

August 9, 2023

Dear Members of Congress,

We write today in strong support of S. 2683, the Accelerating Movement of Essential Rx Items to Create Access to National Drug Resources for US Government Services Act (AMERICAN DRUGS Act). This legislation, sponsored by Senator Rick Scott (R-FL), seeks to solve a critical problem plaguing our nation: U.S. dependence on foreign manufacturers in China and India for generic drugs.

The Coalition for a Prosperous America (CPA) is proud to represent exclusively U.S. domestic producers and workers, including American generic pharmaceutical manufacturers. Today, the U.S. is dangerously dependent on foreign manufacturers—particularly in China and India—for essential, lifesaving generic medicines. This is a health care and national security crisis that continues to affect nearly every American.

Generic medicines account for roughly 90% of all prescriptions dispensed in the U.S. and are critical to our nation’s health care system, as well as hundreds of millions of patients every day. In recent decades, U.S. domestic production of generic pharmaceuticals has been offshored to China and India. Subsidized foreign manufacturers have sought to eliminate U.S. competition by racing to the bottom in price, only to drastically increase and price gouge American patients once they have monopolized a product.

Equally concerning, Chinese and Indian manufacturers have demonstrated a pattern of repeatedly violating FDA regulations, which has resulted in the FDA issuing Form 483 observations and Warning Letters, and even import bans to manufacturers that have committed the most serious violations. According to FDA data on drug shortages from 2015 to 2022, drug shortages have shot up to an eight-year high.¹ This raises real questions regarding the FDA’s efforts to mitigate shortages in light of increased risk of non-compliance. In our view, the data shows a disturbing pattern of rising shortages and more risk—the worst outcome.

Our nation’s dependency on foreign producers and supply chains has been a direct cause in the increase in generic drug shortages in the U.S. The data paints an alarming picture. Currently, the U.S. is reliant on imports for at least two-thirds of our generic medicines, and nearly 90% of generic active pharmaceutical ingredient (API) facilities are overseas.² The majority of those supply chains run through China and India.

¹ FDA Drug Shortages Database. “Current and Resolved Drug Shortages and Discontinuations Reported to FDA.” <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

² (“FACT SHEET: Biden-Harris Administration Announces Supply Chain Disruptions Task Force to Address Short-Term Supply Chain Discontinuities”) <https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/08/fact-sheet-biden-harris-administration-announces-supply-chain-disruptions-task-force-to-address-short-term-supply-chain-discontinuities/>.

China, in particular, has a strong hold on the production of API and key starting materials (KSMs). For example, China manufactures roughly 70% of the precursors to acetaminophen, but supplies some of these precursors to India so the share of API from China is less.

In the last ten years, U.S. pharmaceutical imports have skyrocketed, with imports from China and India leading the surge.³ India and China are increasingly the leading U.S. source for generic pharmaceuticals, which account for 90% of all prescriptions written in the U.S. In 2021, China was the leading source for U.S. pharmaceutical imports measured by weight, accounting for 418 million pounds, or 23% of total pharma imports.⁴

Growing U.S. dependence on China and India for widely-used generic pharmaceuticals creates serious risks to national security and patient safety. China now accounts for 95% of imports of ibuprofen, 91% of imports of hydrocortisone, 70% of imports of acetaminophen, and 40% to 45% of imports of penicillin.⁵ China's and India's dominance of the U.S. generic pharmaceutical supply chain is growing. These two countries account for 85% of filings for new active pharmaceutical ingredients, according to data from an industry watchdog.⁶

The U.S. once led the world in pharmaceutical manufacturing. Today, however, we cannot even manufacture the most basic essential medicines domestically. Our nation's overdependence on foreign production has left America vulnerable—both from a national security standpoint and a public health and readiness perspective.

It is clear that Congress must work to address this dependence and to pass legislation that would rapidly increase America's capacity to manufacture generic drugs domestically. Importantly, the AMERICAN DRUGS Act is a good step forward to accomplishing this goal.

Sincerely,



Michael Stumo, CEO
Coalition for a Prosperous America

³ Andrew Heritage, Coalition for a Prosperous America. "Skyrocketing Pharmaceutical Imports to the U.S. Endanger National Security." <https://prosperousamerica.org/skyrocketing-pharmaceutical-imports-to-the-u-s-endanger-national-security/>.

⁴ Ibid.

⁵ Ibid.

⁶ Ibid.