

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.

MOTION FOR LEAVE TO FILE A NONPARTY BRIEF

The Association of American Physicians and Surgeons (“AAPS”), a proposed *amicus curiae* in this case, hereby moves the court pursuant to Wis. Stat. §§ 809.14(1) and 809.19(7)(a) for leave to file a nonparty brief as *amicus curiae* in the above-captioned matter.

This Court recently granted such leave to two medical associations on the side of the Respondent hospital system, while AAPS seeks leave to file an amicus brief on the side of the Petitioner patient. At stake here is the availability of judicial review in a dispute concerning the denial of medical care to a hospitalized patient, as prescribed by a physician.

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 American Medical Association (AMA) that was recently granted leave to file an amicus brief here, 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. AAPS, unlike the AMA, opposes one-size-fits-all guidelines that AAPS thinks can be misused to deny patients timely access to needed medical care.

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). On the topic of ivermectin at issue here, the federal court for the Southern District of Texas, Galveston Division, recently 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).

Proposed *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. Hospitals do

not practice medicine. The Food & Drug Administration (FDA) does not practice medicine. The Centers for Disease Control and Prevention (CDC) does not practice medicine. The AMA and its state affiliate do not practice medicine. When a patient is in a hospital that blocks a prescription for that patient as written by a physician, then judicial review is necessary to ensure that the hospital is not improperly interfering with the practice of medicine. AAPS's amicus brief would provide valuable information to this court to assist it in reviewing the decision below, including the appellate court's unfounded assertions that a hospital rather than a physician ascertains the standard of care, and the impact of this ruling in denying access by hospitalized patients to judicial review. *See Gahl v. Aurora Health Care, Inc.*, 403 Wis. 2d 539, 545, 977 N.W.2d 756, 759 (Ct. App. 2022).

The panel majority below relies on its incomplete 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.’” 403 Wis. 2d at 564, 977 N.W.2d at 769. Apparently the panel majority below thought there was something irregular about an off-label use of a medication, when in fact such usage is commonplace and ethically required in many circumstances. The FDA approves the safety of medication, and then physicians decide when it can be helpful to a patient in a wide variety of possible circumstances. The panel majority overlooked that new applications for approval to the FDA are typically not submitted for new uses of approved medications. 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 senseless wasteful of resources. AAPS members quickly saved the lives of thousands of Covid-19 patients by prescribing them ivermectin, as was entirely appropriate and ethical to do.

As explained by an eminent physician (and past-president of AAPS) who has a J.D. in addition to her medical degree, and has also practiced law:

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.¹ Off label prescribing is left to the judgment of the physician and is not only legal but ethical.² 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].”³

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, 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.⁴ The truth is, numerous studies show that when started early, hydroxychloroquine and ivermectin significantly reduce symptoms and prevent hospitalizations and deaths.

¹ Congressional Research Service, “Off-Label Use of Prescription Drugs,” (Feb. 23, 2021). <https://sgp.fas.org/crs/misc/R45792.pdf> (viewed Nov. 24, 2022).

² 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).

³ K. Miller, “Off-Label Drug Use: What You Need to Know,” WebMD (2009) <https://www.webmd.com/a-to-z-guides/features/off-label-drug-use-what-you-need-to-know> (viewed Nov. 25, 2022).

⁴ 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).

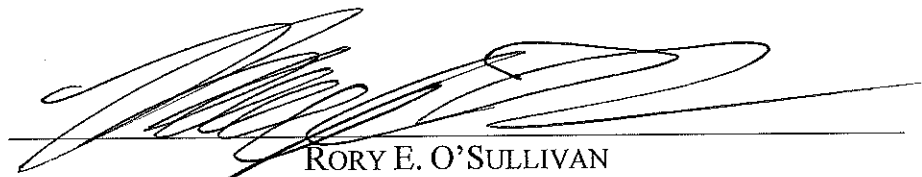
Marilyn M. Singleton, M.D., J.D., “Dear AMA: The Oath of Hippocrates Is Enough,” 26 *Journal of American Physicians and Surgeons* 109, 111 (Winter 2021).⁵

Proposed *Amicus* AAPS has a substantial interest in opposing interference by hospitals with the practice of medicine by licensed physicians. Furthermore, AAPS has a strong interest in seeking continued access to the courts by patients to contest interference with patients’ access to medical treatment as prescribed by their physician.

Proposed *Amicus* AAPS hereby respectfully requests that the Court grant its motion for leave to file its nonparty *amicus curiae* brief in this matter.

Dated this 1st day of December 2022.

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⁵ <https://www.jpands.org/vol26no4/singleton.pdf> (viewed Nov. 24, 2022).