



August 29, 2023

The Honorable Kevin McCarthy
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

The Honorable Chuck Schumer
Majority Leader
U.S. Senate
Washington, DC 20510

The Honorable Hakeem Jeffries
Minority Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Minority Leader
U.S. Senate
Washington, DC 20510

Dear Speaker McCarthy, Leader Schumer, Leader Jeffries, and Leader McConnell:

As an elected member of Congress, we know that you take the health of your constituents and the American people seriously. We, as Governors of our states, have a responsibility to our citizens' health, as well. A widespread and long-lasting shortage of critical drugs has been impacting the United States of America for years. Many of the most used prescription drugs in the country are facing extensive shortages – drugs like albuterol, amoxicillin, and chemotherapy drugs. Too often, there is no good explanation for why.

These shortages are not new, but they are becoming more frequent and more severe. Pharmacists in our states are having to tell patients that they don't have critical medicine available. Nobody should have to experience that kind of worry, especially not in the United States of America.

Over 80% of the active ingredients in prescription drugs sold throughout the United States now come from foreign countries, primarily China and India. This limited supply chain creates a national security risk and leaves America competing with other nations for essential resources.

To date, little has been done to address this crisis. States are taking what limited action we can to combat prescription drug shortages. Individual states have expanded our medical caches to increase the diversity of prescription drugs that are stockpiled in case of emergency shortages.

To create real change, the states need Washington to take action. FDA Commissioner Robert Califf has indicated a willingness to work with Congress on this issue. According to the *New York Times*, "The F.D.A., which employs a team of about 10 people who do the day-to-day work of mitigating and reporting drug shortages, has said it is seeking authority from Congress to get additional information about the drug manufacturing and supply chain."

In light of the nationwide prescription drug shortage, we are calling on Congress to consider adding the following important policy solutions to any upcoming legislation aimed at addressing drug shortages:

- Transparency in the pharmaceutical manufacturing chain from sourcing raw materials to the finished product, including country of origin labeling;
- Increased diversity in the manufacturing of generic medications with regards to both raw materials and final manufacturing;
- Require transparency from the FDA related to shortages and events that cause supply disruption;
- Extending useful life of medications when appropriate by re-examining FDA guidance related to expiration dates;
- Waivers to allow purchasing of medications from Canada to expand our supply chain capability quickly;
- Creation of a regulatory environment that is more favorable to U.S. manufacturing to include instituting shorter “cure periods” for U.S. manufacturing plants; and,
- Requiring a risk assessment of foreign source active pharmaceutical ingredients.

The FDA and medical companies are currently restricted by federal law regarding their transparency policies. Congress must grant additional authorities that allow more transparency throughout the drug manufacturing process. The American people deserve to know the truth behind where their prescription drugs are coming from and how they are quality tested, especially when those drugs are originating overseas.

Many overseas manufacturing plants have aging systems and processes. Once prescription drugs are in the United States, they are quality tested, but the risk of something going wrong is high. If a batch of prescription drugs comes to America and fails the quality tests, it could create a serious nationwide shortage of a lifesaving medication. Congress needs to improve the inspection process for these manufacturers to decrease the risk that everyday Americans are currently facing.

Unfortunately, contracts currently allow companies to walk away from a manufacturer too easily when the price of production rises above a certain threshold. Over time, this has priced American manufacturers out of the market, pushing more production overseas. As this overseas production has centralized in a few countries, the Chinese Communist Party has gained far too great of an influence over our prescription drug manufacturing.

Congress can address this challenge by amending contract laws to ensure that more than just the lowest possible price is considered. Other considerations should include quality of the finished product, safety standards within the manufacturing facilities, and other quality control mechanisms that will give American manufacturers a fair shake. Congress can also ensure that contracts last longer. If contracts last at least 10 years, it will result in game-changing long-term investments in American manufacturing.

These practical steps toward greater transparency and flexibility will ensure safety and dependability in our pharmaceutical supply chain. We look forward to your action in these areas, and as always, stand ready to help in our own states to advance these goals.

Sincerely,



Governor Kristi Noem
State of South Dakota



Governor Sarah Sanders
State of Arkansas



Governor Eric Holcomb
State of Indiana



Governor Kim Reynolds
State of Iowa



Governor Tate Reeves
State of Mississippi



Governor Mike Parson
State of Missouri



Governor Greg Gianforte
State of Montana



Governor Joe Lombardo
State of Nevada



Governor Chris Sununu
State of New Hampshire



Governor Greg Abbott
State of Texas



Governor Mark Gordon
State of Wyoming

CC: The Honorable Cathy McMorris Rogers, Chairwoman, House Energy and Commerce Committee
The Honorable Jason Smith, Chairman, House Ways and Means Committee
The Honorable Bernie Sanders, Chairman, Senate Health, Education, Labor, and Pensions Committee
The Honorable Frank Pallone, Ranking Member, House Energy and Commerce Committee
The Honorable Richard Neal, Ranking Member, House Energy and Commerce Committee
The Honorable Bill Cassidy, Ranking Member, Senate Health, Education, Labor, and Pensions Committee