COALITION for a PROSPEROUS AMERICA

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May 24, 2022

The Hon. Joseph R. Biden, Jr
President of the United States
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Re: Essential generic medicines - Excessive offshoring and failure of safety and efficacy

Dear President Biden:

We write to you regarding the crisis facing our nation as a result of decades of dereliction of duty by the Food and Drug Administration (FDA) to ensure our nation has a safe, affordable, and readily accessible supply of generic and other essential medicines. The FDA is not merely failing, it is worsening the problem of excessive reliance on shoddy foreign manufacturers.

Currently, hundreds of essential medicines are on shortage, including nearly half of all generic pharmaceuticals on the FDA's newly created essential medicines list that appear in some form on the FDA's drug shortage list. The FDA does nothing to resolve the problem and reshore production. As a result, hospital procedures are being delayed. Patients across the country are being harmed.

Additionally, FDA does not test imported medicines or inspect the Chinese and Indian plants making them. Recent reports show that imports of generic medicines from foreign manufacturers in India and China are not functioning as they should. For example, absorption rates when examined are off the charts and sometimes nonexistent. Contrary to the understanding of most Americans, the FDA does not even test medicines imported into the U.S. from foreign manufacturers that have received a Warning Letter for significantly violating the agency's regulations for safety and quality control.

According to a recent poll conducted by Morning Consult, 86 percent of Americans support the FDA testing generic medicines imported into the U.S. from foreign manufacturers that have received a Warning Letter. Additionally, 84 percent of Americans want the FDA to ban imports of generic medicines from foreign manufacturers that have received a Warning Letter.

The FDA's lack of inspection, testing and enforcement for foreign drug manufacturers in China and India is a serious problem that is jeopardizing the health of millions of Americans. Overseas manufacturers have a long history of evading the bulk of the FDA's oversight, as the agency's

inspectors have no statutory authority abroad and their ability to inspect facilities is restricted to the level of access that foreign countries and companies are willing to provide.

The FDA's uneven enforcement of its authority has created a multibillion-dollar regulatory loophole for Chinese and Indian manufacturers that undermines the agency's ability to protect the American people. It incentivizes companies to shift production to foreign countries beyond the reach of the FDA's more rigorous inspections. The consequence is less resilient pharmaceutical supply chains, and more American people exposed to potentially substandard, harmful, and even lethal generic drugs.

A basic and common but key ingredient for medical imaging, contrast dye, is now in shortage as a result of a GE Healthcare factory in China being shutdown due to a Covid lockdown. This means that CT scans and fluoroscopes used to see inside the body will have to be delayed. Patients will no longer be able to have important and necessary imaging done because Contrast media (dye), which is used in virtually every hospital – cannot be sourced.

Alarmingly, arterial blockages around the heart, placement for stents in catheter labs, and the diagnosis and treatment of strokes – including monitoring of cancerous tumors – are all sidelined. This shortage will cause patients to get sicker and not receive the treatment they need because we have become a nation dependent on the Chinese Communist Party for medicine, ingredients, supplies.

These problems, however, are no surprise. Over the last thirty years, the U.S. manufacturing base for generic medicine has been hollowed out. The Hatch-Waxman Act was designed to increase access to affordable generic medicine by creating greater competition and lowering cost for consumers. Unfortunately, the law failed to anticipate the race to the bottom in price by foreign manufacturers in China and India, sacrificing quality by offshoring production to unchecked, poorly monitored facilities that now receive the overwhelming majority of Warning Letters from the FDA.

The FDA is well aware of this problem, but instead of correctly identifying and addressing it, the agency is worsening the problem by approving the drug applications of many more Asian manufacturers than US companies. Frustratingly, the COVID pandemic shortages did not change the FDA bias in favor of foreign and US multinationals' production anywhere but here. Report after report points the finger at the wrong reason as to why America lacks supply. But never has the FDA acknowledged that the reason for shortages is because our nation lost the ability to manufacture products domestically. Instead of correctly identifying the problem and working with your administration and Congress on a solution, the FDA has only become more beholden to uninspected foreign manufacturers in China and India.

Take for example, Aurobindo, an Indian generic pharmaceutical company. Aurobindo is the largest manufacturer of generics in the world — and the largest volume supplier to the U.S. — because of FDA's inaction to halt their poor-quality manufacturing practices. Aurobindo has received multiple Warning Letters and more than a dozen recalls for unsafe or substandard drugs. Instead of blocking importation of Aurobindo's products and finding alternative suppliers, the FDA has instead continued to reward Aurobindo with countless first generics – the first approval FDA permits which allows for a period of exclusivity in sales.

This month alone, the FDA cited Aurobindo with six new findings of deviations of good manufacturing practices at their oral manufacturing facility in Hyderabad, India. Couple this with past impurity concerns, mold and hair found in drug product, facility leaks that caused contamination, and FDA's finding this past January that called into question the changing of ingredients for the Active Pharmaceutical Ingredients (API) at their manufacturing facility in India. As one pharmaceutical publication noted, Aurobindo has been repeatedly violating FDA regulations since 2011, yet the FDA has failed to shut down this company or ensure its products being imported to the U.S. are safe and effective.

We ask that your administration begin an immediate overhaul of FDA operations, and a review of its leadership, to reverse the offshoring of medicine manufacturing, resolve the shortages plaguing our nation, and inspect and test foreign manufacturers and their products. We are concerned that current FDA officials are not the change agents the country needs for this effort, including Commissioner Robert Califf, Sally Choe (Director of the Office of Generic Drugs) or Donald Ashley (Center for Drug Evaluation and Research, Office of Compliance).

American companies have opened up new domestic facilities that can fill the void and offer safer, more reliable medicine. Existing tools, such as the Defense Production Act, should be used to rapidly grow domestic production. Your administration should support Hatch-Waxman law changes that stop preferencing foreign production, including full inspections and testing of imported drugs as Europe does.

While the FDA has historically been viewed as the "Gold Standard" in safety and efficacy, the agency's no longer deserves that designation. While European nations routinely rebuke the FDA by not importing product from India and China, the FDA is allowing foreign manufacturers in these nations to repeatedly violate the agency's safety regulations without any consequences.

Our member companies that manufacture API and essential generic medicines are well received in nations throughout the world. It is clear that regulators and governments in these nations do not trust the quality of products from Indian and Chinese manufacturers. This dichotomy in approach brings into question the long standing "Gold Standard" of the FDA.

To address these problems, the White House should immediately:

I. Use all authority to identify U.S. companies that can manufacture essential generics and work to get them approved and manufacturing at scale, rather than prioritizing the approval of poor-quality imported product;
II. Increase in-person foreign inspections without advanced notice to create parity with the standard applied to U.S. facilities;
III. Work in coordination with Health and Human Services (HHS), the Department of Defense (DOD), and with the White House to invoke the Defense Production Act to finance and build new production facilities and procure domestically made essential generics;
IV. Amend internal procedures across agencies, including with new regulations or guidance, to prioritize increasing U.S. manufacturing across all essential medicines and dramatically reduce reliance on foreign sources; and
V. Review and change FDA leadership and personnel who are failing to fix the shortages, refusing to enable foreign inspection and testing, and unwilling to bar shoddy foreign manufacturers from selling medicines in the U.S.
VI. Companies under Warning Letter should not be able to continue selling product into the United States. The United States Government should work to ramp up domestic production and ban the product under Warning Letter. FDA needs to take action against manufacturers who continue to skirt good manufacturing practices – jeopardizing patient safety.

We fear the industry, academia, and government revolving door has resulted in FDA being held hostage and resistant to change that may harm large company profits and interests. We also fear that the trade associations with the most FDA influence favor foreign over domestic production because of their foreign company members.

We stand ready to work with you to ensure Americans have access to safe, affordable, and reliable medicine.

Sincerely,

Zach Mottl, Chairman
Coalition for a Prosperous America

Michael Stumo, CEO
Coalition for a Prosperous America