

AN ONGOING CE PROGRAM of the University of Connecticut School of Pharmacy

EDUCATIONAL OBJECTIVES

After completing the continuing education activity, pharmacists and technicians will be able to

- Discuss the effect of health misinformation on public health
- Review the controversy over ivermectin as a treatment for COVID-19
- Characterize the basis for lawsuits seeking to compel specific treatments during a pandemic
- Describe the role of regulatory bodies in disciplinary actions for misinformation

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Pharmacists and pharmacy technicians are eligible to participate in this application-based activity and will receive up to 0.2 CEU (2 contact hours) for completing the activity, passing the post-test with a grade of 70% or better, and completing an online evaluation. Statements of credit are available via the CPE Monitor online system and your participation will be recorded with CPE Monitor within 72 hours of submission

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LAW: Science Says "NO!" but Social Media Says "GO!"

ABSTRACT: The continuing public health crisis has spurred an increase in the demand for unauthorized remedies. Many approaches are of dubious value and the appeal often has been driven by misinformation and uncertainty, frequently with endorsement from health care providers. This continuing education activity will examine the controversial promotion of unauthorized medications for the treatment for COVID-19, with an emphasis on the antiparasitic drug, ivermectin. Its focus is the efforts by patients to use the legal system to obtain the drug against the advice of mainstream medical practitioners and the efforts by some regulatory and professional organizations to restrict the dissemination of debatably distorted information about ivermectin.

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FACULTY DISCLOSURE: The author has no financial relationships with an ineligible company.

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INTRODUCTION

"People of the Middle Ages largely believed that bad air (caused by misaligned planets) was the cause of the bubonic plague. They tragically took medical precautions based on misinformation, such as wearing perfume satchels around their nose and mouth, when it was really infected fleas who were the perpetrators."¹

The ongoing COVID-19 pandemic has brought forth many experiences including overcrowded emergency rooms, masking, social isolation, lockdowns, "warp speed" vaccine development—and health misinformation. Disagreements over appropriate treatment of infected patients are numerous and heated and often spill into the political arena. Alternative treatments arising from desperation and inconsistent, everchanging advisories are highly sought, fueled by social media and other Internet resources. In many cases, health care professionals are sources of dubious information.

PAUSE AND PONDER: A patient approaches you and asks you about a rumor she saw on the Internet stating that cocaine would counteract the virus responsible for COVID-19 (yes, this is a real event^{5,7}). How do you respond?

Pharmacists and pharmacy technicians, of course, have responsibilities during a health care crisis and can be either another source of misinformation or a resource to clarify and refute poor advice. This continuing education activity examines some recent instances of conflicting health information. It focuses on lawsuits by patients requesting access to unproven or unconventional therapies for COVID-19 against mainstream medical advice and the sanctioning (or lack thereof) of health care providers for encouraging such therapies.

Disclaimer: Please be advised that the author chose the examples referred to in this continuing education activity based upon their high-profile and impact. Learners should not interpret these choices as representing any political commentary, agenda, or endorsement by the author or the University of Connecticut Office of Pharmacy Professional Development. We acknowledge that "misinformation" is hard to characterize, and a consensus can shift as more data are developed. Learners should also not infer that the examples used represent a deliberate intent to deceive by their advocates.

MISINFORMATION

Misinformation was chosen by Dictionary.com as its word of the year in 2018 and has maintained a strong presence during the COVID-19 pandemic.² Misinformation has been defined as "false information that is spread, regardless of whether there is intent to mislead."² Hence, misinformation can be provided in good faith or be malicious and motivated by personal gain; malicious misinformation is sometimes also referred to as disinformation.³ This continuing education activity uses the term misinformation without regard to intent.

Health misinformation has been defined as information that is false, inaccurate, or misleading according to the best available evidence *at the time* (emphasis added).³ The trustworthiness of information, therefore, can change with time. Misinformation can arrive in many ways, but social media is a major contributor.²⁻⁴ A study of information spread over Twitter found that false news reached more people and diffused faster than truthful news.⁴ There are many possible reasons for this including novelty of the information, the recipient's emotional reaction and heightened anxiety, cognitive biases, social media platforms that incentivize sharing, and algorithms that prioritize content based on its popularity.^{3,4}

Health misinformation can be problematic and can influence political, economic, and social well-being.⁴ Health misinformation can be harmful. U.S. Surgeon General Vivek Murthy has



stated that "misinformation takes away our freedom to make informed decisions about our health and the health of our loved ones. Simply put, health misinformation has cost us lives."³ Additionally, people can become confused and anxious when faced with contradictory information, and this is especially harmful during a public health crisis.^{3,5} It can expose patients to wasteful and harmful products and procedures, delay the discovery of effective treatments, delay treatment with a more scientificallybased therapy, and divide families and communities.⁵ As we have seen, it can also erode trust in health care personnel, scientists, and public health agencies.

Spreading dangerous health misinformation is not a new phenomenon, especially during a global health crisis. One example occurred during the bubonic plague pandemic during the Middle Ages and is described above. During the 1918 flu pandemic, the U.S. Surgeon General supported the use of high doses of aspirin (1 to 1.3 g every one to three hours) and an epidemiologic analysis concluded that a significant number of fatalities were due to aspirin poisoning.⁶ More recently, learners may recall the indiscriminate use of chloroquine and hydroxychloroquine during the COVID-19 pandemic resulting in numerous fatal adverse events and a drug shortage.⁶

TURNING TO THE COURTS FOR MEDICAL TREATMENT

It should not be surprising, given the large number of hospitalizations and deaths from COVID-19 infections, that patients would go to great lengths to obtain unconventional but highly promoted, treatments, even if they are not approved or authorized by the U.S. Food and Drug Administration (FDA).⁸ This is especially true if health care professionals or social media "influencers" endorse the drugs.

Ivermectin is an example of a drug that has been extensively sought by people seeking to treat or prevent COVID. Ivermectin has generated a great deal of controversy, with strong validation from advocates while public health agencies generally expressed disapproval. Ivermectin will be used as a model of a drug that is an unapproved COVID-19 therapy, but highly popularized by non-mainstream sources. The intent is not to resolve issues about its efficacy but to illustrate patient efforts to bypass conventional treatment pathways and seek a remedy via legal challenges.

Ivermectin

Ivermectin is an established, inexpensive FDA-approved drug introduced for medical use in 1982. It is used in humans, but more extensively in animals. It is effective against various types of nematodes and helminths (parasitic worms), and ectoparasites such as mites and lice.9 It is used to treat parasitic tropical diseases such as onchocerciasis (River Blindness) and intestinal strongyloidiasis and is used in high dose concentrated topical and injectable formulations for parasitic infestations in animals, including treating heartworm.^{8,9,10} It is also approved for human use to treat parasitic worms and in topical formulations for head lice and rosacea.⁸ Ivermectin is also being evaluated to kill mosquitoes responsible for transmitting malaria.⁹ Ivermectin's proposed mechanism of action is by binding to specific cell membrane channels that only reside in invertebrates.¹⁰ Activation of these channels leads to chloride-induced hyperpolarization and inhibition of cell signal transmission which results in paralysis and, ultimately, death of the parasites. However, it is not FDA-approved for the treatment of any viral infection and the FDA has not authorized or approved it for treating or preventing COVID-19.8

Interest in ivermectin as a COVID treatment stems from *in vitro* (meaning the research was conducted in culture dishes, not live animals or humans) research on the virus responsible for human immunodeficiency virus (HIV). Studies reported that the drug can inhibit the transport of protein to the nucleus by cargo proteins and inhibit viral replication. Similar *in vitro* investigations have been extended to other viruses.^{8,10,11} It has also been proposed that ivermectin may interfere with the binding of the coronavirus spike protein to human cells and some studies have reported potential anti-inflammatory properties.⁹ These would support the notion of a possibly favorable effect in COVID-19.

However, pharmacokinetic and pharmacodynamic analyses suggest that achieving the plasma concentrations necessary for the antiviral efficacy detected *in vitro* would require administration of doses up to 100-fold higher than those approved for use in humans,⁹ although it has been proposed that intravenous and aerosol preparations may achieve higher tissue levels than those attainable by the oral route.¹¹

Despite promising *in vitro* activity, clinical reports have generally not provided evidence of a clinical benefit for ivermectin in patients with viruses.⁹ Public health agencies, including the FDA, World Health Organization (WHO), and Centers for Disease Control and Prevention (CDC) recommend against using ivermectin to treat COVID-19, citing a lack of data from large, randomized controlled trials confirming its effectiveness.¹² The National Institutes of Health's COVID-19 Treatment Guidelines Panel has also determined that there are currently insufficient data to recommend ivermectin for treatment of COVID-19.¹³ The FDA has warned against self-medicating with ivermectin preparations intended for livestock citing multiple reports of patients requiring medical attention, including hospitalization.⁸ Adverse effects include gastrointestinal symptoms such as nausea, vomiting, and diarrhea and more severe overdoses associated with hypotension and neurologic effects such as decreased consciousness, ataxia, confusion, hallucinations, seizures, coma, and death.^{8,13,14} Ivermectin may also interact with anticoagulants and potentiate the effects of CNS depressants such as benzodiazepines and barbiturates.^{8,13}

Supporters of using ivermectin cite multiple smaller studies and firsthand experience with the drug. They claim ivermectin can work to prevent patients from developing COVID-19 symptoms and can shorten recovery time for those already infected.^{14,15} Detractors point out that, generally, these studies were incomplete, had no control group, or had other methodological limitations such as small sample sizes or patients receiving additional treatments along with ivermectin.^{14,15}

A recent meta-analysis concluded that, "There is limited evidence for the benefit of ivermectin for COVID-19 treatment and prophylaxis, and most of this evidence is of low quality." The researchers urged further investigation to provide support for optimal treatment protocols.¹⁵ The analysis found some evidence of decreasing mortality and disease progression in patients with severe disease (but not in mild or moderate disease) and an increase in the rate of patients with a negative RT-PCR test, but with low quality of evidence due to factors such as risk of bias, inconsistency, and lack of precision.¹⁵

The WHO guidelines also recommend against using ivermectin in patients with COVID-19 except in a clinical trial.¹⁶ WHO updated the guidelines in September 2021 and included newer, relatively small trials published since an earlier recommendation and noted that one key trial was retracted due to concerns about research fraud. In a joint statement, the American Medical Association, American Pharmacists Association, and American Society of Health-System Pharmacists strongly opposed the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial.

Furthermore, one of ivermectin's largest manufacturers does not support the use of the drug stating that it finds "(n)o meaningful evidence for clinical activity or clinical efficacy in patients with COVID-19 disease" and a "concerning lack of safety data in the majority of studies."¹⁴

The high level of attention focused on ivermectin has resulted in increased demand. A recent study examining trends in ivermectin dispensing from U.S. retail pharmacies during the COVID-19 pandemic showed an increase in the number of prescriptions to 39,000 per week by January 2021, compared with a weekly average of 3,600 prescriptions per week prior to the pandemic.¹³



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More than 88,000 prescriptions were dispensed by August 2021, representing a 24-fold increase from the pre-pandemic baseline.

Adverse effects associated with ivermectin misuse and overdose are also on the rise. Calls to poison control centers report more overdoses and more people experiencing adverse events.¹³ The National Poison Data System, which collects information from the nation's 55 poison control centers, reported 1,143 ivermectin exposure cases between January 1 and August 31, 2021, many from the use of high dose veterinary products. This is a 163% increase compared with the same period in the previous year. There was a 245% increase in reported cases (133 to 459) between July and August alone.¹⁷ In Mississippi, 70% of recent calls to the state poison control centers were due to ivermectin ingestion.¹⁷

Australia's drug regulatory administration, responding to a three-to-four-fold increase in prescriptions, banned medical practitioners from off-label prescribing of ivermectin, including treatment of COVID-19. It took this action because of reported drug shortages, concerns that patients would self-medicate with the drug instead of seeking treatment or vaccination, and the risk of using unsafe doses.¹⁸ Prior to the ban, social media encouraged the rise in prescribing with posters sharing the names of sympathetic doctors who were willing to prescribe the drug.

Lawsuits

Despite the large increase in the number of prescriptions for ivermectin, a growing number of patients with COVID have been unable to receive treatment with the drug. Subsequently, some of them have filed lawsuits trying to compel health care providers and organizations to supply it as a therapeutic alternative.^{19,20} Typically, a case is brought by a guardian or representative of a patient who is severely ill and is believed to have no remaining treatment options. The plaintiff usually raises the argument that the defendant (hospital, practitioner) must comply with the patient's prescription order as an appropriate standard of care, or that the patient has a constitutional right to receive treatment with ivermectin.²¹

The family of an 80-year-old patient who was on a ventilator and was given a 20% chance of surviving a COVID-19 infection filed

Pause and Ponder: Who should decide whether a patient should receive a particular therapy?

the first ivermectin lawsuit in 2021 against a hospital near Buffalo, NY.²² The family (who did not consult a healthcare provider external to the hospital) pressured an intensive care unit (ICU) physician to give the woman ivermectin, which he agreed to do. After she was transferred to another wing in the hospital, physicians there refused to give her additional doses and her condition deteriorated. The family sued to reinstate the treatment. The hospital argued that physicians, and not the courts, should make decisions about medical care. However, the judge ordered the hospital to immediately provide ivermectin if the patient's family physician would prescribe it, which he did. The patient's condition subsequently improved.²² The ability of the court to override clinician treatment decisions in this case helped spur additional suits.

In another case, a 68-year-old woman in Illinois was admitted to intensive care at a hospital in early April 2021 and after about a month, was placed on a ventilator.²³ Her daughter searched the Internet and discovered a news report about the Buffalo lawsuit; she asked the hospital to administer ivermectin to her mother, which it refused to do. At the hearing, the hospital claimed that none of its physicians would agree to administer ivermectin for COVID-19. Moreover, its internal ethics panel concluded that the use of ivermectin could not be justified.²³ The hospital's lawyer argued that judges should not overrule medical decisions made by health care personnel. The lawyer stated that a court "doesn't have the authority to order a medical corporation to use particular medications, particularly when it's an off-label use, particularly when the federal government has said it could be dangerous."²³ The judge hearing the case countered by saying "If someone has been in the ICU for a month and not improving, why would the hospital not consider another medication?"23 He ordered the hospital to administer the drug.

The hospital responded that no health care professional on staff (including pharmacists) would agree to give the drug. The court ordered the hospital to locate an outside practitioner. The hospital found a local physician who administered ivermectin. He testified at a subsequent court hearing that the patient was taken off the ventilator and discharged from the hospital after receiving the drug for 20 consecutive days.²⁴

In another case in suburban Chicago, a 68-year-old woman was being treated for COVID-19. When the hospital refused to supply ivermectin, her daughter transferred her to another hospital. When the second hospital also refused, the daughter sued the hospital and a judge ordered that the drug be given.²⁵ After receiving a few doses, the patient's heart rate dropped dramatically (in one instance to 28 beats per minute; normal varies by age, but is generally considered 60 or 75 to 100 bpm) and the hospital went back to court arguing that further treatment would be dangerous.²⁵ The family decided to withdraw the treatment.^{20,25} However, in an interview, the family's lawyer stated that the ivermectin was showing benefit and that the bradycardia was due to a different medication that was being used to control her blood pressure.²⁶

In addition to judicial action, hospitals face public backlash over refusal to administer ivermectin.^{20,27} One Chicago area hospital reported receiving hundreds of phone calls and emails and an in-person protest supporting a hospitalized patient who was seeking treatment with ivermectin.^{20,27} Prominent advocates (aligned with popular conspiracy movements) shared the hospital's contact information and encouraged followers to support the movement.²⁰

Not all lawsuits have resulted in a victory for the patient.²⁰ In one case, an Ohio man tested positive for COVID-19 and was hospitalized and admitted to the ICU. He was intubated and placed on a ventilator a few weeks later.²⁸ His wife discovered information about ivermectin and connected with a physician known to use the drug who prescribed it, but the hospital refused to administer it. The hospital was sued, and a judge ordered the hospital to provide the man with 30 mg of Ivermectin daily for three weeks.²⁸

In an interview, the prescribing physician said the science behind the use of ivermectin in COVID-19 patients is "irrefutable" and that the CDC and FDA are engaged in a "conspiracy" to block its use to protect the FDA's emergency use authorization for COVID-19 vaccines.^{28,29} He further maintained that the mainstream media and social media have engaged in "censorship" regarding ivermectin's benefits, and that the U.S. government's refusal to acknowledge the drug's value amounts to "genocide."²⁸ The physician allegedly wrote the prescription without reviewing the patient's clinical information or consulting with any of the patient's treating physicians.²⁹

The hospital appealed the order, and the court reversed it.²⁹ The first paragraph of the court's decision captures the dilemma posed by these cases: "It is impossible not to feel sympathetic to



PAUSE AND PONDER: How would you handle a public demonstration outside the pharmacy by a group protesting a refusal to fill a prescription?

the Plaintiff in the case at bar. The Plaintiff wants her husband to get better. She has sought out a doctor who prescribed ivermectin with the hopes that it could help. The Defendant Hospital wants to follow what it believes are appropriate medical standards and make the husband get better using those protocols."³⁰

In overturning the previous decision, the judge noted that "based upon the evidence, it (ivermectin) has not been shown to be effective at this juncture" and criticized some of the studies used to support its use.³⁰ He went on to say that "While this court is sympathetic to the Plaintiff and understands the idea of wanting to do anything to help her loved one, public policy should not and does not support allowing a physician to try 'any' type of treatment on human beings."³⁰ In general, healthcare professionals are expected to adhere to the prevailing standard of care.

The ivermectin cases generally revolve around the concepts of bodily integrity, patient autonomy, and informed consent. It is a long-standing legal principle that all competent adults have the right to choose what can be done to their own body and refuse unwanted medical treatment, even if the person may die as a result.^{31,32} (Some exceptions exist, such as suicide prevention,³² but these are not relevant to this continuing education activity.)

One of many significant Supreme Court rulings addressing this issue is *Cruzan v. Director, Missouri Department of Health* which was decided in 1990.³³ Nancy Cruzan was involved in an auto accident that left her in a vegetative state. Her parents sought a court order to terminate their daughter's artificial feeding and hydration equipment after it became apparent that she had virtually no chance of recovering her cognitive faculties. The hospital refused the request without a court order and the parents

filed a suit. The Supreme Court turned down the parent's request and in so doing held that there must be clear and convincing evidence of a patient's wishes, in this case to withdraw life support, and that it must be the patient who expresses these wishes. The Court concluded that "Every human being of adult years and sound mind has a right to determine what shall be done with his own body ... The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment."³³ The right to refuse medical treatment has been incorporated into many state laws on informed consent.³²

While patients clearly have a right to *refuse* a treatment, most courts have long held that patients, including the terminally ill, do not have a fundamental right to *access* a particular type of treatment, even if it is legally available.^{21,34}

A recent case from Delaware examined this legal issue when it denied a request to compel a healthcare provider to treat a patient hospitalized with COVID-19 with ivermectin.³⁵ In this case, a patient with COVID-19 was admitted to the hospital and, as his health declined, his wife sought and obtained a prescription for ivermectin from a doctor who never met the patient, and who was unaffiliated with the hospital. Consistent with its guidelines, the hospital refused to administer the drug and the lawsuit followed.

The court held that the health care provider "does not have an enforceable duty" to treat the patient with ivermectin, nor does the patient have "an enforceable legal right to that treatment."³⁵ The hospital's duty to the patient did not extend beyond the standard of care according to the judge. Since ivermectin is not part of the standard for treating COVID-19, and its effectiveness is disputed, a physician who refuses to administer the drug is not deviating from the applicable standard of care. Healthcare providers do not have a duty to administer ivermectin to a patient with COVID-19. The court reiterated the concept that the plaintiff's right of healthcare self-determination is limited to "the right to refuse medical or surgical treatment if such refusal is not contrary to existing public health laws."³⁵ Applying that limit, courts have held that a patient does not have a constitutional right to obtain a particular type of treatment nor to obtain treatment from a particular provider. Granting the patient's request, the Court said, would risk harm to the patient and would be detrimental to public policy that expects a healthcare provider to deliver a standard of care based on "prevailing scientific and ethical norms."³⁵ Since ivermectin lacks proven efficacy, the patient could not legally demonstrate that any irreparable harm would ensue by refusing the request. The Court also warned that "compelling a provider to operate outside the standard of care would improperly and imprudently move health care treatment decision making from the patient's bedside to a judge's bench."35



In a different twist on this issue, a physician, rather than a patient, is suing a hospital over its ban of certain treatments, including ivermectin, for COVID-19.³⁶ According to the complaint, patients will be "denied their right to choose life-saving medicines their attending physician considers appropriate for them."³⁶ The physician describes himself as "a world-leading authority on the pathophysiology and treatment of COVID"³⁶ and has authored several papers on clinical treatment of COVID, including one that was retracted by the journal that published it on the day the suit was filed. In contrast to suits filed by patients seeking treatment, he asserts that he is not asking the court to practice medicine or make a medical determination, only that the hospital respect his and his critically ill patients' right to "discuss and decide to use FDA-approved, potentially life-saving medicines."³⁶ He also argues that double blind, randomized controlled clinical trials are not superior to observational studies, which he has conducted. "Physicians are free to disagree" he states, but "a prudent, knowledgeable physician with COVD clinical experience" such as him, can make a "reasonable professionally sound judgement" that ivermectin is medically appropriate for treating COVID.³⁶ The SIDEBAR (next page) discusses issues related to prescribing and provides background on off-label prescribing.

SANCTIONS FOR MISINFORMATION?

Patients declining vaccinations or seeking unapproved treatments for COVID may be following advice posted on news outlets or social media, sometimes by health care practitioners who reject mainstream guidance from public health agencies. Is there a risk of disciplinary action against these practitioners for disseminating this information?

Some medical boards have declared that physicians may be subject to disciplinary action if they engage in conduct which is "unethical or unprofessional" related to COVID-19.³⁷ (Note: this applies to all COVID-19-related information including vaccines, masking, and drug treatments.) As with all things associated with the pandemic, outlooks are widely divergent.

The Federation of State Medical Boards (FSMB) took note of the "dramatic increase in the dissemination of COVID-19 vaccine misinformation and disinformation by physicians and other health care professionals on social media platforms, online and in the media." It issued a warning to physicians that they risk suspension or revocation of their medical licenses by state medical boards if they generate and spread COVID-19 vaccine misinformation or disinformation.³⁸ The FSMB commented that, "Due to their specialized knowledge and training, licensed physicians possess a high degree of public trust and therefore have a powerful platform in society, whether they recognize it or not. They also have an ethical and professional responsibility to practice medicine in the best interests of their patients and must share information that is factual, scientifically grounded and consensus-driven for the betterment of public health." Although the statement focused on vaccination, it could apply to all health information. Spreading inaccurate information undermines that responsibility and "threatens to further erode public trust in the medical profession and puts all patients at risk."³⁸ Of course, the same comments could also apply to pharmacists. At least five state medical boards (Illinois, Maine, Mississippi, New Mexico, Washington) and numerous certifying and professional organizations have expressed support for the FSMB statement.³⁹

It is not clear how frequently physicians are sanctioned for spreading misinformation, but it appears to be uncommon.^{40,41} The president of the FSMB has said that medical license renewals are designed to be simple for doctors and it is usually an automatic procedural step. He added that medical boards do not have the capacity to review the large number of renewals that occur each year.⁴¹ The license suspension process is long and slow with procedural barriers and investigations, and will ordinarily begin only if someone makes a complaint.⁴² Moreover, both non-renewals and suspensions require protections to comply with due process.⁴¹ Investigations can take months or years to complete and many proceedings are conducted in private.³⁹ Licensing boards are primarily concerned with medical malpractice, patient abuse, and illegal activity, so that the potential that misinformation disseminated by a physician could impact public

SIDEBAR: PRESCRIPTIVE AUTHORITY

Traditionally, American prescribers were physicians. Today, many types of healthcare provider can prescribe medication. During the drug approval process, the FDA works with the sponsoring pharmaceutical company to

- Evaluate the medications' benefits and risks for a specific use(s) carefully
- Ensure any decision to approve the drug is supported by strong scientific data.
- Approve drug labeling for healthcare providers specifying how to use the drug safely and effectively for the intended use(s)

The sponsoring pharmaceutical company must provide supporting data for each individual indication it proposes.

However, once the FDA approves and markets a medication, clinicians with prescriptive authority have the right to prescribe FDA-approved therapies for diseases and disorders outside of their FDA-approved indications. Healthcare providers may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient. This is called off-label use, and it is generally employed when the prescriber wants to use the medication

- For disease or medical condition not listed in the FDA-approved labeling
- In a different way, such as when the FDA has approved a capsule or tablet, but the prescriber has it made into an oral solution or a topical
- In a different dose than that approved by the FDA

But, under some conditions, off-label prescribing is not allowed—not disallowed by the FDA, but by other organizations that pull the prescribing strings. For example, Pharmacy and Therapeutic Committees, which are composed of health professionals, have the authority to prevent the use of a therapy or to limit the conditions under which it can be prescribed to patients treated in its healthcare system. And, payors (insurers or whoever is paying for the prescription) have the right to impose restrictions, too. Even if a prescriber chooses a medication off-label and a patients agree to take it, payors have the right to refuse to pay.

Off-label use is common in a few situations. In children, many drugs lack data on safety and efficacy and are only approved for adults. Pediatricians may rely on available evidence to use medication off-label. Another area in which off-label use is common is cancer. Good references often include lists of offlabel indications and refer the reader to the data supporting the use, even if it is limited. The most important thing to remember is that off-label drug use has risks.

health takes a relatively low priority.⁴² In addition, it can be difficult to evaluate whether a comment is sufficiently outside the range of scientific and medical consensus and boards are reluctant to take action on a "fringe" opinion.⁴²

A survey by the FSMB found that 67% of medical boards have seen an increase in complaints about physicians disseminating



false COVID-19 information and 21% of respondents had instituted some type of disciplinary action.^{39,41} However, one report investigating the "20 most vocal physicians spreading COVID falsehoods" found that as of January 2022, none of them had been disciplined.⁴⁰ Similarly, a recent analysis by NPR of 16 physicians who are known to promote misinformation about COVID-19 found that 15 were still licensed to practice; the sole exception apparently voluntarily did not renew his license.⁴¹

Nevertheless. some states have taken action. Boards in at least a dozen states, including Oregon, Rhode Island, Maine, and Texas have issued sanctions against physicians.³⁹

In September 2021, the Oregon Medical Board revoked a physician's license and fined him \$10,000, viewing him as a serious and immediate danger to the public for refusing to follow COVID-19 guidelines in his office.^{43,44} The physician refused to wear a mask and did not ensure that his staff was masked. In addition to not following guidelines, the Board said he advised patients not to wear masks (unless highly symptomatic) and spread misinformation about masking. According to the Board's complaint, the physician told patients in person and through fliers in his office that masks were ineffective against COVID-19 and could cause serious unproven health issues, including carbon dioxide poisoning.^{43,44} He also spoke at a political rally where he made anti-masking statements.⁴³ The Board accused him of "gross negligence" and the order described his conduct as "contrary to medical ethics" and said it "does or might constitute a danger to the health or safety of the public."44

The physician filed a lawsuit against the Oregon Medical Board after his license was suspended (prior to being revoked). He alleged that the board violated his constitutional rights to due process and free speech, due to a "mere difference in medical opinion."^{44,45} He further contends that the Board's opinions "have been largely disputed by reputable studies and medical experts."^{44,45}

In a similar action, the Rhode Island Board of Medical Licensure and Discipline investigated a physician who made multiple assertions to his patients that were "misinformed" or "patently false."⁴⁶ The physician sent a letter advising his patients not to receive a vaccine for COVID-19. The letter claimed that the vaccine would produce "unpredictable long-term health consequences" including sterilization and disruption of the recipient's DNA. He also told his patients that government authorities were promoting "a poorly and inadequately tested product" (vaccine) and claimed that treatment with vitamins C and D is safer and more effective than a vaccine. The physician stated that he receives his information from multiple media sources, which do not include mainstream media, and also admitted he did not attend any of the state's accredited COVID update programs.⁴⁶ He agreed to a consent order reprimanding him and agreed to complete an ethics course and pay administrative costs of \$1100.⁴⁷

The Texas Medical Board levied a \$500 fine against a physician for promoting the use of hydroxychloroquine and ordered her to improve her procedures for obtaining consent. She had prescribed hydroxychloroquine to a COVID-19 patient without adequate explanation of the potential health risks.³⁹ In Idaho, the state's medical association took the highly unusual step of filing a complaint with the state medical board against a physician for promoting ivermectin.³⁹

However, not all states are supportive of legal sanctions against physicians for disseminating information. The Tennessee Board of Medical Examiners issued a statement supporting the FSMB position but removed the policy form their website due to pressure from the state legislature, although they claim that the policy has not been rescinded.⁴⁸ Moreover, two bills were introduced in the Tennessee legislature that would forbid state licensing officials from disciplining doctors for how they treat COVID-19 or what they express about vaccines. One bill would protect any recommendation made by a physician so long as the physician has exercised independent medical judgement in the best interest of the patient. The other would prohibit disciplining a physician on the sole basis of to their "prescription, recommendation, use, or opinion relative to a treatment for COVID-19."49 Although the bills are worded to protect opinions, it may permit physicians to assert that false claims are legally protected opinions.49

A Georgia physician made a number of controversial statements about the pandemic including saying that vaccines have not been studied sufficiently, are not worth the risk, and might re**PAUSE AND PONDER:** Should a pharmacist who makes negative comments about vaccinations during a counseling session with a patient be disciplined?

sult in a more serious disease.⁵⁰ He also said that hydroxychloroquine and ivermectin are effective in preventing a COVID-19 infection. Other physicians in the state have made similar statements including physicians stating on television that "there is a lot of evidence" that ivermectin "works well" against the COVID-19 virus and rejecting vaccines. Despite receiving numerous complaints from other practitioners about these practices, the Georgia medical board has not taken any action and in at least one instance the Board determined that there was no violation and closed the case.⁵⁰

It's critical to note that prevailing medical opinion is not always correct. All entities need to be careful when restricting prescribers' ability to personalize treatment outside standards of care because between the black and the white of science, numerous shades of grey exist.

In addition to licensing sanctions, health care practitioners can face other penalties. A Mississippi emergency room physician and noted anti-vaccine spokesperson claims he was fired by a hospital for discontinuing remdesivir, an FDA-approved treatment for COVID, in patients with COVID and replacing it with ivermectin.⁵¹ In Texas, a physician who frequently posted criticisms of vaccine mandates and praised the use of ivermectin on social media had her medical staff privileges suspended by the hospital where she worked over the posted misinformation.⁵²

SUMMARY AND CONCLUDING REMARKS

"Misinformation often arises when there are information gaps or unsettled science."⁵³

The severity of the coronavirus pandemic and rapidly evolving scientific knowledge and public health recommendations has created confusion and reliance on unsubstantiated and unconventional advice, often from social media. Misinformation can be harmful, leading patients to favor unreliable therapies and delaying or avoiding more scientifically substantiated treatments.

One approach to addressing health misinformation is to sanction health care practitioners who spread it. Some regulatory bodies and organizations have threatened physicians with penalties for promoting misinformation, but others have given this issue a low priority or even opposed it. The current regulatory environment makes disciplinary actions cumbersome and slow; it's difficult to determine when an alternative medical opinion crosses the line and becomes unethical or unprofessional, especially when public health guidelines are in flux during a crisis. Pharmacists who promote inaccurate or misleading information may also run the risk of finding themselves subject to disciplinary actions.

Another approach is to try to counteract misinformation.³ The CDC recommends the strategies of communicating accurate information, responding to information gaps, and confronting misinformation with evidence-based messaging from credible sources.⁵³ Dr. Murthy has remarked that "without sufficient communication that provides clarity and context, many people have had trouble figuring out what to believe, which sources to trust, and how to keep up with changing knowledge and guidance."³



Who will provide the clarity and context? This is an opportunity, and, arguably, a responsibility, for pharmacists. Pharmacists are ideally positioned to begin a dialog with patients as trusted, knowledgeable, and accessible health care professionals.^{54,55}

The popular perception that unproven medications for COVID-19, such as ivermectin, are an alternative form of treatment has led to numerous lawsuits attempting to compel physicians and hospitals to provide the drug. The results of these suits have been mixed, with some courts ruling in favor of patients and ordering that they be made available, even when mainstream public health and medical organizations have issued safety and efficacy warnings. Others have supported practitioners who adhere to the prevailing standard of care, even in life-threatening circumstances. These rulings often distinguish between a wellaccepted right to refuse treatment and a more nebulous privilege to demand treatment.

On a final note, a pharmacy in Minnesota is facing a possible lawsuit for failure to fill a prescription for ivermectin to treat COVID-19. The patient and his wife were both infected and obtained prescriptions for ivermectin, but the pharmacist refused to fill the prescriptions. The wife stated that the pharmacist "did not have the right to stand between our physician's prescription and the patient," but the pharmacist disagreed.⁵⁶ An attorney called the pharmacist's position "abhorrent" and accused the pharmacists of "play(ing) God" with the patients' lives at stake. The patient allegedly obtained a veterinary formulation of ivermectin instead and claimed that he felt relief after eight hours.⁵⁶ It is likely that these kinds of legal actions against pharmacists will become more frequent, and pharmacists and pharmacies need to evaluate how they will develop policies to respond to demands for an unconventional treatment whether it is for COVID or the next public health crisis.

Figure 1. Quick Points to Handle Misinformation in the Pharmacy



BE COMMUNITY CHAMPIONS. Work with local public health departments to encourage good information sharing.

2 Don't be afraid to say, "I don't know!" Rather than passing along misinformation, take the high road and admit you are unsure—then look up the correct answer or find help to look it up.

3 Have a high index of suspicion! If something sounds too good to be true, verify.

Better

1 Analyze studies carefully looking at sample sizes, study design, results and especially, limitations.

2 Monitor social media and the news and correct misinformation respectfully when you can.

Remind coworkers and managers that the public expects reliable information from pharmacy staff.

Good

1 Know that off-label use of drugs is legal and a common occurance.

2 Communicate concerns constructively using nonjudgmental language.

3 Field questions from patients with an open mind.

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