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LAW: "An Apple A Day Keeps COVID Away": Legal Issues in Suppressing Health Misinformation

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EDUCATIONAL OBJECTIVES

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

- Discuss the characteristics of health misinformation and its effect on public health
- Characterize the role of the states in disciplinary actions for misinformation
- Describe the legal issues that emerge when state authorities try to control the flow of information
- Contrast different approaches taken by states in addressing the dissemination of healthcare information

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TARGET AUDIENCE: Pharmacists and pharmacy technicians who need law CE and are concerned about misinformation.

ABSTRACT: Health misinformation is an age-old problem that has become more visible due to the influence of social media and the COVID pandemic. Various governmental and professional bodies have sought to temper the influence of misinformation that emanates from healthcare professionals but have encountered logistical and constitutional barriers. State licensing boards exist to regulate the professions and are the most appropriate body to exert influence. However, state boards are government entities and have faced First Amendment limitations. Lawsuits from individual prescribers as well as opposition from legislative bodies in some states have hampered the ability of boards to act. Recently, the FDA has also been sued for its messaging with potentially far-reaching consequences. This activity will review these events.

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FACULTY DISCLOSURE: Dr. Gianutsos has no financial relationships with an ineligible company.

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"I believe that misinformation is now our leading cause of death... People are distracted and misled by the medical information Tower of Babel."[1] Dr. Robert Califf, Commissioner, Food and Drug Administration.

INTRODUCTION

The world faced a deadly infection running rampant. Some health experts believed that a vaccine could confer protection against the infection, but this view was met with skepticism and distrust. Misinformation spread within and beyond

the scientific community and debates about the inoculation's safety and efficacy emerged on many fronts. Physicians observed infections in some vaccinated individuals and opponents began speaking publicly about their distrust of the vaccine. The use of an animal source for the vaccine contributed to the belief that miniature cow heads could grow from sites of vaccination. Vaccine hesitancy and fear grew among the public.[2]

While this may sound like recent events, it describes the atmosphere surrounding the development of a vaccine for smallpox in 1796.[2] Many years later, the increasing popularity of television [like social media today] exaggerated fears of smallpox vaccination by broadcasting both descriptions and visual footage of the rare instances in which the smallpox vaccine produced severe adverse effects.[2] This messaging skewed perceptions about the vaccine's risk/benefit profile and further eroded trust in the scientific community. Overall, these misperceptions delayed the worldwide eradication of smallpox by more than 200 years.[2]

This narrative illustrates that misinformation is not a recent phenomenon. Examples can be cited going back thousands of years.[3] More significantly, it demonstrates misinformation's destructive consequences. Recently, misinformation rose to unprecedented prominence with the COVID-19 pandemic, with the Director of the International Fact Checking Network calling COVID-19 "the biggest challenge fact-checkers have ever faced."[4]

Health misinformation can be harmful. U.S. Surgeon General Dr. Vivek Murthy has stated, "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."[5]

Health misinformation can influence political, economic, and social well-being. People can become confused and anxious when faced with contradictory information, and this is especially dangerous during a public health crisis.[5,6] It can expose patients to wasteful and harmful products and procedures, delay treatment with a more scientifically based therapy, and divide families and communities.[6]

Pharmacists, of course, also have a role during a healthcare crisis and can be either another source of misinformation or a resource to clarify and refute poor advice. This continuing education activity will examine some recent efforts by governmental and non-governmental organizations to limit information that is contrary to mainstream medical advice and the sanctioning (or lack thereof) of healthcare providers for encouraging such therapies. Various approaches by governmental agencies to deal with conflicting information have raised legal issues when trying to restrict the free flow of information.

Disclaimer: Please note that the examples referred to in this lesson were chosen based upon their high-profile and impact and should not be interpreted as representing any political commentary, agenda, or endorsement by the author or publisher. It is acknowledged that "misinformation" is hard to characterize, and a consensus can shift as more data are developed. One should also not infer that the examples represent a deliberate intent to deceive by their sponsors.

PAUSE AND PONDER: What should be the role for pharmacists and pharmacy technicians in mitigating the impact of misinformation?

MISINFORMATION

Misinformation is frequently used as a catch-all term for related concepts such as disinformation, ignorance, rumor, and conspiracy theories, often resulting in different interpretations and imprecise definitions.[7] Misinformation is often distinguished from disinformation on the basis of intent. In this context, misinformation is used to describe information that is unintentionally erroneous (e.g., mistakenly repeated or due to ignorance) while disinformation is information that is deliberately intended to mislead or deceive (e.g., malicious, fraudulent, or for propaganda).[7]

Health misinformation has been defined as information that is false, inaccurate, or misleading according to the best available evidence *at the time* (emphasis added).[5] This definition recognizes that the accuracy and recognition of information can change as new data or experiences emerge. Although not a health example, one needs to look no further than the writings of Galileo, who was branded a heretic for claiming that the earth rotated around the sun, to find an example of information that was once condemned and humiliated. Galileo's ideas later became the fundamental basis for astronomy and space travel.[8]

Public health recommendations changed rapidly during the progression of the COVID pandemic and resulted in confusion among the public and distrust of public health agencies. A recent

survey found that 60% of adults in the U.S. say they have felt confused as a result of changes to public health officials' recommendations on how to slow the spread of the coronavirus.[9] In addition to confusing patients, negative consequences of health misinformation include misallocation of health resources, fraud, increased reliance on unreliable cures, a negative impact on mental health, and an increased hesitancy to seek medical care.

CAN MISINFORMATION BE REGULATED?

If misinformation is a dangerous phenomenon, as many have suggested, can anything be done to control its flow? During COVID, officials from the federal government, many states, and healthcare and professional organizations promulgated regulations and policies aimed at limiting or promoting health information as will be described below. Some of these approaches have threatened to impose sanctions against practitioners who have disseminated erroneous or misleading information.

However, the suppression of information can face constitutional challenges.[12] Healthcare professionals, like all Americans, have a right to speech that is free of government restrictions even if the content is false.[13]

Justice Thurgood Marshall wrote in a Supreme Court decision in 1972, "…the First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content."[14] The rights enumerated in the First Amendment protect individuals against government infringement on their expression, but do not protect them from other individuals, businesses, or private organizations.[15] Healthcare professionals can be disciplined by professional licensing boards and health departments for certain actions, but these organizations are governmental bodies (termed state actors in constitutional law) and they, along with public hospitals and universities, are prohibited from infringing on free speech.[15]

A content-based restriction "discriminates against speech based on the substance of what it communicates" and receives the greatest protection from any government-imposed restrictions.[16] Content-based restrictions are presumptively unconstitutional and can only be applied if the state shows that the prohibition is the least restrictive means of achieving a compelling state interest such as the protection of public health and safety.[16] (Compelling means essential or necessary rather than a matter of choice, preference, or discretion.)[16] The Supreme Court recognizes that certain narrow categories of expression, such as obscenity, child pornography, true threats, and incitement to imminent lawless action, can be barred because of their harmful content.[16] Learners who are interested in learning more about how the courts scrutinize speech can find excellent information here: https://crsreports.congress.gov/product/pdf/R/R47986

Commercial speech, on the other hand, does not receive as much protection as content speech. Commercial speech applies when there is some form of transaction and includes commercial advertising and solicitations.[12,16] Historically, commercial speech did not receive any First Amendment protection, but an important 1976 Supreme Court decision involving pharmacies extended protection to commercial speech.[16] The case, *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, challenged a state law that made it illegal for pharmacies to advertise drug prices. The Court reasoned that the First Amendment not only granted the speaker the right to speak, it also granted the listener the right to receive information. Commercial speech receives some protection because it serves the important societal interests of providing information to consumers and promoting the economic interests of the speaker.[12] In the case cited, consumers had a right to receive lawful information about drug prices.[16] This narrow exception to free speech could apply in cases where a healthcare practitioner monetizes health misinformation.[12]

Commercial speech can be restricted if it is false, misleading, or proposes an illegal transaction since consumers must be able to make informed decisions.[12] Unlike political speech, where it may be difficult to ascertain what is truthful, courts recognize that commercial advertising is more objective and more readily subject to determination of its truthfulness.[16]

Courts have also traditionally recognized a third form of speech, professional speech, which is "uttered in the course of professional practice" as distinct from "speech . . . uttered by a professional."[17] This form of speech could also be restricted. Some courts have ruled that healthcare practitioners are entitled to less stringent First Amendment protection when providing professional advice to individual patients than when speaking to a larger audience about public issues.[13]

However, a 2018 Supreme Court decision overturned the prior recognition of professional speech as a separate category that would receive lesser First Amendment protection.[12] The Court's

decision stated that “speech is not unprotected merely because it is uttered by 'professionals.’” Consequently, speech expressed by professionals receives complete protection unless it falls under the commercial exception.

There are also practical concerns that sanctioning health professionals for questioning accepted medical standards when they feel they are inaccurate or misguided may stifle advances in practice.[13] This is especially troublesome during a public health crisis when guidance from public health officials evolves as circumstances and knowledge unfold. The many examples of shifting public health recommendations during the COVID pandemic underscore this concern.[18] Generally, healthcare providers have greater latitude when speaking on medical matters to the general public, such as on social media, than they do when providing medical advice to a specific patient.[19]

While constitutional protection is available to healthcare providers when sharing their view on medical matters, other legal situations can impact speech.[19] An employment contract can restrict how much leeway a healthcare provider has, and tort law (malpractice claims) may provide penalties for improper medical advice, especially in the context of informed consent.[15,19]

DISCIPLINING HEALTHCARE PROVIDERS FOR MISINFORMATION

Professional licensing boards provide oversight to ensure that rules governing the profession are followed.[13] The structure and authority of medical and pharmacy boards vary from state to state.[13] Each state has Practice Acts that prohibit licensed healthcare practitioners from engaging in “unprofessional conduct,” although the definition of unprofessional conduct may vary from state to state. Unprofessional conduct is the most common reason for disciplinary action against healthcare personnel.[13] States have applied standards of professional conduct when trying to sanction healthcare personnel for misinformation (see below).

It should be apparent that when attempting to sanction a healthcare provider for misinformation, state regulatory agencies must walk a fine line. During COVID, a number of healthcare organizations endorsed revocation of the licenses and certifications of physicians who disseminated harmful health misinformation such as rejection of widely accepted preventive measures and endorsement of unproven treatments. The organizations included the Federation of State Medical Boards (FSMB) and professional certification boards such as the American Boards of Family Medicine (ABFM), Internal Medicine (ABIM), and Pediatrics (ABP).[13]

The FSMB took note of the “dramatic increase in the dissemination of COVID-19 vaccine misinformation and disinformation by physicians and other healthcare professionals on social media platforms, online and in the media” and issued a warning to physicians that 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.[20]

The FSMB commented, “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 and spreading inaccurate information undermines that responsibility and “threatens to further erode public trust in the medical profession and puts all patients at risk.”[20] Of course, the same comments would apply to pharmacists and other health professionals.

State medical boards have traditionally brought disciplinary actions against physicians for making false or misleading statements in situations such as serving as an expert witness in malpractice cases.[21] Some state laws explicitly authorize disciplinary action against physicians who make false, deceptive, or misleading statements to the public. In most cases, these statutes apply to statements made in connection with advertising, especially when solicitating patients. (See distinction between content-based and commercial speech above.) However, some are worded broadly enough to cover other forms of misrepresentation.[13,21] For example, Minnesota authorizes disciplinary action against physicians who engage in “conduct likely to deceive or defraud the public.”[21]

It is not clear how often healthcare professionals are sanctioned for spreading misinformation, but it appears to be infrequent.[22] The president of the FSMB has pointed out that medical license renewals are designed to be simple for applicants 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.[22]

The license suspension process is long and slow with procedural barriers. Investigations will ordinarily begin only in response to a complaint, rather than being initiated by the board itself.[23] Licensing boards are primarily concerned with medical malpractice, patient abuse, and illegal activity, so misinformation takes a relatively low priority.[23] Moreover, both non-renewals and suspensions require due process.[22] In addition, it can be difficult to evaluate whether a comment is outside the range of scientific and medical consensus and boards are reluctant to take action on a "fringe" opinion.[23] Investigations can take months or years to complete and many proceedings are conducted in private.[24] In many states the legal framework for discipline, which was developed in the 20th century, may narrowly apply to actions or speech related directly to patients under the physician's care and not to broader circumstances like social media.[25] Moreover, boards face daunting legal and policy obstacles if they try to take action (see below).[25,26] Political opposition from legislators in some states can also impede a board's actions (see below).[25]

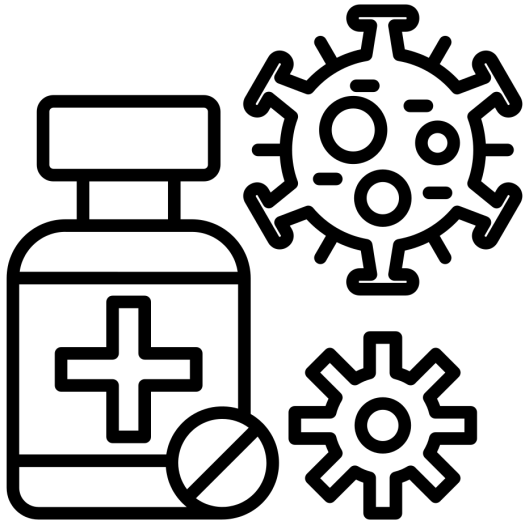
The arguments for disciplinary proceedings by licensing boards usually emphasize the potential harm to public health.[13] However, this may be insufficient to achieve constitutionality in most cases where it would be necessary to apply the "least restrictive means" test mentioned above.[13] A state can instead mitigate the harm by disseminating factually accurate messages, especially in instances where the commercial speech exception would not apply.[13]

PAUSE AND PONDER: Is a state licensing board the best party to try to dissuade healthcare practitioners from issuing information of questionable validity?

Professional credentialing boards (private organizations providing certification) can also take steps to minimize misinformation. For example, consider a pharmacist who works in a large health system and has a specialized position running a hypertension clinic; she has been credentialed to prescribe medication and adjust dosing. The terms of her credentialing may restrict the type and quality of the information she can provide to patients and the credentialing board can retract her credentials if she begins to tell patients that ACE inhibitors are terrible antihypertensives. A joint statement from the ABFM, ABIM, and ABP declared that providing misinformation about the COVID-19 vaccine contradicts physicians' ethical and professional responsibilities and warned physicians that such conduct may prompt a Board to take action that could put their certification at risk.[28] (Credentialing boards as non-state actors have more latitude to impose penalties.)

STATE ACTIONS AND PUSHBACK

Concerns over misinformation during the pandemic prompted various health related organizations to take steps. Boards in at least a dozen states have issued sanctions against physicians for spreading dubious information.[24]



While private professional organizations can impose loss of credentialing, state licensing boards can levy more serious sanctions such as loss of licensure or fines. Recent Board actions have generated a number of legal skirmishes. In addition to state regulatory bodies like licensing boards, state legislatures have acted directly to address misinformation. Different states have taken different – even opposite – approaches to this issue.

California

In 2022, the California legislature passed a bill stating that "the dissemination of misinformation or disinformation related to COVID-19 by physicians and surgeons constitutes unprofessional conduct."[28] The types of false or misleading information that could lead to disciplinary action include communication about the nature and risks of the COVID-19 virus; its prevention and treatment; and the development, safety, and effectiveness of COVID-19 vaccines. False statements regarding prevention and treatment "would presumably include the promotion of treatments and therapies that have no proven effectiveness against the virus." The bill's proponents expressed the view that "providing patients with accurate, science-based information on the pandemic and COVID-19 vaccinations is imperative to protecting public health." They also said that the bill was necessary because "licensed physicians ... possess a high degree of public trust and therefore must be held accountable for the information they spread."[28] By passing this legislation, the law continues, "California will show its unwavering support for a scientifically informed populous to protect ourselves from COVID-19."[28]

PAUSE AND PONDER: Should laws such as those discussed above include other healthcare professionals, such as pharmacists, instead of focusing only on physicians?

Under the statute, the misinformation or disinformation must be conveyed "[by] the licensee to a patient under the licensee's care in the form of treatment or advice."[28] It excludes speech outside of a direct physician-relationship such as social media postings.[29]

California Governor Newsom also indicated that he is “confident that discussing emerging ideas or treatments including the subsequent risks and benefits does not constitute misinformation or disinformation under this bill's criteria."[29]

The bill’s original intent was an effort to grant California’s Medical Board the power to discipline providers who were found to have conveyed misinformation about COVID vaccines and treatments. The proposed bill included statements they might make on social media or in other public forums such as public protests. It was narrowed, however, to apply only to conversations between a provider and a patient in clinical settings when the practitioner made statements that were "contradicted by contemporary scientific consensus contrary to the standard of care."[30] Opponents said the statute was overly broad and that information considered scientific consensus about the rapidly-mutating virus could change daily.[30] They also argued that providers had the right to express their opinions in clinical settings.[30]

Two different lawsuits were filed seeking an injunction against enforcing the law and the judges hearing the cases reached different conclusions.[31] In one case, the judge declined to grant the injunction.[31]

In the other, filed in a different California judicial district, a group of physicians licensed in California were joined by organizations representing the interests of doctors and patients. They sued the State alleging that the above statute was in breach of their First and Fourteenth Amendments rights (i.e., free speech and equal protection rights).[32] The physicians had provided advice and treatments contrary to public health recommendations (universal masking or vaccines) and intended to continue to do so, claiming it was consistent with the standard of care.[32,33] They also claimed that the law’s definition of misinformation as false information that is “contradicted by contemporary scientific consensus” would suppress the ability of physicians to advise patients about the pros and cons of alternative COVID-19 treatment and practices.[32,33]

The court in this case granted a temporary injunction, ruling that the law’s definitions of misinformation and the uncertainty about its enforcement were “unconstitutionally vague”[32] The Court noted that a phrase defining the unlawful conduct, as contradicting “contemporary scientific consensus,” lacked any established meaning within the medical community and was not clarified further in the statute.[32] They went on to say that it “fails to provide sufficiently objective standards to focus the statute’s reach.” The judge found this particularly problematic in the context of the pandemic since scientific understanding of the virus had repeatedly changed, negating a true consensus.[32]

He went on to say that the law leaves many questions unanswered, such as who determines whether a consensus exists? Moreover, the judge ruled that the term “scientific consensus” is so ill-defined that the physicians would be “unable to determine if their intended conduct contradicts the scientific consensus, and accordingly ‘what is prohibited by the law.’”

The conflicting decisions necessitated a resolution (since the law could not be simultaneously upheld and enjoined). The first case was appealed, but the state repealed the law before the court could rule.[34] Following the court’s decision granting the injunction, the state rescinded the law about a year after it was signed.[30,31]

Missouri

Missouri also enacted statutes dealing with the dissemination of COVID-related health information, but their approach was quite different from California. A law passed in 2022 prohibits the state boards overseeing medicine and pharmacy from disciplining a registered practitioner for “lawfully” prescribing or dispensing ivermectin or hydroxychloroquine for human use.[35] In other words, the prescribing or promotion of these drugs could not be used as a basis for establishing unprofessional conduct and sanctioning a healthcare practitioner.

A second part of the law prohibits pharmacists from contacting the prescribing physician or the patient to dispute the efficacy of ivermectin or hydroxychloroquine unless the physician or patient inquires of the pharmacist about the drug’s efficacy.[35] In other words, a pharmacist would be prohibited from expressing legitimate concern about questionable treatments.[36] (The Missouri Pharmacy Association issued a clarification that pharmacies are not required to dispense nor stock the drugs, nor does it prevent a pharmacist from counseling a patient who should not take these drugs due to certain health conditions or interactions.[36])

A sponsor of the bill indicated that these actions were necessary because “certain pharmacists wanted to begin acting like physicians and denying the filling of the prescriptions. This re-establishes the professional equilibrium between doctors and pharmacists.”[37] No doubt most pharmacists are grateful that the equilibrium has been reestablished.

A pharmacist also challenged this law on First Amendment grounds. The pharmacist's suit alleged that "all pharmacists in Missouri, now face the impossible—and constitutionally impermissible—conundrum of deciding whether to endanger their livelihood when choosing whether to speak in a manner that is both vital to their professional duties to patients and protected by the First Amendment."[38] The pharmacist believed that it is a matter of legitimate professional ethics to contact a patient or prescriber to dispute a medication's efficacy.

The court granted an injunction against implementation of the new law stating that the relevant section quoted above "infringes the free speech rights of Plaintiff and other Missouri-licensed pharmacists by threatening to impose liability based on the viewpoint of their speech."[38] The court pointed out that the regulation "does not prohibit pharmacists from initiating contact to tout, endorse, or acclaim the drugs, thus it is taking sides in a politically charged debate about the drugs efficacy."[38] In other words, it was a content-based restriction of speech (see above) and therefore was an impermissible infringement of the First Amendment.

The Board replied that the statute was constitutional because it regulated conduct and not speech.[38] Unpersuaded by this argument, the court noted that the statute does not prohibit initiating contact with patients or prescribers which would be a permissible regulation of conduct. Instead, it prohibits contact only if the pharmacist wishes to "dispute the efficacy of ivermectin tablets or hydroxychloroquine sulfate tablets for human use." The court also said that this interpretation is "consistent with the legislature's apparent purpose in enacting (the law): to insulate ivermectin or hydroxychloroquine from criticism."[38]

Elsewhere Around the U.S.

In other states, attempts by medical boards to restrict dissemination of health information that deviates from mainstream medicine have faced backlash from state legislatures. Dozens of state legislatures (e.g., North Dakota) have introduced or passed measures that would prevent a regulatory agency from punishing medical providers who promote COVID-19 misinformation or unproven treatments.[15,39]

A particularly contentious dispute arose in Tennessee between the state licensing board and the state legislature. The Board of Medical Examiners unanimously declared that physicians spreading false information about COVID would put their license in jeopardy and the board posted the new policy on its website.[40] Soon afterwards, state legislators charged that the board had overstepped its authority and demanded that the statement be deleted from the state's website. The state threatened to disband the board.[39,40]

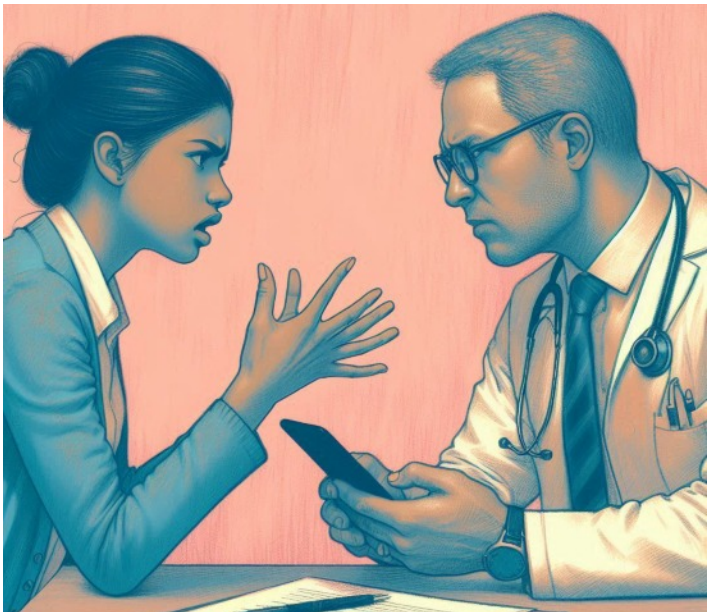
Many of the same Tennessee legislators had previously threatened to defund the Health Department when it promoted COVID vaccines to teens and introduced a bill that would have prevented the Board from disciplining physicians for administering any treatment for COVID-19, even if it is not recommended by the Department of Health nor the FDA.[39] Another proposed bill would have prevented pharmacists from interfering with prescriptions to treat COVID.

Despite the threats, the Tennessee board voted to retain the misinformation policy with a tweaking of the definition of misinformation.[41]

A similar situation arose in Washington state. Four physicians threatened with disciplinary action by the state Medical Commission for misinformation challenged the commission's policy statement. They claimed that the commission did not follow their standard procedures in implementing the policy and that the position statement infringed their constitutional right to free speech.[42] The physicians faced charges over their alleged care for COVID patients with unproven treatments and "false and misleading" statements regarding the pandemic and vaccination. The physicians maintained that the distinction between them and "other medical professional[s] who were not investigated and charged under the Statement is that plaintiffs dissented politically, scientifically and medically from health officials on various matters related to COVID."[43] The physicians were charged with negligent care; one physician allegedly "failed to discuss alternative treatments" (monoclonal antibodies) with an elderly, unvaccinated patient with a COVID-19 infection who later died.[43]

FDA Lawsuit

On a broader scale, the controversy over misinformation has even touched the FDA. In 2024, a lawsuit was brought against the FDA's messaging with potentially very significant consequences. Three physicians in Texas who prescribed ivermectin to thousands of their patients for COVID initiated the suit.[44] They objected to the FDA's public advisory and social media posts ("You are not a horse," a post that is no longer available) warning



patients not to use the drug. (See image here: https://www.pharmamanufacturing.com/compliance/regulatory-guidance/news/11291402/you-are-not-a-cow-fda-warns-public).[45] The physicians claimed that the messages exceeded the FDA's authority and encroached on the practice of medicine.[44] The physicians alleged that the posts interfered with their "ability to exercise professional medical judgment in practicing medicine" and harmed their reputations.

The FDA claimed sovereign immunity (a legal doctrine that the government cannot be sued without its consent) in its defense.[46]

The District Court (first level) judge hearing the case dismissed it, ruling that sovereign immunity protects the FDA.[46] The court also noted that Congress charged the FDA "with protecting public health and ensuring that regulated medical products are safe and effective" and that "FDA has the authority, generally, to make public statements in-line with these purposes."[46]

The physicians appealed, and the appellate judge reversed the decision, finding, often in very colorful language, that the FDA did exceed its legal authority.[46] The judge stated that no legal basis allows the FDA to issue recommendations or give medical advice. He wrote that the "FDA is not a physician. It has authority to inform, announce, and apprise—but not to endorse, denounce, or advise."[46]

The FDA argued that it has the authority to communicate information to the public and that the posts are purely informational and not imperative. The court, however, disagreed, finding that the posts contained syntax that directed patients to take action such as "Stop it with the #ivermectin."[46] The court also chided the FDA for failing to mention that there is also a human version of ivermectin which was being used off-label to treat the coronavirus.[46]

The FDA responded to the decision by agreeing to retire the consumer update entitled "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19" and to delete various related social media posts.[47] The FDA issued a statement stating that "the agency has chosen to resolve this lawsuit rather than continuing to litigate over statements that are between two and nearly four years old" and that it "stands by its authority to communicate with the public regarding the products it regulates."[47] Furthermore, the agency indicated that it "has not changed its position that currently available clinical trial data do not demonstrate that ivermectin is effective against COVID-19" and reiterated that it "has not authorized or approved ivermectin for use in preventing or treating COVID-19."[47]

While this might appear to be a minor dispute involving the agency and aggrieved prescribers, there are fears that it could have far-reaching implications. There is a concern that the FDA, and possibly other consumer-related regulatory agencies, may need to reevaluate all their communications to the public to ensure that they comply with the decision.[48] This would obviously limit the agency's role as a public health educator. It could also disrupt the FDA's ability to limit a manufacturer's promotion of off label drug use.[48] In addition, the physicians' claim that they suffered harm as a result of the FDA's actions could lead to more claims against regulatory agencies for damages.[48] On the other hand, there is a consideration that the ruling could be challenged since it may be at odds with the constitutional principle of government speech in which the government can itself be a speaker and is not required to be neutral when expressing an opinion.[48]

PAUSE AND PONDER: What should the FDA's role be in discouraging misinformation?

SUMMARY AND FINAL COMMENTS

Misinformation about health matters became more troublesome during the COVID pandemic, raising concerns that this has had negative consequences for society and public health. Many professional and governmental organizations have expressed apprehension about the influence of health misinformation and have sought to limit its spread by sanctioning healthcare professionals. This has been met with legal challenges by the affected healthcare providers centering around First Amendment protection of speech. At the same time, legislators in many states have tried to suppress these efforts and limit the ability of licensing boards to discipline healthcare providers for their promotion of remedies outside of mainstream medicine. Some legislative efforts have also tried to restrict the ability of healthcare providers, including pharmacists, to express concerns about unproven treatments. Recently, messaging by the FDA has also been challenged with potentially far-reaching consequences. It is important for pharmacists to be aware of the positions taken by governmental agencies and legislators in their state and to respond accordingly.

Figure 1. Dealing with Medical Misinformation

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