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IN THE SUPREME COURT OF WISCONSIN

2021AP001787-FT

ALLEN GAHL, Attorney in fact, on behalf of his principal,
JOHN J. ZINGSHEIM,
Petitioner-Respondent-Petitioner,

v.

AURORA HEALTH CARE, INC.
d/b/a AURORA MEDICAL CENTER-SUMMIT,
Respondent-Appellant.

BRIEF AND APPENDIX OF FRONT LINE COVID-19 CRITICAL CARE ALLIANCE AS NON-PARTY *AMICUS CURIAE*

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STATEMENT OF INTEREST

The Front Line COVID-19 Critical Care Alliance (FLCCC) is a 501(c)(3) organization founded by leaders in critical care. FLCCC has extensively researched and published metastudies on using ivermectin to treat COVID-19. Its MATH+ Hospital Treatment Protocol saved tens of thousands of patients critically ill with COVID-19.[1] FLCCC physicians led large ICUs and boast nearly 2,000 published peer reviewed publications. FLCCC developed consensus based standards among its physician members supported by global academic physicians and researchers.

FLCCC has testified before Congress and state legislatures and a co-founder appeared[2] as an expert in this matter. FLCCC is interested in ensuring patient access to reasonable therapies recommended by their physicians. FLCCC wishes to inform the Court of extensive scientific data on the safety and effectiveness of ivermectin in treating COVID-19 and correct misperceptions of public health positions underlying Aurora's rejection of such treatment.

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[1] A copy of the current MATH+ protocol is attached as Amicus FLCCC at Appendix A. Note that it contains 290 references to peer-reviewed, published literature supporting the protocol, including numerous publications regarding ivermectin.

[2] Pierre Kory, M.D., Chief Medical Officer and a founding member of FLCCC, is a former Critical Care Service Chief and Associate Professor of Medicine at the University of Wisconsin School of Medicine and Public Health. He appeared as an expert for Mr. Gahl.

ARGUMENT

"Wherever the art of Medicine is loved, there is also a love of Humanity" Hippocrates, quoted in The Journal of American Medicine, Medicine and Humanities (H. B. Simon) (2012), available at https://www.amjmed.com/article/S0002-9343(12)00494-9/fulltext. The practice of medicine is "both an art and a science" to which physicians bring diverse methods of care. Ajai R. Singh.: Medicine: Science Or Art (2006), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3190445.

Given the novelty of COVID, professional disagreement is not surprising. Surprising, though, is the gulf between the mistaken perception that public health agencies have rejected ivermectin and the reality that they have not done so.

Patients on their deathbed should not suffer from this institutional debate. A circuit court judge convinced by a qualified expert of the validity of reasonable alternative care did not abuse his discretion[3] by entering an order for potential live-saving treatment. Without a clearly established gold standard of

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[3] The standard of review under Wis. Stat. 813.02 is abuse of the discretion vested in the trial court. *Milwaukee Deputy Sheriffs' Association v. Milwaukee County*, 2016 WI App 56, 370 Wis. 2d 644, 883 N.W.2d 154, 15-1577. To prevail, Aurora would have to show that the Circuit court overstepped. This is particularly difficult given that the court had alleviated Aurora's objection by arranging for a non-staff physician to provide the therapy before the Court of Appeals stepped in and overrode this resolution.

care, which is not yet available, the evidence before the circuit court was sufficient. Aurora had no therapies left to offer, and physicians with substantial experience offered a safe treatment with sufficient evidentiary support. The Court of Appeals overstepped in upsetting the circuit court's decision.

This was particularly unnecessary given that the court had alleviated Aurora's objection by arranging for a non-staff physician to provide the therapy before the Court of Appeals stepped in and overrode this resolution. It disregarded the fact that reasonable physicians often select different –yet still appropriate –plans of care, and such professional disagreement is not only ordinary, it leads to healthy advancements in medicine. Accepting Aurora's determination that this therapy was below the standard of care, (App Dec. at 2 n. 5 and passim), bars the judiciary from any reasonable role in a patient's interests. As noted by the dissent, it is not sensible to hold that one hospital, in which Gahl's uncle found himself by necessity, was the sole arbiter of his care, particularly in light of a patient's right to consider all available treatments. The circuit court considered a legitimate professional dispute in a now or never situation –the man was on his deathbed– and under those exigent circumstances appropriately exercised its discretion. (App. Dec. at 51).

I. Aurora's Citations to Public Health Agency Characterizations of Ivermectin Are Incorrect.

Public perception on the use of ivermectin in COVID-19 has arisen in an echo chamber of agency positions targeting consumer-self-medication with ivermectin along with the challenge of evolving data. But the oft-repeated narrative that no evidence supports the use of ivermectin in COVID-19 is false. While there is disagreement whether the totality of evidence favors or disfavors use, there is a large body of evidence supporting this indication. As ivermectin is a repurposed use of an approved generic drug, there is no financially feasible means to bring the issue before the FDA. Counter to Aurora's argument, the FDA has never considered the question. FDA, NIH and CDC positions arose when public health agencies became concerned about self-medication with veterinary or internet products and that such use may interfere with public efforts for vaccination.

A. The FDA has not stated, nor does any relevant law dictate, that ivermectin use violates the standard of care.

Aurora makes four misstatements about the FDAas supporting its view that ivermectin's use in COVID-19 is below the standard of care. (Aurora Br., 11-12):

Myth 1: The FDA sets standards of care for the use of drugs.

The FDA does not set standards of care. That would directly interfere in the state regulation of medical practice. *See Chaney v. Heckler*, 718 F.2d 1174, 1179 (D.C.Cir. 1983) ("FDCA's legislative history expresses a specific intent to prohibit FDAfrom regulating physicians' practice of medicine.") rev'd on other grounds, 470 U.S. 821 (1985). What is commonly called FDA's "practice of medicine exception" developed from Congress "not want[ing] to interfere with physicians' treatment of their patients."*U.S. v. Algon*, 879 F.2d 1154 (3d.Cir. 1989).

Myth 2: "Off-label" uses of drugs indicate failure to meet standard of care.

The fact that a specific indication has not been approved does not mean such use violates the standard of care. As the FDA cannot dictate standards in medicine, it does not comment on off-label uses.[4] If Aurora's physicians are typical, 20% of the drugs they prescribe are "off-label."[5] Allowing such use is particularly important where, as with COVID-19, the only approved drugs were authorized using abbreviated methods, have high risk profiles and have not been sufficiently studied to become a gold standard against which to judge treatment. At the time, the only approved drug was Remdesivir. To compare

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[4]. "Once a drug has been approved by the FDA for marketing for anyuse, the actual prescription choices regarding those drugs are left to the discretion of the physician.

[5] https://www.ahrq.gov/patients-consumers/patient-involvement/off-label-drug-usage.html

safety: there have been 420 U.S. deaths attributed to ivermectin over a 20-year period,[6] while there have been 2,014 deaths attributed to Remdesivir[7] though it was only approved by FDA on October 22, 2020 and given to far fewer patients. Remdesivir, which Aurora insisted the patient receive because it was the "standard of care," was approved contrary to WHO recommendations against its use[8] and a significant body of literature finding its risks outweigh any benefit.[9]

Myth 3: That FDA's "You are not a horse" and other campaigns stated an FDA position against prescription.

The FDA launched a media campaign directed at veterinary and other forms of self-prescribing, yet its "You Are Not a Horse" campaign[10] was taken as a directive that physicians should not prescribe it. The FDA disavowed this unlawful view in litigation.[11]As a result, but the FDA disavowed the position

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[6] https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4

[7] https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4

[8] https://www.who.int/news-room/feature-stories/detail/who-recommends-against-the-use-of-remdesivir-in-covid-19-patients#:~:text=WHO%20has%20issued%20a%20conditional,other%20outcomes%20in%20these%20patients.

[9] *See for e.g.* Singh S, Khera D, Chugh A, et al. Efficacy and safety of remdesivir in COVID-19 caused by SARS-CoV-2: a systematic review and meta-analysis. *BMJ Open* 2021;11:e048416. doi: 10.1136/bmjopen-2020-048416

[10] https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19

[11] Amicus asks this Court to take judicial notice of *Apter et al v. HHS, FDA, et al.* S. D. Tex. 3:22-cv-00184 (filed 6/6/2022). The matter was dismissed on sovereign immunity grounds but the admission by FDA at oral argument remains.

that physicians may not prescribe ivermectin. See Appendix C, Transcript of oral argument dated November 1, 2022, notably at pg.5, "These statements included non-binding recommendations to consumers who could purchase animal-use ivermectin over the counter not to take ivermectin to treat COVID-19, *but the statements did not say that doctors could not prescribe ivermectin to treat COVID-19 or that consumers could not take ivermectin for that purpose.*" (emphasis added.)

Myth 4: The FDA had studied the use of ivermectin in COVID-19 and concluded it was not safe or effective.

The FDA has never studied the treatment of COVID-19 with ivermectin. The sole FDA position, on a consumer-facing page addressing self-prescribing, did not purport to guide physicians. The FDA has not made that statement to physicians, nor could it, as the FDA has never conducted any review of the safety or efficacy of ivermectin to treat COVID-19. The Agency could not meaningfully or lawfully issue such a statement given the lack of formal review or publication of any guidance noticed for comment about ivermectin's use.

B. The Centers for Disease Control and the Facts about the Safety of Ivermectin.

Aurora also wrongly cites the CDC(Aurora Br. at 12). The CDC's concern was also for ivermectin use outside of physician supervision, in particular in veterinary forms. The concern about animal drugs or

self-prescription is legitimate, but the CDC cites no instance of harm from a human drug prescribed by a physician. Ivermectin, on the WHO's list of essential medicines and whose discoverer received the Nobel Prize, has been given nearly 4 billion times around the globe, widely considered safe[12] and according to the WHO is safer than aspirin or Tylenol.

C. The National Institutes of Health Position Has Vacillated with the Evidence and Is Not Ripe as a Medical Directive.

The only agency that analyzed the data for ivermectin for use against COVID-19 is the NIH. Its view has varied and for a time was "neither for nor against," sharing the same category with monoclonal antibodies and convalescent plasma which were widely used subject to the discretion of physician and patient. This determination was made after the scientific evidence supporting this use was presented directly to the NIH by FLCCC physicians who met with the NIH in mid-January 2021. After FLCCC's presentation the NIH immediately elevated ivermectin from its original "do not use" to a "neither recommend for or against" policy. Developments are fluid with Covid as with any novel health issue and NIH later updated its view, still stating that "it is important to stress that the rated treatment recommendations in these Guidelines should not be considered mandates. The choice of what to do or not

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[12] https://www.who.int/publications/i/item/WHOMVPEMPIAU201907

to do for an individual patient *is ultimately decided by the patient* and their provider."[13] (emphasis added.)

II. Substantial Evidence Supports the use of Ivermectin in COVID-19.

There is substantial evidence that ivermectin is a safe and effective treatment for COVID-19. This evidence is shown in published clinical studies, peer-reviewed meta-studies, epidemiological evidence and clinical experience. These studies are summarized at https://c19ivermectin.com and a meta-analysis can be found at https://ivmmeta.com, which is constantly being updated as new data comes in. FLCCC has dedicated extensive resources on its website to help physicians assess the evidence for themselves. A graphic tells the story:

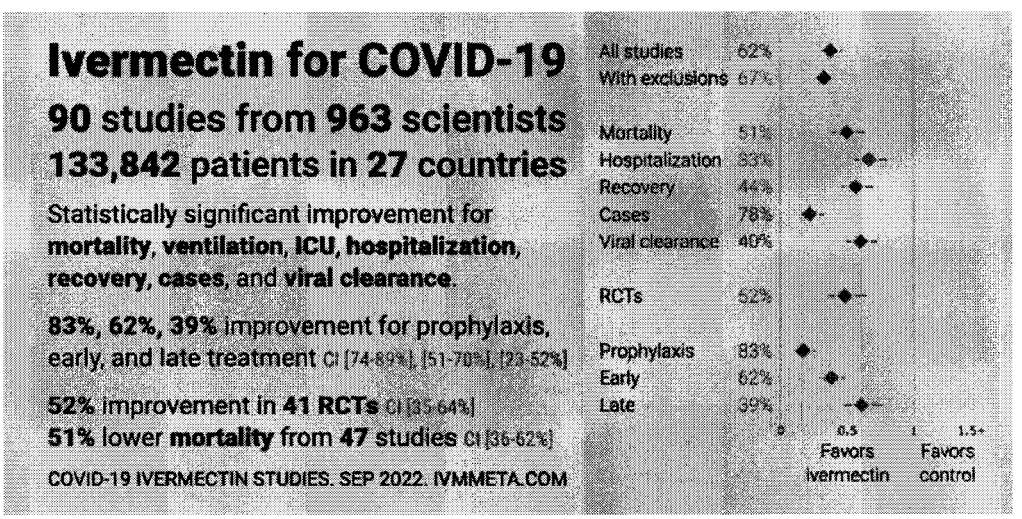

Figure 1. Source: https://covid19criticalcare.com/ivermectin/.

[13] https://www.covid19treatmentguidelines.nih.gov/about-the-guidelines/guidelines-development/

Over 133,842 patients have been studied with the overall signal of benefit strongly positive with tight confidence intervals.[14] [15]

In addition to these trials, the epidemiologic data presented by FLCCC may provide the strongest level of medical evidence attainable, given findings from large, real-world "natural experiments" that occurred when health ministries in many regions of the world initiated widespread ivermectin distribution to their citizen populations. The "control groups" in these natural experiments were the neighboring regions that did not employ widespread ivermectin distribution. Comparing these regions, large and temporally associated decreases in case counts and fatalities were found after the ivermectin distribution began. The magnitude and reproducibility from city to city, region to region, and country to country is unassailable.[16]

III. The Circuit Court did not Abuse its Discretion in Issuing a Preliminary Injunction Allowing the Patient's Wishes to be Met in These Exigent Circumstances.

A. The patient at risk of death had a right to the reasonable care of his choice in the absence of viable alternatives.

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[14] Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19, Pierre Kory, MD, G. Umberto Meduri, MD2, Jose Iglesias, DO, Joseph Varon, MD, Keith Berkowitz, MD, Howard Kornfeld, MD, Eivind Vinjevoll, MD, Scott Mitchell, MBChB, Fred Wagshul, MD, Paul E. Marik, MD. Appendix B. Note the publication include 5 pages of references to peer-reviewed literature.

[15] https://covid19criticalcare.com/treatment-protocols/totality-of-evidence/

[16] https://covid19criticalcare.com/flccc-alliance-response-to-all-national-and-international-health-agency-recommendations-against-ivermectin-in-covid-19/

The circuit court appropriately exercised its discretion in disallowing an institutional determination to override a patient's opportunity to benefit from a treatment recommended by a patient's chosen health care professional. The exigency of the pandemic, with the patient at substantial risk of death and for which the hospital had exhausted all reasonably safe means, illustrates that the circuit court's decision was consistent with the intent of the legislature and presents no conflict with ordinary jurisprudence regarding hospital care.

Standards of care evolve, are tested over time, and become generally recognized. Even in that context, professional disagreements routinely go to a jury for determination. *Seifert v. Balink*, 2017 WI 2, ¶59 see also dissent App. Dec. at 51-54. The Court of Appeals erred in upsetting the circuit court's decision, suggesting it more abhorrent to abridge Aurora's "right"to dictate treatment despite professional disagreement in an evolving area than to allow the circuit court to consider appropriate, temporary injunctive relief. That cannot be the law. Patient autonomy is not lost because one is hospitalized and infirm and under care by necessity. As Judge Grogan noted in dissent: "Although Wisconsin law does not afford a patient the right to demand any treatment the patient desires, it does recognize a patient's right to request and receive medically viable alternative treatments. Id. at 54.[17]

[17] *Cf.* Wis. Stat. § 450.137 (the "Right to Try" Law).

Further, this issue in Wisconsin is framed by the courts as whether a physician engaged in the minimally competent practice of medicine. *See for e.g., Hartsuch v. Ascension Med. Grp.N. Wis.*, 20-cv-325-jdp, at 9-10 (W.D. Wis. Aug. 26, 2021). The argument over ivermectin is better understood as a struggle about best practices; none of the authorities cited by Aurora have concluded that the use of ivermectin is below the level of minimal competence.

B. The hospital had a duty to make Gahl aware of the proposed treatment and to make it available under Wisconsin Stat. § 448.30.

The Court of Appeals erred in stating that Gahl "failed to identify any source of Wisconsin law that gives a patient or a patient's agent the right toforce a private health care provider to administer a particular treatment that the health care provider concludes is below the standard of care." (App. Dec. at 1-4, passim.). This is contrary to § 448.30, which the dissent ably explained does not allow the physician to limit the therapies they discuss with the patient. *See, e.g., Martin v. Richards*, 192 Wis.2d 156, 181, 531 N.W.2d 70 (1995). *See* discussion in dissent, App. Dec. at 51. To inform but disallow alternative treatment where a patient is confined by necessity undercuts the purpose of the statute. The circuit court's discretionary decision to both preserve Aurora's

ability not to provide the treatment, yet allow an outside physician in to do so, was not wrong.[18]

C. The argument that the circuit court erred because the non-staff physician had not reviewed records is a red herring as these conditions were resolved by the circuit court's order.

The parties below reached an agreement to allow Dr. Hagen limited privileges at the hospital, but this was upset by the Court of Appeals. Had that agreement had been carried out, Dr. Hagen could have reviewed the medical record and seen his patient in the hospital prior to writing any orders. To argue *post hoc* that the circuit court erred because Dr. Hagen had not seen the patient is simply wrong.

CONCLUSION

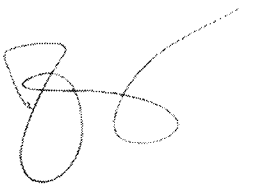
Holding that the circuit court did not abuse its discretion would preserve the equitable and statutory authority under Wisconsin Stat. § 448.30 of trial judges to grant temporary injunctive relief, particularly in matters where a patient is on their deathbed without many, if any, other option.

Given the evolving state of the medical evidence, the discretion vested in our circuit courts, and in light of actual (versus perceived) public health

[18] The principal legal effect of complying with a perceived standard of care is defense against malpractice or regulatory liability. Before the Court of Appeals intervened, the parties reached an agreement that included a waiver of liability removing that risk. With a waiver of liability, the legal consequences of allowing the requested treatment provided by a physician of Gahl's choice granted limited privileges at the hospital.

agency positions, the right to care allowed to Gahl by the circuit court's order should be upheld.

Respectfully submitted this 15th day of December, 2022



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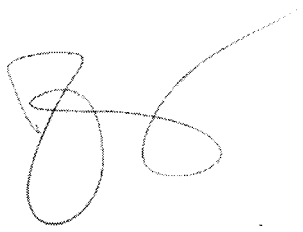
FORM AND LENGTH CERTIFICATION

I certify that this brief conforms to the rules contained in Wis.Stat.§ 809.19(8)(b), (c) and (d) for a brief produced with a proportional serif font. The length of this brief is 2980 words including 76 for the figure 1.

Dated this 15th day of December, 2022



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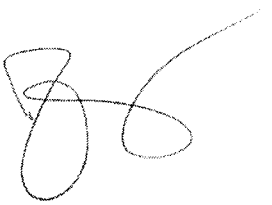
CERTIFICATE OF COMPLIANCE WITH WIS. STAT.§ 809.19(12)

I certify that I have submitted an electronic copy of this brief, excluding the appendix, which complies with the requirements of Wis. Stat. § 809.19(12).

I further certify that the electronic brief is identical in content and format to the printed form of the brief filed as of this date. A copy of this certificate has been served with the paper copies of this brief filed with the court and served on all opposing parties.

Dated this 15th day of December, 2022



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