



December 7, 2021

Hon. Kathy L. Rapp  
150 Main Capitol Building  
P.O. Box 202065  
Harrisburg, PA 17120-2065

Hon. Dan Frankel  
332 Main Capitol Building  
P.O. Box 202023  
Harrisburg, PA 17120-2023

Members, House Health Committee  
Pennsylvania House of Representatives  
330 Ryan Office Building  
State Capitol

**Re: Pharmacy Community Comments on HB 1741**

The Pennsylvania Pharmacists Association, along with the Pennsylvania Association of Chain Drug Stores, the Philadelphia Association of Retail Druggists and Value Drug Company, have serious concerns with the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial.

Ivermectin is approved by the U.S. Food and Drug Administration (FDA) for human use to treat infections caused by internal and external parasites. It is not approved to prevent or treat COVID-19. Ivermectin is also available to treat certain veterinary conditions; medications formulated or intended for use in animals should not be used by humans. We are alarmed by reports that outpatient prescribing for and dispensing of ivermectin have increased 24-fold nationally since before the pandemic and increased exponentially over the past few months. As such, we strongly recommend a pause on any attempts to legislate the prescribing, dispensing, and use of ivermectin for the prevention and treatment of COVID-19 outside of a clinical trial. In addition, we are urging physicians, pharmacists, and other prescribers — trusted healthcare professionals in their communities — to warn patients against the use of ivermectin outside of FDA-approved indications and guidance, whether intended for use in humans or animals, as well as purchasing ivermectin from online stores. Veterinary forms of this medication are highly concentrated for large animals and pose a significant toxicity risk for humans.

The U.S. Centers for Disease Control and Prevention (CDC) and the FDA have issued advisories indicating that ivermectin is not authorized or approved for the prevention or treatment of COVID-19. The National Institutes of Health, World Health Organization, and Merck (the manufacturer of the drug) all state there is insufficient evidence to support the use of ivermectin to treat COVID-19. The Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19 also recommend against the use of ivermectin outside of a clinical trial.

Use of ivermectin for the prevention and treatment of COVID-19 has been demonstrated to be harmful to patients. Calls to poison control centers due to ivermectin ingestion have increased five-fold from

their pre-pandemic baseline. A recent [CDC Health Alert Network Advisory](#) recommends that healthcare professionals should counsel patients against use of ivermectin as a treatment for COVID-19, including 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.”

For more information, we encourage patients and healthcare providers to consult the [FDA’s Consumer Update](#) on Why You Should Not Use Ivermectin to Treat or Prevent COVID-19 and the CDC Health Alert Network Advisory on the Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Products Containing Ivermectin to Prevent or Treat COVID-19.

Chloroquine is an antimalarial drug that was developed in 1934. Hydroxychloroquine, an analogue of chloroquine, was developed in 1946. Hydroxychloroquine is used to chronic treat autoimmune diseases, such as systemic lupus erythematosus and rheumatoid arthritis, in addition to malaria.

The National Institute of Health released updated COVID-19 treatment guidelines for use of chloroquine and hydroxychloroquine in July of 2021.

<https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/chloroquine-or-hydroxychloroquine-and-or-azithromycin/>

Their rationale was based on a large randomized controlled platform trial of hospitalized patients in the United Kingdom (RECOVERY), hydroxychloroquine did not decrease 28-day mortality when compared to the usual standard of care. Patients who were randomized to receive hydroxychloroquine had a longer median hospital stay than those who received the standard of care. In addition, among patients who were not on invasive mechanical ventilation at the time of randomization, those who received hydroxychloroquine were more likely to subsequently require intubation or die during hospitalization than those who received the standard of care.<sup>1</sup> In addition, several randomized trials have not shown a clinical benefit for hydroxychloroquine in non-hospitalized patients with early, asymptomatic, or mild COVID-19.<sup>2,3</sup>

The COVID-19 Treatment Guidelines Panel **recommends against** the use of **chloroquine** or **hydroxychloroquine** for the treatment of COVID-19 in hospitalized patients (**AI**) and in non-hospitalized patients (**AIIa**). Hydroxychloroquine and chloroquine **are not approved** by the Food and Drug Administration (FDA) for the treatment of COVID-19. Furthermore, the FDA Emergency Use Authorization for hydroxychloroquine and chloroquine was [revoked in June 2020](#). Please refer to the [Revocation of the EUA Letter](#) and [FAQs on the Revocation of the EUA for Hydroxychloroquine Sulfate and Chloroquine Phosphate](#) for more information.

Novel off-label use of FDA-approved medications is a matter for the physician’s or other prescriber’s professional judgment. We also strongly support a pharmacist’s professional responsibility to make reasonable inquiries to a prescriber to resolve any questions about a prescription. If a prescription is not for a legitimate medical purpose, it should not be written, and it should not be dispensed. We encourage patient-centered care decisions, made on an individualized basis with patients’ informed consent about the risks and benefits associated with any treatment regimen. However, evidence-based science and practice must guide these determinations. Physicians, pharmacists and other members of the healthcare team are more than capable of working together and resolving questions.

We further urge that patients already on these medications for chronic conditions should not be negatively impacted by new laws, rules or other guidance. In a time of national pandemic, now is not the

time for states to issue conflicting guidance, however well-intentioned, that could lead to unintended consequences.

We applaud the ongoing efforts to conduct clinical trials and generate evidence related to these and other medications during a time of pandemic. We are also encouraged that some pharmaceutical manufacturers are increasing production of high-demand medications as well as supplying them for use in clinical trials.

The Commonwealth's physicians and pharmacists continue to demonstrate remarkable leadership on a daily basis. We are confident in physicians' and pharmacists' judgment to make the right decisions for their patients, communities and the health care system overall.

Patients are encouraged to talk to their physicians, pharmacists, and other prescribers about currently available therapies authorized or approved for the treatment or prevention of COVID-19. The most effective ways to limit the spread of COVID-19 are to get vaccinated, wear a face mask, stay at least six feet from others in public places, wash hands frequently, and avoid large crowds of people. Our organizations strongly urge eligible unvaccinated individuals to get vaccinated.

We appreciate your consideration of our comments and welcome any questions you may have.

Sincerely,



Victoria E. Elliott, RPh, MBA, CAE  
CEO, Pennsylvania Pharmacists Association

#### References:

1. Recovery Collaborative Group, Horby P, Mafham M, et al. Effect of hydroxychloroquine in hospitalized patients with COVID-19. *N Engl J Med*. 2020;383(21):2030-2040. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/33031652>.
2. Skipper CP, Pastick KA, Engen NW, et al. Hydroxychloroquine in nonhospitalized adults with early COVID-19: a randomized trial. *Ann Intern Med*. 2020;173(8):623-631. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/32673060>.
3. Mitja O, Corbacho-Monne M, Ubals M, et al. Hydroxychloroquine for early treatment of adults with mild COVID-19: a randomized-controlled trial. *Clin Infect Dis*. 2020; Published online ahead of print. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/32674126>.