

March 26, 2020

The Honorable Mike Pence
Vice President of the United States
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

The Honorable Mitch McConnell
Senate Majority Leader
United States Senate
Washington, D.C. 20510

The Honorable Charles Schumer
Senate Democratic Leader
United States Senate
Washington, D.C. 20510

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Kevin McCarthy
House Republican Leader
U.S. House of Representatives
Washington, D.C. 20515

Dear Vice President Pence, Speaker Pelosi, Leader McConnell, Leader McCarthy, and Leader Schumer:

As representatives of the drug supply and payment chain, ranging from pharmaceutical manufacturers, pharmacies, specialty pharmacies, managed care pharmacy, pharmacy benefit managers (PBMs), to health plans, we are aligned on the important principle that the private sector and state and federal governments must work together to facilitate Americans' reliable access to needed prescription drugs during the COVID-19 pandemic.

Prescription drugs are essential to the health and well-being of hundreds of millions of Americans. Patients should have the confidence that adequate prescription drug supplies continue to be available.

Our primary concern is the health and well-being of patients. We recognize that all of us in the pharmaceutical supply and payment chain have a duty to minimize impacts on patient care associated with drug shortages.

The companies and organizations that we represent continuously assess their supply chains for potential disruptions to supply or shortages and collaborate with federal, state, and local public health agencies to share critical information and partner on efforts to sustain access to care with as little disruption as possible. As a result, Americans continue to have access to a safe, effective, and reliable supply of prescription drugs.

The U.S. Food & Drug Administration (FDA) has been closely monitoring the drug supply chain for potential disruptions to supply or shortages caused by the COVID-19 pandemic. Through their essential and leading role in monitoring the safety and resiliency of the drug supply chain, the FDA has been in regular communication with more than 180 manufacturers since late January alone to evaluate their entire supply chain, including active pharmaceutical ingredients, finished dose forms, and any components that may be impacted in any area of the supply chain due to the pandemic.

But we know that even with this important ongoing work, Americans are concerned and that we must be prepared to avoid and address any shortages. Following Centers for Disease Control and Prevention (CDC) advice, patients may wish to have a supply of most maintenance medications. Others may opt for home delivery, at the time a refill is needed, to access medications safely. We recommend that federal, state, and local government leaders urge patients to consider their personal circumstances, and if needed, consult their health care prescriber or pharmacist if they feel they need an early refill or other flexibilities. Should there be shortages, or potential shortages, federal and state governments should recognize that patients may be able to have a smaller supply of drugs on hand so that more patients needing a given drug may be able to get it, and should also consider allowing pharmacies to dispense covered therapeutic alternatives if shortages occur.

As drugs are identified as potential treatments for COVID-19, the demand may outstrip the supply. As a nation, it is imperative we balance the need to find drugs that may be helpful to treat COVID-19 while still making them reasonably available to patients who currently rely on them for established treatment. We recommend clinical guidance for health care providers be issued to ensure that patients who have been on therapies for FDA-approved indications prior to the spread of COVID-19 still have appropriate access, as well as those with COVID-19. It is important to prioritize access to drugs for patients in FDA clinical trials, which assist in evidence generation for COVID-19 treatments and vaccines for the entire population.

Without national clinical guidelines on this issue, health care providers and patients will be subject to differing rules and timelines by state and local regulators, resulting in confusion, perceptions of unfairness, and practical complexities, including point-of-sale related issues. This will not facilitate the coordinated, whole-of-government response in confronting COVID-19, thus impeding the nation's ability to help ensure individuals are not stockpiling medications that are needed by others for their immediate care needs.

As you consider how best to respond to this unprecedented crisis, it is critical that the U.S. Government not take steps that may have an unintended impact on the supply of pharmaceuticals in the United States. All of our industries are concerned that a reported "Buy America" Executive Order under consideration by the White House could have an immediate and detrimental impact on the ability of Americans who rely on federally funded health programs to access their medicines.

Finally, we are also increasingly concerned that the reduction in the availability of international air transportation may be increasing costs for shipping critical medicines, upwards of 400 to 500 percent for shipment into the U.S. health care system. This growth in shipment costs create particularly serious challenges for smaller companies and may result in medicine price increases at a time when many Americans are economically vulnerable due to the related economic crisis. We strongly encourage the Trump administration to work with the U.S. airline industry to ensure that airlines that are flying reserve space for pharmaceuticals, medical devices, and medical supplies at reasonable rates.

While COVID-19 is a new and evolving public health challenge, our industries have substantial, collective experience in helping to mitigate prescription drug access concerns in the event of shortages – whether the result of market, public health, or environmental forces. Through FDA-led and industry-supported surveillance efforts, timely information collection and awareness about potential shortages enables the best management of disruptions to supply or shortages, distribution of existing stocks, and contingency solutions to minimize the impact on patient care.

Timely information about disruptions to supply or drug shortages provided to pharmacies, prescribers, and payers will help facilitate adjustments to care through therapeutic alternatives and reduce patient disruption.

Our industries pledge to continue to work collaboratively with each other and with the FDA and other federal, state, and local officials to keep the prescription drug supply chain functioning well as we confront this unprecedented health system challenge.

Sincerely,

Academy of Managed Care Pharmacy

America's Health Insurance Plans

Association for Accessible Medicines

Blue Cross Blue Shield Association

National Association of Chain Drug Stores

National Association of Specialty Pharmacy

Pharmaceutical Care Management Association

Pharmaceutical Research and Manufacturers of America