COALITION for a PROSPEROUS AMERICA

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The Honorable Frank Pallone
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce
2322 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pallone and Ranking Member McMorris Rodgers:

Ahead of Commissioner Califf's testimony, we write with grave concern regarding the Food and Drug Administration's (FDA) failure to ensure our nation has a steady supply of essential medical products. As Chairman of the Committee that has direct oversight over the FDA's operations, we urge you to take action to ensure the FDA is addressing current shortages plaguing our nation.

The latest shortage on baby formula is one of only hundreds of essential products currently on shortage under Commissioner Califf's watch. Everything from common hospital products to the dye necessary for medical scans are currently on shortage. As a result, countless patients are not receiving the adequate care they need, and critical procedures are being delayed because of this shortage endemic.

Shortages have been increasing for years, exacerbating problems in our health care system. Currently, hundreds of drugs are on shortage. The COVID pandemic highlighted our lack of capacity to produce essential medicines in the U.S. Thankfully, this resulted in Executive Orders to boost domestic supply and directed the FDA to take action.

However, neither Congress nor the FDA actually did anything to bolster high quality, high volume domestic manufacturing of essential medicines and products. The FDA continues to approve more drugs from uninspected Chinese and Indian firms that have received Warning Letters from the FDA for significantly violating the agency's regulations. The FDA has cited these foreign manufacturers as having demonstrably bad manufacturing practices and substantial problems of therapeutic efficacy. Despite this, the FDA continues to disproportionately approve applications from foreign companies under Warning Letter far more than American-based producers. Incredibly, the FDA is not inspecting these facilities or testing their products being imported.

In other words, the FDA is failing to conduct proper oversight over foreign manufacturing facilities, a dereliction of duty that contributed to the offshoring of the pharmaceutical manufacturing industry and assisted in the decline of America's domestic manufacturing capacity.

We are very concerned that Congress has not held a single hearing on this issue or passed legislation to reverse this trend and boost domestic pharmaceutical manufacturing. We see no legislative efforts to reverse this trend. In our view, FDA Commissioner Califf's leadership has

been woefully insufficient and it is clear that the FDA needs a serious overhaul. Career staff with oversight authority over foreign manufacturers have shown they are incompetent in effectively protecting our nation from imports from foreign facilities under Warning Letter. In short, the FDA's apparent contentment with the status quo is putting more and more patients at risk every day.

The goal of increasing access to affordable medicine has been corrupted by a race-to-the-bottom in price and quality. This has eliminated competition in the generics industry and allowed Chinese and Indian manufacturers to monopolize products. Generic competition has been displaced by price manipulation. Producers in India and China are able to bottom out the price of a product because their governments heavily subsidize the generic drug industry. They do not regulate quality and the FDA does not test their drug imports for safety and efficacy. This government assisted foreign predation eliminates competition and enables a pattern of price spikes and shortages because of demand and quality issues in manufacturing.

The FDA's response to these shortages has been nonexistent. Most recently with baby formula, the FDA's solution to a lack of domestic supply was to "ease import restrictions." Not only is this not a real solution, but it also completely ignores the underlying problem. We strongly urge the committee to overhaul the statutory framework that has allowed the FDA to enable this rolling disaster.

The FDA's infamous "gold standard" no longer exists. Their continued reliance on cheap, subquality imports is urged on by foreign and domestic multinational pharmaceutical companies and profit-maximizing hospital procurement officials who ignore quality, Warning Letters, and recalls so long as they get the cheapest medicine on offer that day. Countries like Jordan and other Gulf States will actively not procure generic drugs from India and China because they understand there are quality concerns with their products. The FDA is, however, jeopardizing Americans' patient health and safety to appease the leadership of large multinational companies that have left our shores and gone to Asia for production.

Congress failure to require action on the shortage and efficacy crisis cannot continue. We are disheartened to see that this year's reauthorization for generics (GDUFA) contains no policy provisions to support the reshoring of essential generics. Additionally, the GDUFA reauthorization fails to address the dichotomy between foreign and domestic inspections of manufacturing facilities. Today, foreign producers are provided ample advance notice of upcoming inspections as opposed to their domestic counterparts. This inequity is a complete dereliction of duty by the FDA, which actively assists the demise of domestic production and the growth of foreign production in India and China, including those manufacturers receiving Warning Letters for poor quality and contamination of product.

Therefore, we ask that your committee, in coordination with the Ways and Means Committee, take immediate action to put in place comprehensive reform that will update the Hatch-Waxman Act, spur a rebirth of domestic production, and ensure the quality of manufacturing and the therapeutic efficacy of essential medicines. This reform should:

1) Accelerate pathways for ANDA applicants manufacturing in America;

2) Require that the FDA prioritize U.S. based applicants for first generics;
3) Mandate country of origin-labeling for all products – including country of origin for Active Pharmaceutical Ingredients and Key Starting Materials;
4) Require uniformity of inspections between foreign and domestic manufacturing sites;
5) Codify Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs;
6) Require the implementation of a comprehensive testing program for generics for safety, efficacy, and are not contaminated with possible carcinogens or other impurities;
7) Ensure the Centers for Medicare and Medicaid Services are providing a priority for domestically made products – allowing the federal government to better allocate the $300 billion it spends annually at CMS, which will allow the U.S. to compete with government subsidization programs that India and China currently utilize;
8) Require any manufacturer in India and China to have insurance and have a registered agent present in the U.S. so patients harmed by unsafe or ineffective drugs have a remedy for death or injury instead of chasing an offshore ghost that is not subject to our laws;
9) Create and fund a program across Health and Human Services and the Department of Defense that would utilize the Defense Production Act to bolster domestic investment in production when a product is in shortage;
10) Create a production-based tax credit that rewards domestic generic drug manufacturers and API producers based upon the volume they manufacture (i.e., 50c per vial produced etc.); and
11) Require that manufacturers under multiple Warning Letters are prohibited from selling product into the U.S. until the problems have been remediated and upon FDA inspection.
12) Require that Warning Letters and Form 483 disclose the product or product the API will be used to manufacture. Currently Warning Letters and Form 483's do not disclose the actual product that could be tainted – this lack of transparency undermines public health and confidence in FDA's inspections.

We stand ready to assist in this effort and will increasingly educate patients, the media and the general public on the problems we identified here. We are also including our report from last fall titled, **"How Hatch-Waxman Act Loophole Led to Offshoring of Generics Production, Price Gouging, and Shortages**."

Thank you for your attention to this immediate and serious national security health crisis.

Sincerely,

Zach Mottl, Chairman
Coalition for a Prosperous America

Michael Stumo, CEO
Coalition for a Prosperous America