STATE OF WISCONSIN

IN SUPREME COURT

Case No. 2021AP001787

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.*

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 RESPONDENT-APPELLANT BY AMERICAN MEDICAL ASSOCIATION AND WISCONSIN MEDICAL SOCIETY AS *AMICI CURIAE*

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INTRODUCTION

Amici Curiae the American Medical Association ("AMA") and Wisconsin Medical Society represent nearly 10,000 Wisconsin physicians, each of whom is ethically and legally bound to provide quality, evidence-based medical care to their patients. Over the past three years, those physicians have treated nearly 2 million Wisconsinites for COVID-19.[1] Their task has been greatly complicated by misinformation about COVID-19 and risky treatments touted as miracle cures, like ivermectin. To provide competent care within that landscape, Wisconsin's physicians rely on evidence-based treatments, as the law and their ethical obligations require, and avoid untested ones, like ivermectin, that may compromise patient health.

Here, Respondent-Appellant Aurora Health Care, Inc. ("Aurora") met its legal and ethical duties by treating Petitioner-Respondent-Petitioner Allen Gahl's uncle, John J. Zingsheim, according to an evidence-based protocol, which did not include ivermectin. The Court should thus affirm the Court of Appeals as holding otherwise would allow courts to compel treatments that the medical consensus finds to

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[1] *See Tracking Coronavirus in Wisconsin: Latest Map and Case Count*, N.Y. Times, https://www.nytimes.com/interactive/2021/us/wisconsin-covid-cases.html (Dec. 6, 2022).

be substandard. That outcome forces Wisconsin's physicians to choose between the law and their ethical duties, potentially exposing patients to harm and physicians to liability.

ARGUMENT

I. Emergency relief is unavailable because administering ivermectin is not required by the standard of care.

Mr. Gahl argues that, by refusing to administer ivermectin to Mr. Zingsheim, Aurora provided substandard care.[2] As explained below, however, the standard of care in Wisconsin does not require physicians to provide treatment that available medical evidence suggests will not benefit patients and may harm them. Because there is no credible evidence that ivermectin effectively treats COVID-19, and ample evidence it does not, Aurora neither breaches its duties nor harms Mr. Zingsheim by refusing to administer ivermectin or credential a willing physician.

A. Medical standards of care.

In Wisconsin, physicians must "use the degree of care, skill, and judgment which reasonable" providers "would exercise in the same or

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[2] *See* Brief of Petitioner-Respondent-Petitioner ("Pet. Br.") at 13 (asserting that the Court of Appeals applied the wrong standard of care); *see also id.* at 17 (contending Mr. Gahl "argued from the beginning that [i]vermectin was a safe drug" that complied with the standard of care).

similar circumstances, having due regard for the state of medical science at the time" care is provided.[3] To determine whether legally sufficient care has been provided, the treatment is compared to that which would have been provided by "a hypothetical, reasonable physician in similar circumstances."[4] What the "reasonable physician" would have done is determined by looking to what "other members of the medical profession generally" would have done under similar circumstances.[5] The same test applies when the treatment or illness at issue is novel.[6] Thus, the reasonableness of a physician's conduct is measured objectively, by comparison to accepted, evidence-based practices within the medical profession.

Although guidance from health care institutions will not necessarily establish the care standard in "'clinical scenarios involving

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[3] *See* Wis. Jury Instr. Civ. 1023; *see also Nowatske v. Osterloh*, 198 Wis. 2d 419, 442, 543 N.W.2d 265, 274 (1996) ("Reasonable care . . . must be determined by assessing whether a patient received the standard of care he or she might reasonably expect from that practitioner, with due regard for the state of medical science at the time of treatment."), *abrogated on other grounds by Nommensen v. Am. Cont'l Ins. Co.*, 2001 WI 112, ¶ 52, 246 Wis. 2d 132, 629 N.W.2d 301.

[4] *See Jandre v. Wis. Injured Patients & Fams. Comp. Fund*, 2012 WI 39, ¶ 95, 340 Wis. 2d 31, 78, 813 N.W.2d 627, 649.

[5] *Nowatske*, 543 N.W.2d at 274.

[6] *Staudt v. Froedtert Mem'l Lutheran Hosp.*, 217 Wis. 2d 773, 777, 580 N.W.2d 361, 363 (Ct. App. 1998) (requiring physician considering off-label use of an approved medical device to rely "on sound medical evidence and a firm, scientific rationale'" (quoting *Femrite v. Abbott Nw. Hosp.*, 568 N.W.2d 535, 542 (Minn. Ct. App. 1997))).

a high degree of independent judgment and careful attention to the individual characteristics of each patient,'"[7] it can for "[a]spects of care that are highly standardized, and about which there is a high degree of consensus in the medical community."[8] Such cases "are unlikely to pose the problem of determining what constitutes 'custom' in the face of marked variations in clinical practice."[9]

Because the evidence—including clinical treatment guidance—does not suggest that ivermectin effectively or safely treats or prevents COVID-19, it was reasonable for Mr. Zingsheim's physicians to refuse to administer ivermectin or for Aurora to refuse credentials to physicians seeking admission for that purpose.[10]

B. Ivermectin is not within the standard of care for treatment of COVID-19.

Ivermectin is an anti-parasitic drug that the U.S. Food and Drug Administration ("FDA") has approved "to treat certain infections

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[7] *See Seifert v. Balink*, 2017 WI 2, ¶ 85 n.44, 372 Wis. 2d 525, 566, 888 N.W.2d 816, 837 (quoting Michelle M. Mello, *Using Statistical Evidence to Prove the Malpractice Standard of Care: Bridging Legal, Clinical, and Statistical Thinking*, 37 Wake Forest L. Rev. 821, 857 (2002)).

[8] Mello, *supra* note 7, at 858.

[9] *See id.*

[10] *See Johnson v. Misericordia Cmty. Hosp.*, 99 Wis. 2d 708, 301 N.W.2d 156, 164 (1981) (requiring a hospital "to exercise due care in the selection of its medical staff").

caused by internal and external parasites."[11] The FDA has never approved its use as a COVID-19 treatment, as Mr. Gahl concedes.[12] To the contrary, the FDA cautions that taking ivermectin—even in amounts approved for human consumption—can interfere with other medications and "cause nausea, vomiting, diarrhea, hypotension (low blood pressure), allergic reactions (itching and hives), dizziness, ataxia (problems with balance), seizures, coma and even death."[13] The National Institutes of Health ("NIH"), Centers for Disease Control ("CDC"), and World Health Organization ("WHO") also advise against treating COVID-19 with ivermectin, except in clinical trials.[14] And, while Wisconsin's Department of Health Services has not advised

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[11] CDC, *Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Use of Products Containing Ivermectin to Prevent or Treat COVID-19* (Aug. 26, 2021), https://emergency.cdc.gov/han/2021/han00449.asp.

[12] *See* Pet. Br. at 17.

[13] FDA, *Why You Should Not Use Ivermectin to Treat or Prevent COVID-19* (Dec. 10, 2021), http://bit.ly/3EKe8qH.

[14] *See, e.g.*, NIH, *COVID-19 Treatment Guidelines: Ivermectin* (Apr. 29, 2022), http://bit.ly/3GSisqp (recommending "against the use of ivermectin for the treatment of COVID-19, except in clinical trials"); CDC, *Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Use of Products Containing Ivermectin to Prevent or Treat COVID-19* (Aug. 26, 2021), https://emergency.cdc.gov/han/2021/han00449.asp ("Adverse effects associated with ivermectin misuse and overdose are increasing, as shown by a rise in calls to poison control centers[.]"); WHO, *WHO Advises That Ivermectin Only be Used to Treat COVID-19 Within Clinical Trials* (Mar. 31, 2021), http://bit.ly/3VQSEPV; *see generally* AMA et al., *AMA, APhA, ASHP Statement on Ending Use of Ivermectin to Treat COVID-19* (Sept. 1, 2021), https://bit.ly/3urtSdi ("[S]trongly oppos[ing]" using "ivermectin to prevent or treat COVID-19 outside of a clinical trial" (emphasis omitted)).

against its use, it does not recommend treating COVID-19 with ivermectin.[15]

This cautionary guidance is well-founded. The overwhelming majority of studies investigating ivermectin find it is not an effective COVID-19 treatment.[16] The few dissenting studies that exist have "substantially evaporated under close scrutiny"[17] and even ivermectin's manufacturer "do[es] not believe that the data available support the safety and efficacy of ivermectin" for preventing or treating COVID-19.[18]

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[15] *See* Wis. Dept. Health Servs., *COVID-19: Treatments and Medications*, https://www.dhs.wisconsin.gov/covid-19/treatments.htm (Dec. 6, 2022).

[16] *See, e.g.*, Andreea Molnar et al., *Ivermectin in COVID-19: The Case for a Moratorium on Prescriptions*, 56 Therapeutic Innovation & Regul. Sci. 382, 382 (2022) (finding quality data indicating ivermectin effectively treats COVID-19 to be "sparse," and "strongly recommend[ing] a moratorium" on its use, except in clinical trials); Maria Popp et al., *Ivermectin for Preventing and Treating COVID-19*, Cochrane Database of Systematic Revs. at 2 (Jun. 21, 2022), http://bit.ly/3AQtDfo (finding "no evidence to support the use of ivermectin" for treating or preventing COVID-19); Gilmar Reis et al., *Effect of Early Treatment with Ivermectin among Patients with COVID-19*, 386 N. Eng. J. Med. 1721, 1721 (May 5, 2022) ("Treatment with ivermectin did not result in a lower incidence of medical admission to a hospital due to progression of Covid-19 or of prolonged emergency department observation among outpatients with an early diagnosis of Covid-19."); Arman Shafiee et al., *Ivermectin Under Scrutiny: A Systematic Review and Meta-Analysis of Efficacy and Possible Sources of Controversies in COVID-19 Patients*, 19 Virology J. 1, 1 (2022) ("Ivermectin did not have any significant effect on outcomes of COVID-19 patients").

[17] Jack M. Lawrence et al., *The Lesson of Ivermectin: Meta-Analyses Based on Summary Data Alone Are Inherently Unreliable*, 27 Nature Med. 1853, 1853-54 (2021).

[18] *See* Merck, *Merck Statement on Ivermectin Use During the COVID-19 Pandemic* (Feb. 4, 2021), http://bit.ly/3VQR0Of.

Thus, the consensus view of reasonable medical providers is that, apart from clinical trials, physicians should not administer ivermectin to prevent or treat COVID-19.

C. Mr. Gahl's evidence does not show that ivermectin is within the standard of care for COVID-19.

To rebut this scientific consensus, Mr. Gahl principally relies on the opinion testimony of one man: Dr. Pierre Kory, an unorthodox physician who has championed the use of ivermectin as a COVID-19 "miracle drug."[19] The existence of a single doctor with a contrarian view does not make ivermectin a standard treatment for COVID-19, however.[20] The Court of Appeals appropriately rejected Dr. Kory's testimony because it was presented through unsworn declarations, which gave no indication he had considered ivermectin's use for Mr. Zingsheim, in particular.[21]

Even if Dr. Kory's testimony had been properly presented, however, it would still fail to provide evidence of ivermectin's

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[19] *See* Pet. Br. at 16.

[20] *See Westphal v. E.I. du Pont de Nemours & Co.*, 192 Wis. 2d 347, 374, 531 N.W.2d 386, 395 (Ct. App. 1995) (finding "evidence that another physician might have acted differently" insufficient to establish a care standard) (citing *Zintek v. Perchik,* 163 Wis. 2d 439, 457, 471 N.W.2d 522, 529 (Ct. App. 1991)).

[21] *See Gahl ex rel. Zingsheim v. Aurora Health Care, Inc.*, 2022 WI App 29, ¶ 17, 403 Wis. 2d 539, 555, 977 N.W.2d 756, 764; *see also* Respondent-Appellant's Response Brief ("Resp. Br.") at 18.

effectiveness against COVID-19 because the studies on which his opinion is based—including his own—have been thoroughly discredited. For instance, Dr. Kory concluded, based on a survey of 18 ivermectin trials, that ivermectin promises "large, statistically significant reductions in mortality, time to clinical recovery, and time to viral clearance."[22] But additional research determined that meta-analyses touting ivermectin's effectiveness, including Dr. Kory's, had surveyed "largely poor-quality studies."[23] Indeed, one of the studies on which Dr. Kory relied was "potentially fraudulent" and included duplicated data.[24] The journal that published Dr. Kory's survey subsequently issued an "Expression of Concern," which questioned Dr. Kory's conclusions about ivermectin.[25]

Although Dr. Kory repeated his meta-analysis without the fraudulent data (but reaching the same conclusion),[26] another study

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[22] Pierre Kory et al., *Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19*, 28 Am. J. Therapeutics 299, 299 (May/June 2021).

[23] *See* Andrew Hill et al., *Ivermectin for COVID-19: Addressing Potential Bias and Medical Fraud*, 9 Open Forum Infectious Diseases 1, 1-2 (Jan. 17, 2022) (citing Kory, *supra* note 22).

[24] *See id.*; *see also* Kory, *supra* note 22 at 302 (citing study containing fraudulent data).

[25] *See* Peter Manu, *Expression of Concern for Kory P, Meduri GU, Varon J, Iglesias J, Marik PE. Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19*, 29 Am. J. of Therapeutics 231 (Mar./Apr. 2022).

[26] *See* Paul E. Marik & Pierre Kory, *Ivermectin, A Reanalysis of the Data*, 28

found methodological flaws in Dr. Kory's re-analysis that made it of "critically low quality."[27] Excluding flawed studies like Dr. Kory's leaves little evidence that ivermectin is an effective treatment for COVID-19.[28]

The Court need not parse the medical literature to affirm the Court of Appeals, however, because Mr. Gahl's flawed evidence shows, at most, that *some* physicians believe ivermectin is a safe and effective, off-label COVID-19 treatment.[29] If true, that might *allow* physicians to ethically and non-negligently administer ivermectin, but does not *require* them to do so.[30] Ultimately, Mr. Gahl's claims and request for emergency relief fail because he cannot establish that Aurora's refusal to administer ivermectin, or credential a physician for that purpose, was unreasonable.

Am. J. Therapeutics 579 (Sept./Oct. 2021).

[27] Steven G. Rothrock et al., *Meta-Analyses Do Not Establish Improved Mortality with Ivermectin Use in COVID-19*, 29 Am. J. Therapeutics 87, 87 (Jan./Feb. 2022).

[28] *See* Ariel Izcovich et al., *Bias as a Source of Inconsistency in Ivermectin Trials for COVID-19: A Systematic Review*, 144 J. Clinical Epidemiology 43, 43 (Apr. 1, 2022) (concluding that ivermectin's benefits "are uncertain," and warning that optimistic reports were "based on potentially biased results reported by studies with substantial methodological limitations"); *see also* Hill, *supra* note 23 at 1.

[29] Pet. Br. at 15-16.

[30] *See* Wis. Jury Instr. Civ. 1023 ("A doctor is not negligent . . . for failing to use the highest degree of care, skill, and judgment.").

II. Compelling physicians to provide ivermectin conflicts with their ethical obligations.

In addition to the legal infirmities of Mr. Gahl's claims, the Court should affirm the Court of Appeals to relieve Wisconsin's physicians of the unworkable burden placed on them by the Circuit Court's orders, which force them to choose between compliance with those orders and the medical ethical principles of beneficence, non-maleficence, and autonomy.[31]

Beneficence and non-maleficence require physicians "to act for the benefit of the patient" and "not to harm the patient."[32] Accordingly, physicians must provide quality care that "is safe, effective, patient centered, timely, efficient, and equitable."[33] They must also "[p]rescribe drugs, devices, and other treatments based solely on medical considerations, patient need, and reasonable expectations of effectiveness for the particular patient."[34] In Wisconsin, the "fail[ure] to conform to the standard of minimally competent medical practice,"

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[31] *See* Basil Varkey, *Principles of Clinical Ethics and Their Application to Practice*, 30 Med. Principles & Prac. 17, 18 (2021); *see also* Timothy M. Smith, *Why COVID-19 Has Provided a Timeless Lesson in Ethics* (Feb. 1, 2022), http://bit.ly/3XFcjDV. A fourth principle, justice, is not relevant here.

[32] Varkey, *supra* note 31 at 18.

[33] AMA Code of Medical Ethics § 1.1.6.

[34] *See id.* § 9.6.6(a).

including with respect to "administering" drugs, constitutes "unprofessional conduct."[35]

Physicians may administer off-label prescriptions under this framework, provided they minimize patient risk, and ensure the treatment is backed by "scientific evidence and appropriate clinical expertise,"[36] and is "demonstrated to improve patient outcomes and experience of care."[37] Novel treatments do not become part of the standard of care simply because they can be ethically attempted, however. And physicians do not breach ethical or legal duties by declining to administer them. Consequently, even if a physician could ethically treat COVID-19 with ivermectin, patients have no legal or ethical entitlement to that care.

The obligation to respect Mr. Zingsheim's autonomy does not change this conclusion. That principle required his physicians to inform him about viable options and to respect his decision to "accept or refuse

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[35] *See* Wis. Admin. Code Med. § 10.03 (2022).

[36] *See* AMA Code of Medical Ethics § 1.2.11(a), (c); *see also id.* § 1.2.11(b) (recommending "[s]eek[ing] input from colleagues or other medical professionals in advance" of administering novel treatment).

[37] *See id.* § 1.1.6(c); *see also* AMA, *Patient Access to Treatments Prescribed by Their Physicians*, Op. H-120.988, (2020), https://bit.ly/3HffD2I.

any recommended medical intervention."[38] It did not require them to "do whatever patients ask of them."[39]

Here, Mr. Zingsheim (through Mr. Gahl) was adequately informed of Aurora's treatment plan, and had an opportunity to discuss that plan and to refuse a recommended treatment, Remdesivir.[40] Further, Mr. Zingsheim's physicians fully explained their objection to administering the ivermectin prescription Mr. Gahl obtained.[41] Mr. Gahl does not argue otherwise; he simply disagrees with Aurora's medical judgment.[42] Mr. Gahl's displeasure notwithstanding, Aurora plainly fulfilled its ethical obligations to Mr. Zingsheim—who ultimately cleared his COVID-19 infection and was discharged from Aurora—by balancing Mr. Zingsheim's autonomy as a patient with Aurora's duty to reject a course of treatment that "scientific evidence" and "appropriate clinical expertise" shows carries substantial risk and little benefit.[43]

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[38] *See* AMA Code of Medical Ethics § 1.1.3(d); *see also generally id.* § 1.1.3(a)-(c), (g).

[39] *See* Patrick C. Beeman & Ryan C. VanWoerkom, *Patient Autonomy and Physician Responsibility, Commentary 1*, 11 AMA J. Ethics 598, 600 (Aug. 2009).

[40] *See* Pet. Br. at 8.

[41] *See* Resp. Br. at 11-12.

[42] *See generally* Pet. Br.

[43] *See* AMA Code of Medical Ethics § 1.1.6(c); *see also id.* § 1.2.11(a), (c).

Because Aurora acted ethically in refusing to either administer ivermectin to Mr. Zingsheim or credential an outside physician for that purpose, a court order compelling either action leaves physicians in Wisconsin with an impossible choice: ignore the court or their ethical obligations. Even if compelled by a court and requested by a patient, ethical breaches, like providing substandard care, expose physicians to possible administrative sanction for "unprofessional conduct," including license revocation,[44] and civil liability.[45] The Court should relieve Wisconsin's physicians of that perilous dilemma by affirming the Court of Appeals.

CONCLUSION

For the foregoing reasons, and those set forth in Aurora's brief, the Court should affirm the decision below.

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[44] *See* Wis. Stat. § 448.02(3)(a), (c) (2020) (establishing the Wisconsin Medical Examining Board's authority to investigate and punish allegations of unprofessional conduct); *see also* Wis. Admin. Code Med. § 10.03(2)(b) (2022) (defining "[u]nprofessional conduct" to include "[d]eparting from or failing to conform to the standard of minimally competent medical practice which creates an unacceptable risk of harm to a patient or the public").

[45] *See Gahl*, 977 N.W.2d at 777 ("[W]hether a release would shield Aurora and its health care professionals from liability could remain uncertain until decided in future litigation.").

Dated this 7th day of December, 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 2,962 words.

Dated: December 7, 2022.

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Dated: December 7, 2022.

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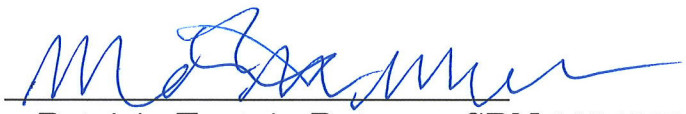
By: 

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