I

116TH CONGRESS
2D SESSION

H. R. 5982

To direct the Secretary of Health and Human Services to study American dependence on Chinese pharmaceuticals and to empower the Food and Drug Administration to issue boxed warnings in the case of critical contamination.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 26, 2020

Mr. POSEY (for himself and Mr. RYAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To direct the Secretary of Health and Human Services to study American dependence on Chinese pharmaceuticals and to empower the Food and Drug Administration to issue boxed warnings in the case of critical contamination.

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.

(a) 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) Domestic pharmaceutical facilities are inspected every 2 years, whereas foreign pharmaceutical facilities are inspected only every 9 years. Further, inspections of foreign facilities by the Food and Drug Administration have declined in the past 2 years. In the People's Republic of China, these inspections have fallen by more than 10 percent.

(6) 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 two 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. United States dependence on Chinese medicine and pharmaceutical ingredients poses a national security risk.

(b) PURPOSES.—The purposes of this Act are—

(1) to direct the Secretary of Health and Human Services to study the dependence of the United States on Chinese drugs; and

(2) to authorize the Food and Drug Administration to order a temporary boxed warning on potentially contaminated drugs.

SEC. 3. STUDY OF DEPENDENCE OF UNITED STATES ON CHINESE DRUGS.

Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services, in consultation with the heads of other appropriate Federal departments and agencies, shall submit to

Congress a report on vulnerabilities to the United States medicine supply chain. Such report shall include—

(1) an identification of any finished drugs and their essential components including raw materials, chemical components, and active ingredients necessary for the manufacture of medicines whose supply is at risk of disruption due to dependence on a single or limited number of providing countries;

(2) an identification of the defense and geopolitical contingencies that are sufficiently likely to arise that may disrupt, strain, compromise, or eliminate supply chains of medicines and their essential components and recommendations for reasonable preparation for the occurrence of such contingencies;

(3) an assessment of the resilience and capacity of the current supply chain and industrial base to support the population of the United States upon the occurrence of the contingencies identified pursuant to paragraph (2), including with respect to—

(A) the manufacturing capacity of the United States;

(B) gaps in domestic manufacturing capabilities including non-existent, extinct, threatened, and single-point-of-failure capabilities; and

(C) supply chains with single points of failure and limited resiliency;

(4) legislative, regulatory, and policy changes necessary to avoid, or prepare for, contingencies identified pursuant to paragraph (2);

(5) recommendations to diversify supply away from predominant dependency on sources of supply in competitor countries and politically unstable countries that may cut off United States supply, and address critical bottlenecks and mitigate single points of failure and limited resilience; and

(6) an assessment of the potential impact on domestic drug prices if the People's Republic of China were to embargo the export of drugs and pharmaceutical ingredients to the United States.

SEC. 4. AUTHORIZING TEMPORARY BOXED WARNINGS ON POTENTIALLY CONTAMINATED DRUGS.

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, may issue a temporary order deeming certain drugs to be misbranded within the meaning of section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352), if—

(1) such drugs, or the active pharmaceutical ingredients thereof, are 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 such drugs or active pharmaceutical ingredients; and

(2) the labeling of such drugs does not bear a boxed warning of the potential for contamination.

○