

117TH CONGRESS
1ST SESSION

H. R. 5003

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.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 10, 2021

Mr. POSEY (for himself and Mr. RYAN) 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

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.

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

1 **SECTION 1. SHORT TITLE.**

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

3 **SEC. 2. FINDINGS.**

4 Congress finds the following:

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

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

25 (3) In 2008, the counterfeiting of Heparin pre-
26 cursor chemicals by a Chinese-based pharmaceutical

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

6 (4) In 2018, the Secretary of Health and
7 Human Services, acting through the Commissioner
8 of Food and Drugs, issued recalls of Valsartan,
9 Losartan, and Irbesartan, common blood pressure
10 drugs. The Secretary of Health and Human Serv-
11 ices, acting through the Commissioner of Food and
12 Drugs, determined that versions of such drugs have
13 been contaminated as a result of Chinese and Indian
14 manufacturing practices and that one Chinese com-
15 pany, Zhejiaiang Huahai Pharmaceuticals, had “sys-
16 temic problems of supervision”, with the potent car-
17 cinogens N-Nitroso-N-methyl-4-aminobutyric acid
18 (NMBA), N-Nitrosodimethylamine (NDMA), and
19 N-Nitrosodiethylamine (NDEA), for a period of 4
20 years before being detected.

21 (5) During an October 30, 2020, hearing before
22 the Health Subcommittee of the Energy and Com-
23 merce Committee of the House of Representatives, it
24 was discovered that the Food and Drug Administra-
25 tion (FDA) has data on active pharmaceutical ingre-

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

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

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

18 (8) In 2010, the People's Republic of China
19 embargoed the shipment of rare earth metals to
20 Japan as political leverage in its negotiations over a
21 boating incident that took place between the 2 coun-
22 tries in the East China Sea. National security ex-
23 perts warn that if such an incident were to take
24 place between the United States and China, and
25 China were to embargo medicine and pharmaceutical

1 ingredients, the United States would be helpless.
2 Sun Yu and Demetri Sevastopulo, “China Targets
3 Rare Earth Export Curbs To Hobble US Defense
4 Industry.” Ars Technica, February 16, 2021,
5 [arstechnica.com/tech-policy/2021/02/china-targets-](https://arstechnica.com/tech-policy/2021/02/china-targets-rare-earth-export-curbs-to-hobble-us-defense-industry/)
6 [rare-earth-export-curbs-to-hobble-us-defense-indus-](https://arstechnica.com/tech-policy/2021/02/china-targets-rare-earth-export-curbs-to-hobble-us-defense-industry/)
7 [try/](https://arstechnica.com/tech-policy/2021/02/china-targets-rare-earth-export-curbs-to-hobble-us-defense-industry/). United States dependence on Chinese medicine
8 and pharmaceutical ingredients poses a national se-
9 curity risk.

10 (9) The United States is dependent on other
11 nations, particularly China, for our generic medicine
12 and key ingredients that are used to make these
13 drugs. Inspections at Chinese facilities are inad-
14 equate compared to inspections at facilities located
15 in the United States.

16 (10) The United States cannot rely on ques-
17 tionable inspections at facilities located in China.

18 (11) To protect Americans, we must encourage
19 the development of essential generic drug manufac-
20 turing here in the United States and countries allied
21 with the United States in a current defense effort
22 for the 227 essential medicines and medical counter-
23 measures identified by the FDA in accordance with
24 Executive Order 13944, issued on August 6, 2020.

1 **SEC. 3. DOMESTIC MANUFACTURING TO END OVER-DE-**
2 **PENDENCE OF THE UNITED STATES ON CHI-**
3 **NESE DRUGS.**

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

8 (1) not later than 180 days after the date of
9 enactment of this Act, develop a procurement strat-
10 egy, including for long-term contracts, to strengthen
11 and mobilize the Public Health Industrial Base to
12 increase the manufacture in the United States of es-
13 sential medicines, medical countermeasures, and
14 critical inputs, including the 227 essential medicines,
15 medical countermeasures, and critical inputs pub-
16 lished on October 30, 2020, by the Food and Drug
17 Administration in accordance with Executive Order
18 13944; and

19 (2) beginning as soon as feasible after the de-
20 velopment of such strategy, and not later than 5
21 years after the development of such strategy, imple-
22 ment such strategy.

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

25 (1) be consistent with all applicable Federal
26 law;

1 (2) identify essential components, including key
2 starting materials, active ingredients, and critical in-
3 puts, necessary for manufacturing the essential
4 medicines and medical countermeasures published on
5 October 30, 2020, by the Food and Drug Adminis-
6 tration in accordance with Executive Order 13944;
7 and

8 (3) address the capacity of the supply chain
9 and industrial base to strengthen and mobilize the
10 Public Health Industrial Base to increase the manu-
11 facture in the United States of essential medicines,
12 medical countermeasures, and critical inputs.

13 (c) DEFINITIONS.—In this section:

14 (1) The term “critical inputs” means active
15 pharmaceutical ingredients, active pharmaceutical
16 ingredient starting material, and other ingredients of
17 drugs and components of medical devices that the
18 Commissioner of Food and Drugs determines to be
19 critical in assessing the safety and effectiveness of
20 essential medicines and medical countermeasures.

21 (2) The term “essential medicine” means medi-
22 cine—

23 (A) that is needed to protect the American
24 public at all times, including from outbreaks of
25 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

1 the United States, including research and develop-
2 ment facilities, that help produce essential medi-
3 cines, medical countermeasures, and critical inputs
4 for the health care and public health sector.

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

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

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

16 (A) is manufactured in a country that the
17 Secretary determines may be producing con-
18 taminated drugs or active pharmaceutical ingre-
19 dients because of systemic problems of super-
20 vision in the manufacture of drugs or active
21 pharmaceutical ingredients; and

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

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

3 (3) renew each such order each time the pre-
4 ceding order ends and the criteria listed in para-
5 graph (1) continue to apply.

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

9 (1) may waive the requirement to issue or
10 renew an order under subsection (a) so long as the
11 labeling of the drug or active pharmaceutical ingre-
12 dient (or category thereof) bears a boxed warning of
13 the potential for contamination;

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

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

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

20 Section 301 of the Trade Agreements Act of 1979
21 (19 U.S.C. 2511) is amended by adding at the end the
22 following:

23 “(g) LIMITATION ON WAIVER AUTHORITY RELATING
24 TO ESSENTIAL MEDICINES, MEDICAL COUNTER-
25 MEASURES, AND CRITICAL INPUTS.—

1 “(1) IN GENERAL.—The authority of the Presi-
2 dent under subsection (a) to waive the application of
3 any law, regulation, procedure, or practice regarding
4 Government procurement does not authorize the
5 waiver of any preferences for goods that are essen-
6 tial medicines, medical countermeasures, or critical
7 inputs.

8 “(2) DEFINITIONS.—In this subsection, the
9 terms ‘essential medicines’, ‘medical counter-
10 measures’, and ‘critical inputs’—

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

13 “(B) include the 227 essential medicines,
14 medical countermeasures, and critical inputs
15 published on October 30, 2020, by the Food
16 and Drug Administration in accordance with
17 Executive Order 13944.”.

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