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When Desperate Patients Go to Court for Unproven Treatments — The Battle for Hospital Independence

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As the Covid-19 pandemic wears on, patients have asked courts to compel hospitals to administer unproven therapies, with mixed legal results. Although talk radio hosts, politicians, and social media users have promoted various treatment approaches, they have given particular attention to ivermectin. The Food and Drug Administration (FDA) has approved ivermectin for use in humans for treating onchocerciasis (river blindness), intestinal strongyloidiasis, certain other parasitic worms, head lice, and skin conditions such as rosacea. Although this approval facilitates legal off-label use for prophylaxis against or treatment of other conditions, both the FDA and the Centers for Disease Control and Prevention have cautioned against using ivermectin for Covid-19, citing adverse gastrointestinal and neurologic effects. In addition, a Cochrane review concluded that "overall, the reliable evidence available does not support the use of ivermectin for treatment or prevention of COVID-19 outside of well-designed randomized trials."[1]

In U.S. hospitals, requests for ivermectin to treat Covid-19 have generally come as last-ditch efforts by family members of critically sick patients. For example, Jason Jones, a patient in Texas, was on a ventilator and in a medically induced coma for weeks before his wife requested that ivermectin be administered (see table). When the hospital didn't provide the medication, Jones' wife found an unaffiliated doctor who was willing to prescribe it and brought a court challenge seeking to compel the hospital to administer it. She ultimately lost, but several other patients and surrogates have prevailed in similar suits among the hundreds filed nationwide, according to media reports.

Because these cases are often filed in local courts on an emergency basis and few have been appealed, extensive court records aren't always created. In three cases for which legal dockets are available — from Illinois, Ohio, and the Jones case in Texas — the lower court granted the plaintiffs' requests for ivermectin. In the Ohio case, however, the court refused to issue continued injunctive relief after a 14-day period, and in the Texas case, an appeals court overturned the trial court's decision. In three other cases — from Delaware, Michigan, and New York — trial courts refused the plaintiffs' requests. In the Michigan case, the decision was upheld on appeal.

This wave of litigation has its roots in legal frameworks related to prescribing medication, the doctor–patient relationship, physician licensing, and hospital-credentialing procedures. Although state laws are fairly consistent, these frameworks are pliable enough that various judges have decided differently on the same issue. As the court in Michigan wrote, the question is "whether the judiciary has the legal authority to compel a hospital to administer a drug, on an off-label use, that the hospital considers may harm its patient, and where that use is not sanctioned by the FDA and other health authorities." However, these lawsuits have also called into question the judiciary's role in medical decision making.

According to common law, establishing a doctor–patient relationship is typically voluntary for both parties. Once this relationship is formed, doctors have a duty to use their medical judgment to provide competent care and may face discipline or liability for providing substandard care. Physicians have no obligation to provide futile or harmful care; requiring them to do so could cause moral distress.[2] The provision of futile care can also affect the interests of other patients, even outside the pandemic context of extreme scarcity.[3]

Doctor–patient relationships aren't exclusive, however — patients can establish relationships with several doctors, and they aren't confined to a particular hospital when seeking new medical advice. In the recent ivermectin cases, patients who were stymied by their treating hospitals sought out other doctors to prescribe the medication, including doctors who have become notorious specifically for their willingness to provide this service.

In tension with this philosophy of patients' choice regarding their physicians, hospital bylaws determine the membership of the medical staff and thus who can order medication within the hospital. This system is a function of hospital-accreditation standards,

Selected U.S. Court Cases in Which Patients Sought Access to Ivermectin in Hospitals.

Case and State	Outcome	Rationale
DeMarco v. Christiana Care Health Services, Inc., Delaware	Hospital won; the court didn't compel the hospital to administer ivermectin.	Patients, even gravely ill ones, don't have a right to a particular treatment.
Frey v. Trinity Health-Michigan, Michigan	Hospital won; the court didn't compel the hospital to comply with an unaffiliated physician's ivermectin prescription.	A court ordering a hospital to do something (i.e., an injunction) is an "extraordinary" action. Although the court has sympathy for the ill patient, the court limited its analysis to whether the patient met the criteria for an injunction. The court held that the patient did not, because, among other considerations, the patient didn't show that irreparable harm would occur if ivermectin wasn't administered.
Texas Health Huguley, Inc. v. Jones, Texas	Hospital lost originally, then won; the lower court required the hospital to give the prescribing physician emergency ICU privileges to administer ivermectin; on appeal, the court didn't force the hospital to allow administration of ivermectin within the hospital.	The appeals court emphasized that "judges are not doctors." The court is "not empowered to decide whether a particular medication should be administered, or whether a particular doctor should be granted ICU privileges."
Smith v. West Chester Hospital, LLC, Ohio	Hospital lost originally, then won; the court initially ordered the hospital to administer ivermectin for 14 days; later, the court denied the patient's request for continued ivermectin treatment.	There is no strong scientific evidence that ivermectin is effective; the patient could be transferred to another hospital; and public policy doesn't allow "a physician to try 'any' type of treatment on human beings."
D.J.C. v. Staten Island University Hospital-Northwell Health, New York	Hospital won; the court didn't compel the hospital to administer ivermectin prescribed by a third-party physician.	The patient didn't submit any evidence that ivermectin is an effective or approved treatment for Covid-19. The patient also failed to show that irreparable harm would occur without the legal remedy.
Ng v. Edward-Elmhurst Healthcare, Illinois	Patient won; the court compelled the hospital to grant a third-party physician privileges to administer ivermectin.	There is no situation more extraordinary than when a person's life is hanging in the balance.

which are required by payers, including Medicare. As courts have recognized, although the practice of medicine is the responsibility of licensed physicians, hospitals are also bound by an independent legal duty to patients. This duty requires hospitals "to use reasonable care in formulating the policies and procedures that govern its medical staff and nonphysician personnel, to exercise reasonable care in the selection of its medical staff, and to periodically monitor and review the medical staff's competence."[4]

Traditionally, there have been two workarounds for resolving conflicts between patient choice and hospital independence. First, physicians who have hospital privileges can exercise their own judgment to confirm an outside doctor's prescription and order medication for a hospitalized patient. Second, when a hospital refuses to provide certain care, the patient can be transferred to a different hospital. In the ivermectin cases, apparently no hospital physician was willing to prescribe the drug and transfer was infeasible, because of either patient-related risks or the lack of a physician with privileges at a hospital that was willing to accept the transfer.

When the quandary has remained, several courts have sided with hospitals. The judges in these cases haven't focused on the medical issue of whether ivermectin would or wouldn't be safe and effective for treating Covid-19 — a question that they aren't competent to answer, especially in the setting of an emergency petition with no opportunity for robust fact-finding. Instead, these courts have focused on whether the judiciary has the authority to issue an injunction compelling a hospital to act contrary to its staff's judgment. As the court in Texas wrote, "It would be illogical to impose a duty to use reasonable care upon a hospital, but to deprive the hospital of the ability to implement policies and programs that it deems reasonable."

In other cases, trial courts have taken the opposite tack. Arguing that because petitioning patients are near death, and therefore there is little downside to

administering ivermectin, some judges have ordered hospitals to grant prescribing doctors emergency privileges. In the Illinois case, for example, the judge stated, "I can't think of a more extraordinary situation than when we are talking about a man's life." Yet of course having lives at stake isn't exceptional in hospitals, and it is all the more reason to ensure that practice is evidence based. Although a hospital granting emergency privileges is arguably a fine outcome for an individual patient — if treatment with ivermectin reflects the patient's or a surrogate's informed choice and the advice of a competent physician — such an ad hoc approach undermines the policy of having independent medical staff oversee the quality of care in U.S. hospitals. According to this view, hospitals aren't accountable institutions, just places where health care happens, for better or worse.

An audio interview with Prof. Robertson is available at NEJM.org

Although these decisions may make it seem as if judges are elevating themselves above doctors and hospitals, the judges might see themselves as merely resolving a dispute between two physicians: one in the hospital, opposed to ivermectin's use, and the other outside the hospital, supporting its use. In this case, the tie goes to the patient's (or surrogate's) preference. But this conflict invites the larger question of why a small minority of physicians should be allowed to promote themselves as practicing in ways not supported by evidence.

In one sense, these court battles are mere echoes of previous controversies involving patients who have demanded treatments that hospitals considered futile or hospitals that wouldn't perform abortions or provide drugs intended to hasten death. However, the present moment represents the strange intersection of a deadly pandemic, the rise of social media sites where treatments are promoted directly to patients, and a decade in which the "right to try" unapproved treatments has been supported by legislatures, Congress, and the White House.[5] The ground may be shifting, but at the moment, courts are preserving the institutional integrity of both health care and the judiciary.

Disclosure forms provided by the authors are available at NEJM.org.

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"The Sombre Aspect of the Entire Landscape" — Epidemiology and the Faroe Islands

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In December 2021, as the impact of the omicron variant of SARS-CoV-2 began to be felt, commentators reached for a comparison to clarify the increased infectiousness of this new variant, which would occasion renewed debate about holiday shutdowns and overwhelmed health systems. Everyone from former Centers for Disease Control and Prevention director Tom Frieden to television news anchors began comparing omicron to the most contagious virus we know: measles. In January 2021, we had drawn a different analogy to measles to argue for vaccinating children against Covid-19 to protect both them and their communities.[1] These newer discussions focused on contagion, the area in which measles is unmatched.

On December 23, amid the flurry of reports trying to elucidate omicron's peculiarities, a preprint appeared: "Omicron Outbreak at a Private Gathering in the Faroe Islands, Infecting 21 of 33 Triple-Vaccinated Healthcare Workers."[2] Though the article didn't mention measles, it evoked the history of that virus and the story of how a 19th-century physician discovered the secrets of its spread.