The Pharmacist Activist

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"Be strong and courageous, and do the work. Do not be afraid or discouraged for the Lord God, my God, is with you." I Chronicles 28:20b

Editorial

The AMA, APhA, and ASHP collaborate! – But Undermine the Rights of Their Members!

The subject of the email message grabbed my attention – "APhA calls for immediate end to use of ivermectin for COVID-19." The message that follows is titled: "Joint statement from APhA, AMA, and ASHP: No ivermectin for COVID-19 outside clinical trials," and starts by saying these associations "**strongly oppose the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial.**" It then states that ivermectin is not approved by the FDA to prevent or treat COVID-19, and "urges physicians, pharmacists, and other prescribers to warn patients against the use of ivermectin outside of FDA-approved indications and guidance."

This statement of the associations is an excellent endorsement of the authority of the FDA, but it severely undermines and betrays the authority, expertise, and professional judgment of their physician and pharmacist members with respect to using drugs off-label for uses and dosages they consider to be appropriate for the patients whom they are serving. This is the most important ramification of the statement and our associations have damaged their credibility in releasing it. Which individuals in our associations wrote this statement? Are they personally involved in providing services for patients with respect to COVID-19 and, if not, why do they think they are better positioned to make these judgments than the health professionals who are personally serving the patients? Is the motivation for issuing the statement a desire to support a politically correct narrative with which they agree, or to obtain political favor with respect to other issues they consider important?

Context

Let's consider the context for these issues.

1. COVID-19 vaccines are the most effective intervention to reduce the risk and transmission of the virus, and should be strongly encouraged for adult patients.

2. There are insufficient studies/data to conclude whether ivermectin is of no value or whether it may be of value. Though data are mixed, there are some patient cases and limited studies (but not randomized controlled clinical trials) that indicate it may be of benefit. I am *not* an advocate for or in opposition to its use to treat or prevent COVID-19, nor am I in a position to make a recommendation regarding its use for a patient whose circumstances I do not know. That is an assessment and decision that must be made by those directly involved in the care of individual patients.

3. With the exception of monoclonal antibodies, there are no therapeutic agents for which there are sufficient studies to anticipate effectiveness in controlling COVID-19 in nonhospitalized patients who test positive and have mild to moderate symptoms. However, there are insufficient supplies of monoclonal antibodies for all patients who might

be candidates for their use, and they are very expensive. Although medications for which there is no reason to anticipate that they would be effective and/or may be associated with significant risk should not be used, the limited experience with ivermectin suggests that it may be of value and safe for use in some patients with COVID-19. Please inform me if you are aware of any better alternatives.

4. The public and individual patients should be warned against using ivermectin products intended for use in animals, and purchasing any ivermectin products online. I fully concur with this warning in the AMA/APhA/ASHP statement, and this should have been the primary focus of their message instead of condemning off-label use of products for human use outside of clinical trials.

   But why would anyone even consider using ivermectin products intended for animal use? There are several reasons. Some know or have heard reports of individuals who appear to have benefited from the use of ivermectin, and they resent the opinions and restrictions of scientists, physicians, politicians, media, and other "experts" who don't know them telling them what they can or can't do to protect their health. In addition, health professionals who prescribe and dispense ivermectin off-label for COVID-19 have been harshly criticized and portrayed as ignorant. They have even been threatened by some government agencies, professional boards, and professional organizations, that allege they could be at risk of having their licenses, specialty credentials, and/or other privileges suspended or revoked if they prescribe or dispense ivermectin off-label for COVID-19. These situations have greatly reduced the number of health professionals willing to prescribe or dispense ivermectin off-label when they believe it may be of value and/or do not have other options. The result is that more patients seek other sources of the drug, including products intended for animal use without being aware that they include larger dosages than are appropriate for human use.

5. Ivermectin in a dosage appropriate for human use is *not* dangerous. In fact, it appears to be very well tolerated and I am not aware of any serious adverse events when ivermectin products for use in humans have been used in patients with COVID-19. That more individuals who have used ivermectin have called poison information centers or visited emergency departments are usually a result of using products intended for animals that contain larger amounts of the drug. Even with those products, I have not heard of one death that has been attributed to overdosage of ivermectin, a sharp contrast to the risk and consequences of COVID-19.

Off-label use often results in important discoveries

There have been dozens of situations in which FDA-approved medications have been used off-label with resultant discoveries of new important uses, the value of which may, or may not, have been subsequently confirmed by comprehensive clinical trials. The following are examples:

Lyme disease – Doxycycline is considered the drug of choice for the treatment of Lyme disease, a conclusion that was reached from off-label use and not clinical trials. Vibramycin is the first doxycycline-containing product to be approved in the U.S. The current package insert as recently updated in April, 2021 identifies approximately 25 infections for which the drug has been approved by the FDA. Lyme disease is *not* included, nor is there any mention of Lyme disease at all in the package insert.

Gastric and duodenal ulcers – For decades GI ulcers were thought to be caused primarily by stress and excessive gastric acid production. In the early 1980s, an Australian physician, Barry Marshall, postulated that bacterial infections of the GI tract had an important role in causing ulcers. His idea was rejected and even ridiculed by his peers. To test his theory he infected himself with the bacterium he suspected, *Helicobacter pylori*, developed ulcer symptoms and successfully treated himself with antibiotics. The studies that followed confirmed that the large majority of GI ulcers are associated with *H. pylori* infection, and that antibiotics and acid-suppressing agents are the treatment of choice. Dr. Marshall and a colleague were subsequently awarded the Nobel prize in medicine for this discovery.

Compounded prescriptions – Millions of compounded prescriptions have been prepared to personalize the treatment of patients who have special needs with respect to medications, dosages, and formulations. All of these prescriptions are off-label and "outside of clinical trials."

During the same time period in which the FDA has been very lax in enforcing existing regulations and taking timely action against "compounders" who have distributed contaminated and inferior products (e.g., the New England Compounding Center tragedy), some within the FDA are obsessed with imposing more rules and restrictions on pharmacists who are using their expertise and skills to compound prescriptions that are used effectively and safely. It can be expected that the AMA/APhA/ASHP statement opposing the use of ivermectin outside of clinical trials and FDA approval will be welcomed by these individuals at FDA who will extrapolate this "support" for their agenda to further restrict the authority of physicians and pharmacists to prescribe and dispense compounded prescriptions.

Back to the statement

In addition to undermining the authority and professional judgment of their members, the AMA/APhA/ASHP leadership engages in scare tactics in their message. Referring to a recent CDC Health Alert Network Advisory against the use of ivermectin as a treatment for COVID-19, the statement recommends counseling of patients and emphasizing the potentially "toxic" effects of this drug, including "nausea, vomiting, and diarrhea. Overdoses are associated with hypotension and neurologic effects such as decreased consciousness, confusion, hallucinations, seizures, coma, and death." Nausea, vomiting, and diarrhea are typically identified as adverse events or side effects that are often mild and readily managed, rather than described as "toxic" effects. The comment that "overdoses are associated with…coma and death" prompts the question, "Can anyone identify even one death that has been attributed to ivermectin overdosage?" To explore this I reviewed the FDA-approved labeling for Stromectol, the first ivermectin product to be approved for systemic use. There is *no mention at all* of coma and death, even in the "Overdosage" section of the labeling. What is the basis/support for the CDC, AMA, APhA, and ASHP identification of these risks?

The AMA, APhA, and ASHP have used the playbook of the pharmaceutical companies in using statistics to describe the effectiveness and safety of their medications in the most favorable and advantageous manner. The statement includes the message, "We are alarmed by reports that outpatient prescribing for and dispensing of ivermectin have increased 24-fold since before the pandemic and increased exponentially over the past few months." What are the actual numbers? The labeled indications for ivermectin for systemic use are onchocerciasis (hardly ever experienced in the U.S.) and strongyloidiasis of the intestinal tract (seldom experienced in the U.S.). Prior to the COVID-19 pandemic, many pharmacists may not have even received one prescription for ivermectin for systemic use. Therefore, a "24-fold increase" probably does not represent a large actual number, and also refers to the *use* of ivermectin and not problems attributed to it.

The AMA/APhA/ASHP statement is a misleading disservice to their members, and to the public and individual patients. The statement should be retracted!

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It Starts in Rhode Island!

I was wrong in thinking that working conditions could not become any worse at CVS, but they have. The horror stories that are shared with me by CVS pharmacists only increase in number – unrealistic metrics, meeting quotas for immunizations, two drive-through lanes, multiple phone lines, people waiting in lines for prescriptions, and the added pressure of knowing you are hundreds of prescriptions behind. This work environment results in errors, angry patients, technicians quitting (e.g., leaving for lunch and not returning), and physically and emotionally exhausted pharmacists leaving at the end of a long day praying that they have not made any serious errors. District leaders expect even more with no additional staffing. However, one stressed CVS pharmacist was objective enough in commenting about the rapid turnover of district leaders to recognize that they are also under tremendous pressure that starts at CVS headquarters in Rhode Island.

Earlier in the year CVS was hiring additional pharmacists and technicians for temporary part-time positions to provide COVID-19 immunizations. Although this eased the workplace demands on the regular staff, the respite was only temporary as management ended the additional staffing when the demand for COVID-19 immunizations declined. Now, as there are increased mandates for individuals to be vaccinated and booster shots are anticipated, demand is high once again but this time there is not additional staffing, and CVS pharmacists who actually have the vaccine in stock turn down the requests to be immunized because they do not have the staffing and time to provide them. One pharmacist noted that the 15-minute period in which patients are to wait following immunization as a precaution in case an adverse event occurs, has become a sick joke. Even if there is a place where immunized patients can sit down and wait for 15 minutes, pharmacists and other staff don't have the time to observe them because of other pressing duties, and patients leave. This pharmacist also informed me how many patient requests for COVID-19 immunizations he turned down in a period of just 3 days because they were already so far behind. I won't identify the specific number of requests turned down because of the likelihood that CVS management will try to identify the pharmacist and terminate her/him for violating some obscure policy. Another pharmacist informed me that a patient whose request for immunization was declined filed a complaint with CVS. Her/his district leader wrote the pharmacist up for poor performance and placed it in the employee's file.

Rather than addressing the critical issues of short-staffing and stressful workplace environments, CVS management aggressively pursues contracts with government agencies to give even more

COVID-19 immunizations. And YES, flu season is coming so roll out the flu vaccine promotions. And if pharmacists quit or become physically or emotionally disabled, there are files of applications from pharmacists who are looking for positions and can be hired at lower salaries.

It starts in Rhode Island where executives view prescription errors, harm to and deaths of patients, and lawsuits as a cost of doing business. One can only wonder how many attorneys CVS has to employ or retain to handle the multiple lawsuits, and the resources needed to reach settlement agreements with confidential terms but acknowledge no wrongdoing to minimize unfavorable publicity.

A CVS story

A CVS pharmacist recently contacted me. He had sent a message to me previously, but under a different identity because of his fear of being terminated. I will not use information unless I have confidence in the integrity of the individual providing it and the validity of the information provided. This time he provided his name and I assured him that I would not reveal it. He has worked for CVS for many years and has eloquently shared his experience below.

> "THERE WAS A TIME WHEN IT WAS BETTER! Namely, when Tom Ryan was the CEO. The benefits for full-time employment were superior to those of any company I had worked for. The work and metrics were reasonable. I COUNSELED my patients – yes patients, not customers. I could spend 10 minutes with a patient who was discharged post-MI, post-TIA, or even after a discharge from a hospital for a mental health admission. These patients often went from taking zero medications daily to now taking 6 or more drugs a day. They needed and deserved knowing what each one was for, how to take it, what side effects to expect and if they would be permanent or transient, as well as what to do if side effects occurred. I fulfilled that role honorably because I was empowered by Tom Ryan to do it. If I couldn't do it at 5:30 on a Friday evening, I would ask if I could call the patient/caregiver at 7 pm and provide the counseling.
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> The moment Tom Ryan retired, things changed. CVS purchases Caremark. Employee benefits are slashed. Technician hours are slashed, which is still never-ending. Stupid phone calls asking someone to refill Flonase, and passing it off as Medication Therapy Management… honestly? What a pathetic joke.
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> There is no end in sight and I am not aware of any positive changes from Woonsocket. I see no efforts to address the worsening work conditions which are so apparent to all those behind the counter and working the bench, and even to customers. A few patients will say, 'Thank you for taking care of us and for everything you do. I'm going to call CVS Corporate and tell them you need more help here.' My response to them is: 'Please do not. All it will do is fall on deaf ears. An email will be sent to my district leader, who in turn will forward it to me and then I'll have to call you and offer an apology for your complaint. I'll have to lie to you and tell you I am going to have the underlying reason for your having to wait addressed with the pharmacy staff by disciplining the responsible person(s) and working to change our work process. In reality, I will speak to you on the phone and that will be the end of the matter. It truly will do no good, but thank you for offering anyway.'
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> COVID-19 immunization – which is the most important health-related service I as a community pharmacist can provide right now really does "help people on a path to better health" (the line from former corporate propaganda). HOWEVER, who will fill the 500 prescriptions while I am giving 30-40 COVID-19 shots in a day? Let us not forget the increased flu shot revenue-based, greedy demands of 10 flu shots per day in August (even though we're still having 95°F weather). Honestly, I can't help recall the old cliché, "the beatings will continue until morale improves."

To be continued:

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