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STATE OF WISCONSIN

IN SUPREME COURT

Appeal number 2021AP001787

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

-vs-

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

On Appeal from Decision of the Wisconsin Court of Appeals, District II, Reversing Order of the Circuit Court for Waukesha County, Case No. 2021CV001469, Judge Lloyd Carter

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NONPARTY BRIEF IN SUPPORT OF PETITIONER-RESPONDENT-PETITIONER BY ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS AS *AMICUS CURIAE*

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Amicus curiae Association of American Physicians and Surgeons ("AAPS") hereby submits its brief in support of Petitioner and in support of reversal of the appellate decision below. By its order dated December 2, 2022, this Court granted leave to AAPS to file this *amicus* brief. At stake here is the availability of judicial review when a hospital blocks access by a hospitalized patient to treatment by a medication prescribed by a physician.

Far from asking this Court to adjudicate or impose a particular standard of care, as implicitly urged by the *amicus* brief filed by the American Medical Association (AMA) and Wisconsin Medical Society ("AMA Brief"), AAPS seeks to reestablish the availability of judicial review when a hospital denies access to medical treatment for a patient, as Respondent-Appellant Aurora Health Care, Inc. ("Aurora") has done here. Specifically, judicial review should remain available when a hospital interferes with medical treatment by an FDA-approved medication, and it was reversible error for the appellate panel below to hold otherwise.

STATEMENT OF INTEREST

Founded in 1943, AAPS is a national association of physicians in virtually every medical specialty and every state. AAPS has, and has long had, members who practice medicine in Wisconsin. In contrast with the AMA, AAPS is funded nearly entirely by physicians who have practiced medicine. Many AAPS members practiced medicine on the front lines of the COVID-19 pandemic, saving the lives of tens of thousands of patients with early treatment and inexpensive medications.

In addition to filing lawsuits itself, AAPS has also filed *amicus* briefs in many state and federal appellate courts on issues concerning the

practice of medicine. *See, e.g.*, *Valfer v. Evanston Nw. Healthcare*, 2016 IL 119220, ¶ 33, 402 Ill. Dec. 398, 408, 52 N.E.3d 319, 329. Over the span of more than a decade, the U.S. Court of Appeals for the Third and Fifth Circuits have expressly cited an *amicus* brief by AAPS in the first paragraph of one of its decisions. *See Springer v. Henry*, 435 F.3d 268, 271 (3d Cir. 2006); *Texas v. United States*, 945 F.3d 355, 369 (5th Cir. 2019). The Southern District of Texas, Galveston Division, granted a motion by AAPS for leave to file its *amicus* brief against improper government statements concerning ivermectin during the COVID-19 pandemic. *Apter v. HHS*, No. 3:22-cv-00184 (S.D. Tex., Dkt. 30, Sept. 30, 2022).

Amicus AAPS has a strong interest in ensuring that patients have timely access to the medications they need, as prescribed by physicians, without interference by hospitals or any other corporate entity. AAPS has an interest in ensuring that judicial review is available to ensure that the hospital is not improperly interfering with the practice of medicine, and in reversing the appellate panel's decision that deferred more to a hospital than to independent physicians as to the standard of care. *See Gahl v. Aurora Health Care, Inc.*, 403 Wis. 2d 539, 545, 977 N.W.2d 756, 759 (Ct. App. 2022).

SUMMARY OF ARGUMENT

The dissent below was right. Wisconsin ***does*** fully recognize the right of a patient to "to request and receive medically viable alternative treatments." *Gahl*, 403 Wis. 2d at 603, 977 N.W.2d at 787-88 (Grogan, J., dissenting, citing *Schreiber v. Physicians Ins. Co.*, 217 Wis. 2d 94, 105, 579 N.W.2d 730 (Ct. App. 1998); Wis. Stat. § 448.30 (2019-20)). That right would be meaningless if a powerful, revenue-maximizing business

such as Aurora could interfere with access to treatment without judicial review, as the panel majority decision mistakenly establishes. Hospitals including Aurora do not have a license to practice medicine, and should not be allowed without judicial review to encroach on this authority that is exclusively granted by the state to physicians and other practitioners.

The AMA Brief urges abdication of the exclusive authority of practicing physicians in favor of the groupthink of entities that are not authorized to practice medicine: Aurora, Merck, the FDA, an imaginary medical consensus consisting of cherrypicked medical articles, and other politicized entities. That is not, and should not be, how patients obtain access to timely medical care from the physicians of their choice. The AMA Brief is filled with distortions about off-label prescribing, which is widespread and often ethically necessary. The AMA Brief unpersuasively disparages ivermectin as a treatment for COVID-19 (which should be for each physician to decide),[1] and the AMA Brief overrelies on one-size-fits-all protocol that should not restrict individualized care to a particular patient. (AMA Br. 1) The AMA Brief fails to address the basic issue here: the need for judicial review of hospital decisions that deny medical care to patients.

The panel majority decision below erred as a matter of law in relying on its finding that "the proposed treatment [ivermectin] for COVID-19 is not approved by the FDA, as it is an 'off-label use of the drug.'" *Gahl*, 403

[1] Studies in peer-reviewed medical journals confirming the benefits of ivermectin to treat COVID-19 have been plentiful since early 2021, yet are omitted in the AMA Brief. *See, e.g.*, Sabeena Ahmed, et al., "A five-day course of ivermectin for the treatment of COVID-19 may reduce the duration of illness," *Int J Infect Dis.* 2021 Feb;103:214-216. https://pubmed.ncbi.nlm.nih.gov/33278625/ (viewed Dec. 19, 2022).

Wis. 2d at 564, 977 N.W.2d at 769. Off-label use of approved medications is commonplace and even ethically required in many circumstances, including dealing with a novel new virus such as COVID-19. The FDA does not properly practice medicine or give medical advice on the new uses to which an already approved-as-safe medication, such as ivermectin, can be prescribed by physicians. The finding by the panel majority below that the use of ivermectin to treat COVID-19 is not approved by the FDA is, in essence, misleading as advanced by opponents of ivermectin. It was an error for this misdirection to have been included in and relied upon by the panel majority decision below.

The panel majority decision opens the floodgate to additional improper interference by hospitals with the practice of medicine by licensed physicians. Reversal is necessary to ensure continued access to the courts by patients to combat interference with their access to medical treatment as prescribed by a physician.

ARGUMENT

Once the FDA approves a medication as safe, then physicians can and should prescribe it as they think best to treat any condition. The panel majority failed to recognize this, and the AMA Brief here misleads on this central issue. In the situation of a fast-moving new virus as COVID-19 has been, an application for new approval by the FDA for a medication long-recognized as safe, as ivermectin is, would be an unnecessary and a senseless wasteful of resources. This Court should restore the authority of physicians to treat patients without interference, as physicians are licensed to do, and for hospitalized patients to have access to that treatment.

I. The AMA Brief is Riddled with Distortions and an Improper Abdication of the Authority to Practice Medicine to Institutions Lacking that Authority.

Contrary to the assertions in the AMA Brief, the following entities have no say about the standard of care, and do not lawfully practice medicine: the FDA, Merck, Aurora, WHO, NIH, and other governmental agencies. For example, the Federal Food, Drug, and Cosmetic Act expressly ***prohibits*** the FDA from "interfer[ing]" with the practice of medicine. *See* 21 U.S.C. § 396. Ignoring this, the AMA Brief insists that:

> Ivermectin is an anti-parasitic drug that the U.S. Food and Drug Administration ("FDA") has approved "to treat certain infections caused by internal and external parasites." The FDA has never approved its use as a COVID-19 treatment, as Mr. Gahl concedes.

(AMA Br. 4-5, footnotes omitted). The above statement in the AMA Brief is severely misleading, and is like saying that the FDA has never approved breathing air, drinking water, or getting a good night's sleep.[2] In fact, the FDA's authority is sharply limited, and the FDA typically does not authorize new uses for already-approved medications.

Decades ago the FDA approved ivermectin as safe, which means it can and has long been properly used for a wide variety of infections and conditions, whenever physicians consider it to be medically effective in treating illness. The FDA has no expertise or authority to interfere with the

[2] Coincidentally, drinking water and getting more sleep are the two of the top three recommendations by the Wisconsin Department of Health Services for fighting COVID-19, on the same website that the AMA Brief cites as support for its argument against ivermectin. *See* COVID-19: Treatments and Medications https://www.dhs.wisconsin.gov/covid-19/treatments.htm (cited by AMA Br. 6).

use of any safe medication, which the FDA established with respect to ivermectin decades ago.

Despite this, the AMA Brief misleads the Court by pretending that there is something unusual and even dangerous about off-label prescribing of ivermectin. (AMA Br. 5) There is not. AAPS physicians quickly and responsibly saved the lives of many tens of thousands of COVID-19 patients by prescribing them ivermectin, as it was entirely appropriate and ethical to do. An eminent physician (and past-president of AAPS), who has a J.D. (and practiced law) in addition to her medical degree, explains this as follows:

> Prescribing a medication for a medical condition other than its FDA-approved purpose is called "off-label" prescribing. According to the Congressional Research Service (CRS) 56 percent of oncology and 12 to 38 percent of prescriptions overall are written for uses not listed on the FDA-approved labeling.[3] Off label prescribing is left to the judgment of the physician and is not only legal but ethical.[4] G. Caleb Alexander, MD, MS, a medical ethics advocate and assistant professor of medicine at the University of Chicago Medical Center noted, "[o]ff-label use is so common, that virtually every drug is used off-label in some circumstances. ... Doctors are free to prescribe a drug for any [reason they think is medically appropriate]."[5]
>
> Off-label prescribing allows patients to benefit from a drug without waiting years for FDA approval. The CRS notes that off-label prescribing can reflect cutting-edge clinical expertise or a new treatment approach when other options have failed. …
>
> Some examples of off-label use are (1) tamoxifen approved for breast cancer and used off label to treat infertility; (2) spironolactone, a diuretic used off label for acne vulgaris; (3) beta blockers approved for treating high blood pressure,

[3] Congressional Research Service, "Off-Label Use of Prescription Drugs" (Feb. 23, 2021). https://sgp.fas.org/crs/misc/R45792.pdf (viewed Nov. 24, 2022).
[4] Federal Drug Administration, "Understanding Unapproved Use of Approved Drugs 'Off Label'" (Feb. 5, 2018). https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label (viewed Nov. 24, 2022).
[5] K. Miller, "Off-Label Drug Use: What You Need to Know," WedMD (2009) https://www.webmd.com/a-to-z-guides/features/off-label-drug-use-what-you-need-to-know (viewed Nov. 25, 2022).

> arrhythmias, coronary artery disease, migraines, and glaucoma used off label for anxiety; and (4) statins approved to lower cholesterol and used off-label to prevent heart attacks in people with diabetes.
>
> It could not be more clear that off-label use of approved medications is an accepted and beneficial component of medical practice. Until COVID-19, off-label prescribing had not faced particular scrutiny. Unfortunately for patients, two low-cost repurposed medications that have been prescribed for years without incident and are on the World Health Organization's list of essential medications are being blackballed.[6] The truth is, numerous studies show that when started early, hydroxychloroquine and ivermectin significantly reduce symptoms and prevent hospitalizations and deaths.

Marilyn M. Singleton, M.D., J.D., "Dear AMA: The Oath of Hippocrates Is Enough," 26 Journal of American Physicians and Surgeons 109, 111 (Winter 2021).[7]

Further distorting the issue in this case, the AMA Brief devotes an entire section (Point II) to argue against "Compelling physicians to provide ivermectin" because that supposedly "conflicts with their ethical obligations." (AMA Br. 10-13) But no physician was ever being compelled to do anything in connection with this case. Ivermectin is merely a medication, taken in capsule form, which many physicians have prescribed for countless COVID-19 patients.

Yet Aurora blocked access to that physician-prescribed medication by patients trapped in its hospital. Aurora never disclosed to the public that patients who admit themselves to that hospital will be automatically denied this medical care that is widely available outside of its hospital. As Aurora benefits enormously from its nonprofit tax status in purportedly serving the public, it can hardly hide behind its private status now to evade judicial

[6] WHO, "Model List of Essential Medicines" (22nd list, 2021) https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02 (viewed Nov. 24, 2022).
[7] https://www.jpands.org/vol26no4/singleton.pdf (viewed Nov. 24, 2022).

review for how it senselessly blocked access to medication by all the patients hospitalized there for COVID-19. Notably, the AMA Brief provides no meaningful defense for the denial of judicial review in the panel majority opinion below.

Instead, the AMA Brief concludes with a feigned plea that this "Court should relieve Wisconsin physicians of that perilous dilemma by affirming the Court of Appeals decision." (AMA Br. 13) But there is no dilemma imposed on any physicians in connection with this case. Aurora, as a rapacious billion-dollar business, was ordered by the circuit court to stop interfering with a physician's treatment recommendation. No physician was ordered to do anything. It is fiction for the AMA Brief to pretend that any physician was caught in a dilemma by the circuit court's judicial review. The only interference on the practice of medicine by physicians was by Aurora, in denying access by a trapped hospitalized patient to medical care widely used outside the hospital for COVID-19.

II. Decisions in Other Jurisdictions Miss the Essential Point.

The panel majority relied on decisions from other jurisdictions that all failed to address the essential issue: a patient trapped in a hospital should not be denied medical care, without access to judicial review, by that hospital, because hospitals do not properly practice medicine and confined patients have rights to access potentially life-saving care. If a hospital can properly deny care to confined patients with safe, approved medications, then such a hospital should disclose that on the front door of its entrance to all before they enter.

The multiple extra-judicial authorities cited below do not survive scrutiny. The first decision relied on by the panel majority is a Texas court ruling that fully recognized the authority of courts to intervene to prevent discontinuation of life-saving care by a hospital, but then inexplicably held the opposite when a hospital denies access to ivermectin for COVID-19:

> This is not to say that the judiciary will never intervene in a hospital's treatment or credentialing procedures. Indeed, this very court has done so. See [*T.L. v. Cook Children's Med. Ctr.*, 607 S.W.3d 9, 94 (Tex. App. 2020)] (holding appellant stated viable cause of action and probable right to recovery on Section 1983 claim premised on imminent discontinuance of medical treatment, and remanding case for entry of temporary injunction to prevent the discontinuance of life-sustaining medical care pending trial). But, unlike the facts in T.L., this is not a case where the hospital is threatening to withdraw Mr. Jones's ventilator or discontinue a similar source of life-sustaining medical care.

Tex. Health Huguley, Inc. v. Jones, 637 S.W.3d 202, 213 (Tex. App. 2021). That court even began its opinion with the observation that "judges are not doctors." *Id.* at 207. But hospitals and the FDA are not doctors either. The Texas court erred by failing to defer to those who are independent doctors, and by instead giving *carte blanche* to a revenue-maximizing hospital to interfere with the practice of medicine by a physician preferred by a patient.

Hospitals should not become unaccountable islands of tyranny, wielding unchecked power to withhold or deny care. While judges are not doctors, judges can and do review and limit abuses of power in many different fields. Blocking access by a hospitalized patient to an FDA-approved medication successfully used by thousands to treat the same illness is appropriate for judicial review, and the deference by the Texas court to hospital administration was a clear error that would allow unchecked denial of care by hospitals in many additional ways, too.

The additional extra-jurisdictional decisions relied on below by the panel majority are likewise flawed. *See, e.g.*, *DeMarco v. Christiana Care Health Servs. Inc.*, 263 A.3d 423, 437 (Del. Ch. 2021) (denying a hospitalized patient access to a physician's prescription for ivermectin because "ivermectin's efficacy in treating COVID-19 is disputed"). Of course many treatments for a novel virus such as COVID-19 are disputed. Most of the vast off-label prescriptions for many conditions by physicians are unproven, and even more so in treating a new virus such as COVID-19. That is no legitimate basis for hospital interference with judgment by a physician in prescribing ivermectin – long recognized as safe by the FDA – for a COVID-19 patient. *See also Abbinanti v. Presence Cent. & Suburban Hosps. Network*, 2021 IL App (2d) 210763, ¶ 7, 455 Ill. Dec. 557, 561, 191 N.E.3d 1265, 1269 (repeatedly relying on "hospital policy" – which does not properly practice medicine – and allowing it to interfere with a physician's medical judgment to administer ivermectin to a COVID-19); *Frey v. Trinity Health-Michigan*, No. 359446, 2021 Mich. App. LEXIS 6988, at *13 (Mich. Ct. App. Dec. 10, 2021) (finding a lack of a right by "gravely ill" patients to object to the interference with care by a hospital); *Pisano v. Mayo Clinic Fla.*, 333 So. 3d 782 (Fla. Dist. Ct. App. 2022) (mischaracterizing the request as one for hospital physicians to administer a treatment, when this is merely an issue of allowing the patient receive a physician's prescribed medication of pills).

III. The Dissent Below Was Right.

The dissent below was correct in reasoning that:

> What is important here is that the circuit court had before it information from two independent physicians (one indicating he was the world's foremost expert on

> treating COVID-19) who both agreed that a protocol different than that which Aurora had administered, without success, would be proper and could be beneficial to Zingsheim.

Gahl, 403 Wis. 2d at 603-04, 977 N.W.2d at 788 (Grogan, J., dissenting).

This case is no different conceptually than an end-of-life dispute about a hospital disconnecting life-support. Judicial review must remain available to provide accountability against hospital interference with medical care.

CONCLUSION

Amicus AAPS requests that the Court reverse the appellate decision below.

Dated: December 21st 2022.

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CERTIFICATION AS TO FORM

I hereby certify that this brief conforms to the rules contained in Wis. Stat. § 809.19(8)(b) and (c) for a brief produced with a proportional serif font. The length of this brief is 2,999 words.

Dated: December 21st 2022.

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

I hereby certify that:

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

I further certify that:

This 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: December 21st 2022.

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