

Opposing the War on Ivermectin—and Supporting Medical Freedom

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Although the COVID-19 lockdowns have subsided, the war rages on against using ivermectin and other inexpensive generic medications to treat novel viruses. Ivermectin is what AAPS physicians and others used successfully to save the lives of thousands of COVID-19 patients. Yet hospitalized patients were denied—and continue to be denied—access to this safe medication by predatory hospital chains, as incited by wrongful pronouncements by the Food and Drug Administration (FDA). A handful of bureaucrats at the FDA and Centers for Disease Control and Prevention (CDC) were biased against ivermectin from the outset of COVID-19, and have doubled down by refusing to admit they were wrong or to yield any of their power.

Amid a travesty of this magnitude one might turn to Shakespeare for wisdom. He famously had Marc Antony say, “The evil that men do lives after them; the good is oft interred with their bones.”¹ So it has been with COVID-19, during which good people trapped in hospitals tragically succumbed when denied ivermectin, while pompous administrators and bureaucrats established precedents favoring their own actions that may live long past COVID-19. Court cases continue concerning whether there will be future replays of this wrongful interference with the practice of private medicine that occurred during COVID-19.

There has been no accountability, legal or political, for those who caused the U.S. to rank among the worst in the world in handling COVID-19, despite the fact that the U.S. spends far more per capita on medical care than any other country. COVID-19-related mandates made things worse. In addition, hospitals caused many patients to die needlessly from COVID-19 by denying them access to ivermectin, which helped so many patients outside of hospitals.

Some trial judges responded to the misconduct by hospitals in interfering with access to ivermectin by ordering the hospitals to stop blocking this treatment. Nearly every patient who benefited from those court rulings survived and later walked out of the hospitals, after taking ivermectin. But some trial judges denied the requested relief, and those patients then typically died of COVID-19.

Whenever hospitals lost in court, they appealed and sought a ruling in their favor even after the patient had been successfully treated with ivermectin. Hospitals wanted to establish precedents for their side, so that next time they could deny treatment by pointing to appellate decisions in their favor. Litigation continues against the FDA about access to ivermectin.

A Quick Review of Ivermectin

Ivermectin is an off-patent (generic), inexpensive medication that is widely considered to be an effective treatment for COVID-19. In addition to numerous studies confirming ivermectin's benefits, the chairman of the Tokyo medical association announced in late August 2021 that physicians should use ivermectin to treat COVID-19. Government publications themselves have admitted how safe and effective ivermectin is.

“A 5-day course of ivermectin was found to be safe and effective in treating adult patients with mild COVID-19,” according to a study published in a journal posted by the NIH's National Library of Medicine.² Its biological mechanism has also been investigated and published.³

As explained in a publication of the Institutes of Health (NIH):

Ivermectin is a drug that many people will never have heard of. Yet thousands of villagers of all ages in communities scattered throughout the remotest parts of Africa and Latin America know its name, and **some experts regard it as one of the greatest health interventions of the past 50 years.** Ivermectin was brought to the commercial market place for multi-purpose use in animal health in 1981. Six years later it was registered for human use. **This remarkable compound has improved the lives and productivity of billions of humans,** livestock and pets around the globe, and promises to help consign to the history books two devastating and disfiguring diseases that have plagued people throughout the tropics for generations—while new uses for it are continually being found [emphasis added].⁴

Distorting this remarkably successful record by ivermectin, the FDA disparaged it as merely a horse drug, as though that somehow disqualified it from human use against COVID-19. That was one of many deceptions that the FDA resorted to during COVID-19 to improperly discourage use of ivermectin, and to justify hospitals blocking access to it by in-patients.

Studies overwhelmingly demonstrated the effectiveness of ivermectin in treating COVID-19. For example, researchers at Queen Mary University of London published a paper in August 2021, which concluded that: “from the Bayesian meta-analysis for patients with severe COVID-19, the mean probability of death without ivermectin treatment is 22.9%, whilst with the application of ivermectin treatment it is 11.7%.”⁵

Earlier, in the summer of 2021, a peer-reviewed journal likewise found significant benefits from ivermectin: “Moderate-certainty evidence finds that large reductions in COVID-19 deaths are possible using ivermectin. Using ivermectin early in the clinical course may reduce numbers progressing to severe disease. The apparent safety and low cost suggest that ivermectin is likely to have a significant impact on the SARS-CoV-2 pandemic globally.”⁶

Indeed, an overwhelming majority of studies show that ivermectin has been effective for early treatment and prophylactic use. Many AAPS members prescribed ivermectin with great success for many thousands of patients during COVID-19.

Appellate Rulings in Favor of Hospitals Blocking Ivermectin

Multiple patients' families were able to win in trial courts against hospitals that denied ivermectin to patients. But when hospitals lost, they appealed in order to set legal precedents in

their favor on this issue of denying treatments to hospitalized patients. Hospitals adopted a strategy of seeking to establish precedents that increased their authority, and to remove any precedents against unlimited power for them. Even after some of these cases became moot when the patients received ivermectin, recovered from COVID-19, and were discharged, hospitals still appealed them in order to establish hospitals' power to deny treatment in the future.

Unfortunately, every intermediate appellate court that heard this issue of the denial of access to ivermectin by hospitalized patients then ruled in favor of the hospitals. Typical among these decisions is one in *Texas Health Huguley, Inc. v. Jones*:

Jason Jones faces death at Texas Health Huguley Hospital Fort Worth South, and his wife Erin—having heard that ivermectin might help her loved one—filed suit to force the hospital and its relevant staff to give her husband the drug. The trial court...issued a temporary injunction ordering Huguley to grant a Houston-based, ivermectin-prescribing physician temporary hospital privileges for the sole purpose of administering ivermectin to Mr. Jones in Huguley's intensive care unit.

But judges are not doctors. We are not empowered to decide whether a particular medication should be administered, or whether a particular doctor should be granted ICU privileges. Our role is to interpret and apply the law as written. Although we may empathize with a wife's desire to try anything and everything to save her husband, we are bound by the law, and the law in this case does not allow judicial intervention. Just as we cannot legislate from the bench, we cannot practice medicine from the bench. Therefore, we vacate the trial court's temporary injunction.⁷

The court's fig leaf of "judges are not doctors" is misleading, because the court deferred to a hospital not licensed to practice medicine rather than to a doctor who is so licensed. It is a central obligation of courts to resolve competing assertions of authority, which this court did while pretending otherwise. This case was no different conceptually from a dispute over property rights, which courts resolve every day.

Other courts around the country decided for hospitals as the Texas appellate court did in *Huguley*, and these decisions were also flawed. Delaware Chancery Court denied a hospitalized patient access to a physician's prescription for ivermectin because "ivermectin's efficacy in treating COVID-19 is disputed."⁸ Of course, many treatments for a novel virus such as COVID-19 are disputed. Most of the vast number of 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 not a 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.

In the Delaware case, David DeMarco sought in-patient medical treatment for COVID-19 by Wilmington Hospital in that city on Sep 9, 2021. The hospital then blocked his attempts to receive treatment with ivermectin. His wife sued in Chancery Court there, which ruled against the patient, relying on FDA's false disparagement of ivermectin: "The U.S. Centers for Disease Control ('CDC') and the FDA have issued advisories indicating that ivermectin is not authorized or approved for the prevention or treatment of COVID-19."⁸

In denying access by this hospitalized patient to ivermectin, the Delaware Chancery Court expressly cited the FDA eight

(8) times. For example, that court relied on this testimony by a physician employed by Wilmington Hospital:

Q. Doctor, why does the medication management team rely on the FDA recommendations?...

A. And so the FDA, part of their role is to provide an opportunity to review [medical literature] and then provide guidance to the rest of us, as healthcare practitioners, in terms of what may be effective, as well as safe, in the management of a disease. So it's a very high bar, and the United States is known, in terms of the FDA, of having a high bar in terms of safety threshold and then efficacy, approving efficacy for management before recommending something....

Q. And is ivermectin part of these treatment guidelines that Christiana Care uses?

A. No."⁸

Contrary to the above assertions, the FDA lacks the expertise or authority to guide physicians in the practice of medicine.

Appellate courts in the large states of Illinois, Michigan, and Florida likewise held in favor of hospitals that denied ivermectin to COVID-19 patients, despite lawsuits by the patients to access it. In *Abbinanati*,⁹ the court repeatedly relied 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 patient. In *Frey*,¹⁰ the court found a lack of a right for "gravely ill" patients to object to a hospital's interference with care. In *Pisano*,¹¹ the court mischaracterized the request as one for hospital physicians to administer a treatment, when this is merely an issue of allowing the patient to receive a physician's prescribed medication.

Wisconsin Appellate Court

Wisconsin is the home state of the leader on the issue of prescribing ivermectin for COVID-19, Sen. Ron Johnson (R-Wis.), whose early U.S. Senate hearing on this issue gave publicity to the benefits of this medication. Wisconsin is also a political "swing state" such that voters, its state supreme court, many of its appellate courts, and its governing representatives are divided almost evenly on nearly every issue. For example, the outcome for Sen. Johnson's reelection in November 2022 was unclear the night of Election Day, and he ultimately prevailed by a reported vote of only 50.4% to 49.4%. His courageous stance for medical freedom made him a target for defeat by the Left, and they almost ousted him by pouring so much money into his opponent's campaign that Johnson's reelection campaign was outspent by nearly a 2-1 margin.

The 50-50 ideological split in Wisconsin was evident in litigation by a patient against Wisconsin's powerful Aurora hospital chain for blocking ivermectin treatment for COVID-19. The patient won at the trial court level, where the trial judge ordered the hospital to stop interfering with the patient's access to ivermectin. But Aurora immediately appealed and prevailed by a narrow 2-1 margin in a Wisconsin appellate court that relied on FDA's disparagement of ivermectin. The dissenting judge had the better of the argument when he observed:

What is important here is that the circuit court [i.e., the trial judge] 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 [the patient] Zingsheim.¹²

Judicial review must remain available for patients in situations where hospitals cut off access to potentially life-saving treatment. The panel majority was wrong to rule against judicial oversight of denial-of-care decisions by hospitals.

Onward to the Wisconsin Supreme Court

In a very pleasant surprise, the seven-justice Wisconsin Supreme Court then granted review of this case, the first to reach the level of any supreme court. AAPS quickly leaped into action. On Dec 2, 2022, the Wisconsin Supreme Court granted leave to AAPS to file an amicus curiae brief. AAPS pointed out that at stake in this case is the availability of judicial review when a hospital blocks access by a hospitalized patient to treatment with a medication prescribed by a physician.

Far from asking the Wisconsin Supreme Court to adjudicate or impose a particular standard of care, as implied by the amicus brief filed by the American Medical Association and Wisconsin Medical Society, AAPS sought to reestablish the availability of judicial review when a hospital denies access to medical treatment for a patient. 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 to hold otherwise.

AAPS argued that foremost among rights improperly taken away from Americans is their right of access as hospitalized patients to medication long approved as safe by the FDA. Imagine being denied access, while a patient in a hospital, to basic medication such as aspirin, AAPS argued. By historical happenstance that drug is available over the counter, and thus we have not heard of hospital administrators denying patient access to it. But access was and continues to be denied to other medications that have a record of decades of safe usage.

Hospitals are often private entities, but they do not disclose to their customers—incoming patients—that all who enter there will be denied the common medication of ivermectin that was widely being prescribed by physicians to treat COVID-19. Not even private entities should be allowed to engage in deceptive business practices by not disclosing their potentially deadly limitation on customer (patient) freedom.

In a terse decision by the Wisconsin Supreme Court rendered on May 2, 2023, a 6-1 majority held in favor of the hospital on a technicality:

We therefore conclude that the circuit court erroneously exercised its discretion by issuing an injunction without referencing any basis demonstrating that Gahl had a reasonable probability of success on the merits of some type of legal claim.¹³

The extensive dissent was compelling in explaining why the patient, who prevailed at the trial level, should have prevailed on appeal also:

The circuit court considered the relevant facts and applied the correct legal standard to reach a reasonable decision in light of the life-or-death circumstances presented. Like the majority of the court of appeals, a majority of this court fails to look for reasons to sustain the circuit court's discretionary decision as the law requires. Under our highly deferential standard of review, the circuit court properly exercised its discretion in entering an order granting temporary injunctive relief to a man near death.¹⁴

Federal Lawsuit against the FDA over Ivermectin

Meanwhile, last year a group of physicians courageously sued the FDA in federal court in Galveston, Texas, for its interference with use of ivermectin to treat COVID-19. The district court then dismissed this lawsuit, captioned *Apter, et al. v. HHS, et al.*, by holding that there was no finality in FDA's pronouncements against ivermectin, and thus there was no right to judicial review of its disparagement of the medication for COVID-19.

Yet the FDA's misconduct in interfering with early treatment of COVID-19 by ivermectin was reprehensible and as harmful as any final declarations by a federal agency. The courthouse doors should be open for FDA accountability when it interferes in an irregular but consequential manner with life-saving treatment as it did. A cause of action should exist in federal court against this federal agency for its misconduct that causes extensive loss of life. Improper interference by a federal agency with the life-saving medical practices of physicians should not be immune from judicial review.

Many state appellate courts, some of which are mentioned above, cited the FDA's unfounded and improper disparagement of ivermectin as a legal basis for hospitals to deny access by dying patients to this long-approved-as-safe medication prescribed by physicians. No one can credibly pretend that the FDA's conduct did not have legal consequences. FDA's campaign to interfere with the medical use of ivermectin to treat COVID-19 patients devastatingly caused many avoidable deaths. This misuse of power by this federal agency can be compared to the withholding of grain from Ukrainian farmers by Josef Stalin in 1932, which is widely acknowledged today as having caused tens of millions of needless deaths. There was plenty of grain in silos for Ukrainian farmers in 1932, but abundant supply does not mean access. The grain was withheld, which is analogous to FDA's impeding access to ivermectin by dying COVID-19 patients. For that, there should be accountability in court.

It is axiomatic that the FDA does not lawfully practice medicine, and the FDA lacks any authority to interfere with medical practice. No state medical board licenses FDA or any Washington, D.C., bureaucrat to practice medicine as FDA improperly did during COVID-19, to the detriment of many. Slamming shut the courthouse doors prior to allowing litigation against FDA, as is ordinarily allowed for plaintiffs in virtually any other case of this magnitude, should be reversed on appeal to the Fifth Circuit. When a federal agency engages in conduct that allegedly causes needless loss of life, courts should be open for full judicial review of the agency's misconduct.

Few would doubt that the FDA's statements against ivermectin were deliberate, forceful, and intended to have the maximum impact that they did. The FDA's interference with early treatment of COVID-19 by ivermectin was relied upon by state regulators and many courts in denying access by COVID-19 patients. Deaths occurred because of FDA's misconduct, which was beyond its proper authority and imposed with an agency bias against inexpensive early treatment of COVID-19. FDA had its own agenda, in opposition to President Trump. It has such a long record of being anti-life that Congress itself has tried to rein in its abuse of power. Courts are not to be mere potted plants as the FDA imposes its anti-life ideology.

FDA been able to evade judicial review for too long. Viewed objectively, its defiant misconduct is appalling. The more the FDA avoids submitting to discovery procedures that are commonplace for every other defendant, the bigger the

mushrooms can grow in the dark at this federal agency. It is time to reverse the premature dismissal of good-faith lawsuits that seek a modicum of judicial scrutiny of FDA's interference with the practice of ethical medicine.

California AB 2098

In 2022, California outdid even its prior COVID-19 tyranny when politicians there enacted a new law authorizing the California medical board and its separate osteopathic board to discipline physicians based merely on what they tell their patients. This new law, called AB 2098 and codified at Cal. Bus. & Prof. Code § 2270, took effect on Jan 1, 2023.

This new law mandates that “[i]t shall constitute unprofessional conduct for a physician and surgeon to disseminate misinformation or disinformation related to COVID-19, including false or misleading information regarding the nature and risks of the virus, its prevention and treatment; and the development, safety, and effectiveness of COVID-19 vaccines” (Cal. Bus. & Prof. Code § 2270(a)).

California thereby became the first state to expressly authorize its medical board to revoke the licenses of physicians based on so-called “misinformation” and “disinformation.” What do those terms even mean, and why are both of the terms often used in tandem? The California legislators were kind enough to place their definitions into the statute itself. “Misinformation” is defined as “false information that is contradicted by contemporary scientific consensus contrary to the standard of care” (*Id.* § 2270(b)(4)). “Disinformation” is defined as “misinformation that the licensee deliberately disseminated with malicious intent or an intent to mislead” (*Id.* § 2270(b)(2)). Thus, the California politicians who passed this unprecedented legislation view disinformation as a particular type of misinformation, namely when it is communicated with a bad intent.

The drafters of this oppressive California statute attempted to avoid First Amendment objections by limiting its scope to statements made by “the licensee to a patient under the licensee’s care in the form of treatment or advice” (*Id.* § 2270(b)(3)). But in practice it seems unlikely that a medical board would care more about what is said to a patient in a private examining room than what a physician says publicly on the internet or in other media.

At least three lawsuits were immediately filed asserting that AB 2098 is unconstitutional, and should not be enforced. The first two were not successful in the trial court, but the third one prevailed in federal court in Sacramento by obtaining an injunction against this bad law.¹⁵ The federal court held that:

Although the court does not reach plaintiffs’ First Amendment challenges, AB 2098 clearly implicates First Amendment concerns. See *Nat’l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361, 2375, 201 L. Ed. 2d 835 (2018) (stating that professional speech, including speech by medical providers, “is [not] exempt from ordinary First Amendment principles”); *Conant*, 309 F.3d at 637 (recognizing “the core First Amendment values of the doctor-patient relationship”). Accordingly, the court will apply a more exacting vagueness analysis.¹⁵

In applying “a more exacting vagueness analysis,” the federal district court enjoined AB 2098 as being void for vagueness. Specifically, the Court held that the definition of “misinformation” in AB 2098 is “unconstitutionally vague.” Notably, the Court also found that “COVID-19 is a quickly evolving area of science

that in many aspects eludes consensus,” and thus so-called “consensus” should not be a basis for discipline on issues such as COVID-19.¹⁵, pp 23-25

Conclusion

To paraphrase Shakespeare, as COVID-19 subsides, the evil that exploited it lives on, in the form of unchecked power by the FDA, CDC, hospital administrators, and state medical boards. AAPS continues to oppose this evil in court and in public opinion. It falls on AAPS to remain vigilant and continue to stand firm against the war on ivermectin, and against similar wars on other generic medications that may treat disease better than expensive, patented, brand-name medications heavily promoted by FDA and Big Pharma.

The government reaction to COVID-19 has caused long-term harm to our society beyond the mortality statistics. But it has also uncovered a misuse of science and an abuse of power, in particular by the FDA and hospitals. More work is needed to restore the liberty lost through restrictions imposed during COVID-19, which could be imposed again. AAPS will continue to lead the way for medical freedom, as it has done for the past 80 years.

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