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118TH CONGRESS
1ST SESSION

# H. R. 5575

To direct the Secretaries of Health and Human Services, Defense, and Veterans Affairs to end American over-dependence on Chinese pharmaceuticals by encouraging the growth of a robust domestic medicine supply chain for generic drugs, to empower the Food and Drug Administration to issue boxed warnings in the case of critical contamination, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 19, 2023

Mr. POSEY introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Armed Services, Veterans' Affairs, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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# A BILL

To direct the Secretaries of Health and Human Services, Defense, and Veterans Affairs to end American over-dependence on Chinese pharmaceuticals by encouraging the growth of a robust domestic medicine supply chain for generic drugs, to empower the Food and Drug Administration to issue boxed warnings in the case of critical contamination, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Safe Medicine Act''.

**SEC. 2. FINDINGS.**

Congress finds the following:

(1) Following the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417), the People's Republic of China was able to corner the market on generic drugs, pharmaceutical ingredients, and related materials through its steady supply of readily exploitable labor and threadbare safety regulations. Ninety percent of the medications taken by individuals in the United States are generic, rendering them especially dependent on supplies originating in the People's Republic of China.

(2) The number of drugs produced outside of the United States doubled between 2001 and 2008. At present, 80 percent of the active pharmaceutical ingredients used in drugs taken by individuals in the United States come from overseas, mainly the People's Republic of China and the Republic of India. The United States no longer produces penicillin, with the last fermentation plant phasing out of production in 2004.

(3) In 2008, the counterfeiting of Heparin precursor chemicals by a Chinese-based pharmaceutical

plant led to the deaths of 81 individuals in the United States, with 785 more being severely injured. The counterfeit product cost one-hundredth of the price of the real product, indicating a clear economic motive for distributing contaminated materials.

(4) In 2018, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, issued recalls of Valsartan, Losartan, and Irbesartan, common blood pressure drugs. The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, determined that versions of such drugs have been contaminated as a result of Chinese and Indian manufacturing practices and that one Chinese company, Zhejaiang Huahai Pharmaceuticals, had ''systemic problems of supervision'', with the potent carcinogens N-Nitroso-N-methyl-4-aminobutyric acid (NMBA), N-Nitrosodimethylamine (NDMA), and N-Nitrosodiethylamine (NDEA), for a period of 4 years before being detected.

(5) During an October 30, 2020, hearing before the Health Subcommittee of the Energy and Commerce Committee of the House of Representatives, it was discovered that the Food and Drug Administration (FDA) has data on active pharmaceutical ingre-

dient facilities and locations because they regulate and inspect them. But the FDA does not know how much volume is produced at these facilities. A single plant could make 90 percent of global supply or 10 percent, but the FDA does not know.

(6) The FDA cannot determine the United States dependence because it does not thoroughly regulate or inspect the facilities where the key chemicals and raw materials to make active pharmaceutical ingredients are made.

(7) Domestic pharmaceutical facilities undergo far more rigorous inspections than manufacturing facilities in the People's Republic of China. Since early 2020, the FDA recalled its inspectors from China and elsewhere to protect them from the Coronavirus. As a result, FDA inspections have plummeted to near zero for the past year.

(8) In 2010, the People's Republic of China embargoed the shipment of rare earth metals to Japan as political leverage in its negotiations over a boating incident that took place between the 2 countries in the East China Sea. National security experts warn that if such an incident were to take place between the United States and China, and China were to embargo medicine and pharmaceutical

ingredients, the United States would be helpless. Sun Yu and Demetri Sevastopulo, ''China Targets Rare Earth Export Curbs To Hobble US Defense Industry.'' Ars Technica, February 16, 2021, arstechnica.com/tech-policy/2021/02/china-targets-rare-earth-export-curbs-to-hobble-us-defense-industry/. United States dependence on Chinese medicine and pharmaceutical ingredients poses a national security risk.

(9) The United States is dependent on other nations, particularly China, for our generic medicine and key ingredients that are used to make these drugs. Inspections at Chinese facilities are inadequate compared to inspections at facilities located in the United States.

(10) The United States cannot rely on questionable inspections at facilities located in China.

(11) To protect Americans, we must encourage the development of essential generic drug manufacturing here in the United States and countries allied with the United States in a current defense effort for the 227 essential medicines and medical countermeasures identified by the FDA in accordance with Executive Order 13944, issued on August 6, 2020.

**SEC. 3. DOMESTIC MANUFACTURING TO END OVER-DEPENDENCE OF THE UNITED STATES ON CHINESE DRUGS.**

(a) IN GENERAL.—The Secretaries of Health and Human Services, Defense, and Veterans Affairs, acting jointly and in consultation with the Commissioner of Food and Drugs, shall—

(1) not later than 180 days after the date of enactment of this Act, develop a procurement strategy, including for long-term contracts, to strengthen and mobilize the Public Health Industrial Base to increase the manufacture in the United States of essential medicines, medical countermeasures, and critical inputs, including the 227 essential medicines, medical countermeasures, and critical inputs published on October 30, 2020, by the Food and Drug Administration in accordance with Executive Order 13944; and

(2) beginning as soon as feasible after the development of such strategy, and not later than 5 years after the development of such strategy, implement such strategy.

(b) CONTENTS.—The strategy under subsection (a) shall—

(1) be consistent with all applicable Federal law;

(2) identify essential components, including key starting materials, active ingredients, and critical inputs, necessary for manufacturing the essential medicines and medical countermeasures published on October 30, 2020, by the Food and Drug Administration in accordance with Executive Order 13944; and

(3) address the capacity of the supply chain and industrial base to strengthen and mobilize the Public Health Industrial Base to increase the manufacture in the United States of essential medicines, medical countermeasures, and critical inputs.

(c) DEFINITIONS.—In this section:

(1) The term ''critical inputs'' means active pharmaceutical ingredients, active pharmaceutical ingredient starting material, and other ingredients of drugs and components of medical devices that the Commissioner of Food and Drugs determines to be critical in assessing the safety and effectiveness of essential medicines and medical countermeasures.

(2) The term ''essential medicine'' means medicine—

(A) that is needed to protect the American public at all times, including from outbreaks of emerging infectious diseases, such as COVID–

19, as well as chemical, biological, radiological, and nuclear threats; and

(B) of which sufficient and reliable, long-term domestic production of these products, mostly generic drugs, their active pharmaceutical ingredients, and key starting materials, is needed to minimize potential shortages by reducing the Nation's dependence on foreign manufacturers of these products.

(3) The term ''medical countermeasure'' means—

(A) a qualified countermeasure (as defined in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a));

(B) a qualified pandemic or epidemic product (as defined in section 319F–3 of such Act (42 U.S.C. 247d–6d));

(C) a security countermeasure (as defined in section 319F–2 of such Act (42 U.S.C. 247d–6b)); or

(D) personal protective equipment (such as gloves, respirators (face masks), and ventilators).

(4) The term ''Public Health Industrial Base'' means the facilities and associated workforces within

the United States, including research and development facilities, that help produce essential medicines, medical countermeasures, and critical inputs for the health care and public health sector.

**SEC. 4. REQUIRING BOXED WARNINGS ON POTENTIALLY CONTAMINATED DRUGS.**

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) issue an order deeming a drug or active pharmaceutical ingredient (or a category thereof) to be misbranded within the meaning of section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) if such drug or active pharmaceutical ingredient (or category thereof)—

(A) is manufactured in a country that the Secretary determines may be producing contaminated drugs or active pharmaceutical ingredients because of systemic problems of supervision in the manufacture of drugs or active pharmaceutical ingredients; and

(B) the labeling of such drug or active pharmaceutical ingredient (or category thereof) does not bear a boxed warning of the potential for contamination;

(2) make each such order effective for a period of not more than 180 days; and

(3) renew each such order each time the preceding order ends and the criteria listed in paragraph (1) continue to apply.

(b) WAIVERS.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs—

(1) may waive the requirement to issue or renew an order under subsection (a) so long as the labeling of the drug or active pharmaceutical ingredient (or category thereof) bears a boxed warning of the potential for contamination;

(2) shall make any such waiver effective for a period not to exceed 180 days; and

(3) may renew any such waiver one or more times.

**SEC. 5. LIMITATION ON WAIVER AUTHORITY UNDER THE TRADE AGREEMENTS ACT OF 1979.**

Section 301 of the Trade Agreements Act of 1979 (19 U.S.C. 2511) is amended by adding at the end the following:

''(g) LIMITATION ON WAIVER AUTHORITY RELATING TO ESSENTIAL MEDICINES, MEDICAL COUNTERMEASURES, AND CRITICAL INPUTS.—

''(1) IN GENERAL.—The authority of the President under subsection (a) to waive the application of any law, regulation, procedure, or practice regarding Government procurement does not authorize the waiver of any preferences for goods that are essential medicines, medical countermeasures, or critical inputs.

''(2) DEFINITIONS.—In this subsection, the terms 'essential medicines', 'medical countermeasures', and 'critical inputs'—

''(A) have the meanings given such terms in section 3(c) of the Safe Medicine Act; and

''(B) include the 227 essential medicines, medical countermeasures, and critical inputs published on October 30, 2020, by the Food and Drug Administration in accordance with Executive Order 13944.''.

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