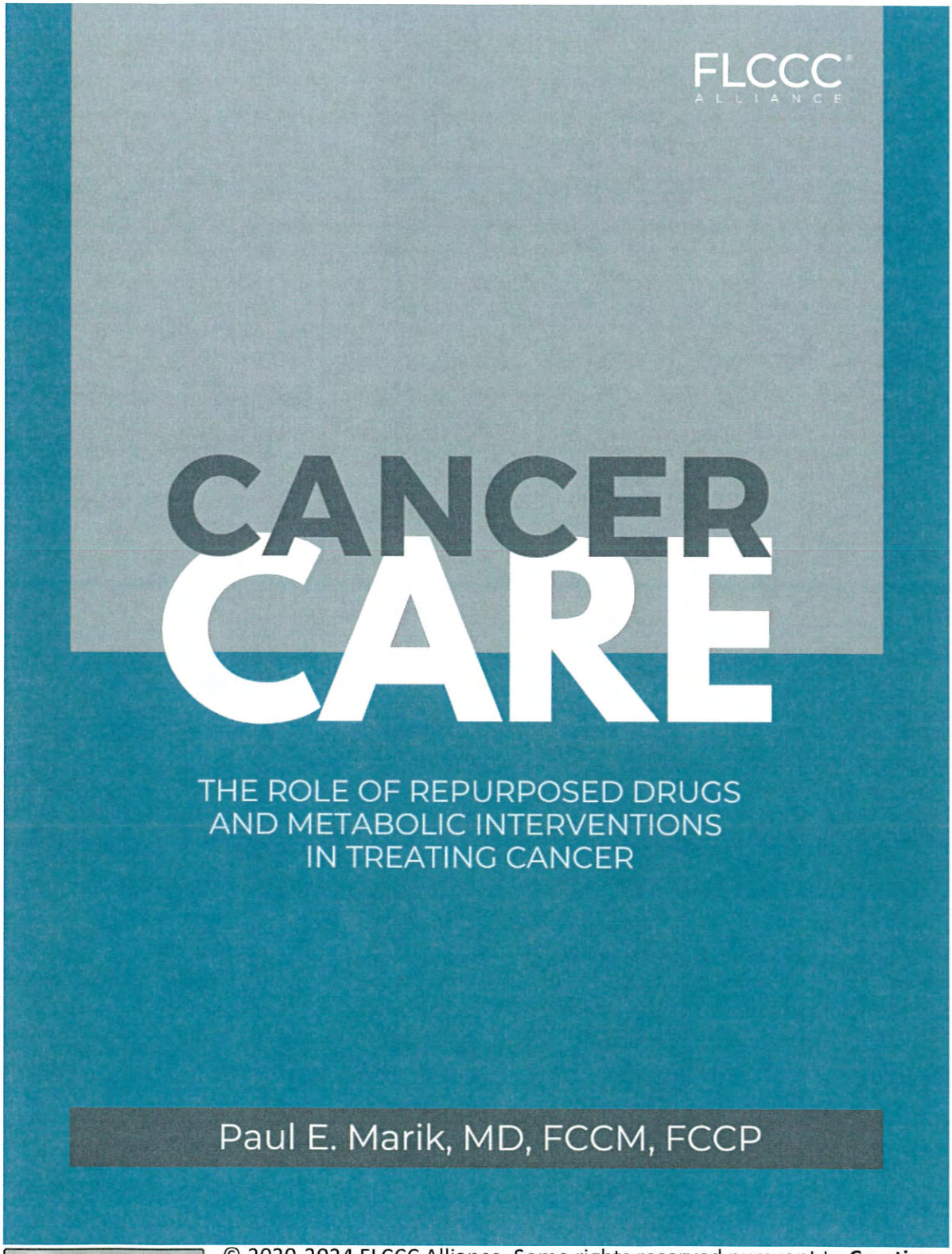
17. The "Frontline Covid Critical Alliance observational cancer study" has not been submitted to the SLUHN IRB.

18. Instructions for submission of research to the SLUHN IRB are available on the St. Luke's Health Network website at https://www.slhn.org/research/institutional-review-board.

19. I make the above statements knowing they are made subject to the penalties of 18 Pa. C.S. § 4904 relating to unsworn falsification to authorities.

Dated: April 18, 2024

/s/ William A. Peters
William A. Peters, D.O.



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Disclaimer

This is a review of the published literature showing options for repurposed drugs and lifestyle/dietary changes that can be used in cancer treatment. It is not intended as a stand-alone guide to treating cancer. Nothing in this document should be taken as a basis to initiate treatment without guidance or avoid any treatment prescribed by your treating physician. This information is offered as a basis to assist mutual decision-making. Cancer care should always be supervised by a healthcare provider. Patients with cancer should ALWAYS consult with their regular oncologist/integrative oncologist as well as an integrative provider, in addition to their primary care provider.

The treatment interventions outlined in this monograph should be used as ***adjunctive therapy*** in addition to the treatment provided by an oncologist. The goal is to reduce the toxicity of standard chemotherapy/radiotherapy (and lower the dose of chemotherapy when possible) to prevent severe immunosuppression, organ toxicities, and death from standard chemotherapy and to improve the Quality of Life (QoL). Note that this document mentions some potential interactions, such as between antioxidants and chemotherapeutic agents, that must be considered.

Standard chemotherapy targets the rapidly dividing population of cancer cells; these agents commonly adversely affect the tumor microenvironment and may promote the proliferation of cancer stem cells, increasing the potential for metastases. Almost all the interventions listed in this document limit the negative effects on the tumor microenvironment. In addition, many of the agents described herein also target cancer stem cells. This data suggests that these interventions should be used simultaneously with conventional chemotherapy to achieve the best outcomes for our patients.

Please note that this is a "living" document that will be continuously updated and refined. Please ensure you are reviewing the most recent version.

Target Audience

This information should be of particular interest to patients with cancer, to help guide them through the complicated issue of using repurposed drugs and lifestyle changes for cancer treatment. However, as noted above, it should not be used by patients to self-treat and should be supervised by a qualified healthcare provider. Primary care providers and integrative providers of patients with cancer will find essential information within this document. Furthermore, this document will be of interest to people who would like to reduce their risk of getting cancer. Patients with existing cancers should attempt to discuss the topics of dietary caloric restriction and adjuvant (concurrent) repurposed drugs with their regular oncologist; however, for obvious reasons (vested interests) many oncologists may be unwilling to discuss these topics.

Caution to Patients

This document is based on the highest level of scientific evidence. Patients should review this information, independently validate the reliability of the data, and discuss the treatment options with their family/healthcare advocates. Patients should formulate a treatment plan with their healthcare provider that is compatible with their values and goals. Patients should, however, vigorously avoid unproven and unscientific interventions that only benefit unscrupulous practitioners (see Alternative Medicine).

A repurposed drug is one that is used "off-label," a common basis for prescribing but which means that it has not been reviewed and approved by the U.S. Food and Drug Administration for that indication. Some recommendations may be subject to controversy and differences of opinion among medical authorities. While we believe this monograph offers an accurate view of the current state of science as it is based on solid evidence and pathophysiological principles, public health agencies and regulatory bodies may take contrary positions.

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