

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Safe Medicine Act”.

5 **SEC. 2. FINDINGS.**

6 (a) FINDINGS.—Congress finds the following:

1 (1) Following the enactment of the Drug Price
2 Competition and Patent Term Restoration Act of
3 1984 (Public Law 98–417), the People’s Republic of
4 China was able to corner the market on generic
5 drugs, pharmaceutical ingredients, and related mate-
6 rials through its steady supply of readily exploitable
7 labor and threadbare safety regulations. Ninety per-
8 cent of the medications taken by individuals in the
9 United States are generic, rendering them especially
10 dependent on supplies originating in the People’s
11 Republic of China.

12 (2) The number of drugs produced outside of
13 the United States doubled between 2001 and 2008.
14 At present, 80 percent of the active pharmaceutical
15 ingredients used in drugs taken by individuals in the
16 United States come from overseas, mainly the Peo-
17 ple’s Republic of China and the Republic of India.
18 The United States no longer produces penicillin,
19 with the last fermentation plant phasing out of pro-
20 duction in 2004.

21 (3) In 2008, the counterfeiting of Heparin pre-
22 cursor chemicals by a Chinese-based pharmaceutical
23 plant led to the deaths of 81 individuals in the
24 United States, with 785 more being severely injured.
25 The counterfeit product cost one-hundredth of the

1 price of the real product, indicating a clear economic
2 motive for distributing contaminated materials.

3 (4) In 2018, the Secretary of Health and
4 Human Services, acting through the Commissioner
5 of Food and Drugs, issued recalls of valsartan,
6 losartan, and irbesartan, common blood pressure
7 drugs. The Secretary of Health and Human Serv-
8 ices, acting through the Commissioner of Food and
9 Drugs, determined that versions of such drugs have
10 been contaminated, as a result of Chinese and In-
11 dian manufacturing practices and that one Chinese
12 company, Zhejiaiang Huahai Pharmaceuticals had
13 “systemic problems of supervision”, with the potent
14 carcinogens N-Nitroso-N-methyl-4-aminobutyric acid
15 (NMBA), N-Nitrosodimethylamine (NDMA), and N-
16 Nitrosodiethylamine (NDEA), for a period of 4
17 years before being detected.

18 (5) Domestic pharmaceutical facilities are in-
19 spected every 2 years, whereas foreign pharma-
20 ceutical facilities are inspected only every 9 years.
21 Further, inspections of foreign facilities by the Food
22 and Drug Administration have declined in the past
23 2 years. In the People’s Republic of China, these in-
24 spections have fallen by more than 10 percent.

1 (6) In 2010, the People’s Republic of China
2 embargoed the shipment of rare earth metals to
3 Japan as political leverage in its negotiations over a
4 boating incident that took place between the two
5 countries in the East China Sea. National security
6 experts warn that if such an incident were to take
7 place between the United States and China, and
8 China were to embargo medicine and pharmaceutical
9 ingredients, the United States would be helpless.
10 United States dependence on Chinese medicine and
11 pharmaceutical ingredients poses a national security
12 risk.

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

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

17 (2) to authorize the Food and Drug Adminis-
18 tration to order a temporary boxed warning on po-
19 tentially contaminated drugs.

20 **SEC. 3. STUDY OF DEPENDENCE OF UNITED STATES ON**
21 **CHINESE DRUGS.**

22 Not later than one year after the date of the enact-
23 ment of this Act, the Secretary of Health and Human
24 Services, in consultation with the heads of other appro-
25 priate Federal departments and agencies, shall submit to

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

3 (1) an identification of any finished drugs and
4 their essential components including raw materials,
5 chemical components, and active ingredients nec-
6 essary for the manufacture of medicines whose sup-
7 ply is at risk of disruption due to dependence on a
8 single or limited number of providing countries;

9 (2) an identification of the defense and geo-
10 political contingencies that are sufficiently likely to
11 arise that may disrupt, strain, compromise, or elimi-
12 nate supply chains of medicines and their essential
13 components and recommendations for reasonable
14 preparation for the occurrence of such contingencies;

15 (3) an assessment of the resilience and capacity
16 of the current supply chain and industrial base to
17 support the population of the United States upon
18 the occurrence of the contingencies identified pursu-
19 ant to paragraph (2), including with respect to—

20 (A) the manufacturing capacity of the
21 United States;

22 (B) gaps in domestic manufacturing capa-
23 bilities including non-existent, extinct, threat-
24 ened, and single-point-of-failure capabilities;
25 and

1 (C) supply chains with single points of fail-
2 ure and limited resiliency;

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

6 (5) recommendations to diversify supply away
7 from predominant dependency on sources of supply
8 in competitor countries and politically unstable coun-
9 tries that may cut off United States supply, and ad-
10 dress critical bottlenecks and mitigate single points
11 of failure and limited resilience; and

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

16 **SEC. 4. AUTHORIZING TEMPORARY BOXED WARNINGS ON**
17 **POTENTIALLY CONTAMINATED DRUGS.**

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

23 (1) such drugs, or the active pharmaceutical in-
24 gredients thereof, are manufactured in a country
25 that the Secretary determines may be producing

1 contaminated drugs (or active pharmaceutical ingre-
2 dients) because of systemic problems of supervision
3 in the manufacture of such drugs or active pharma-
4 ceutical ingredients; and

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

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