Mike Braun
Amendment #7

AMENDMENT NO._____ Calendar No._____

Purpose: To require the Secretary of Health and Human Services to maintain a list of the country of origin of all drugs marketed in the United States and to ban the use of Federal funds for the purchase of drugs manufactured in the People's Republic of China.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 3799

To prepare for, and respond to, existing viruses, emerging new threats, and pandemics.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. BRAUN

Viz:

At the appropriate place in subtitle B of title V, insert the following:

SEC. 5_____. COUNTRY OF ORIGIN OF DRUGS.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SEC. 524B. REGISTRY OF DRUGS PRODUCED OUTSIDE THE US.

"(a) IN GENERAL.—The Secretary shall compile and maintain a list of all drugs approved under subsection (c)

or (j) of section 505 of this Act or licensed under subsection (a) or (k) of section 351 of the Public Health Service Act, and any active ingredients in such drugs, that—

"(1) are manufactured outside of the United States; and

"(2) are determined by the Secretary to be critical to the health and safety of consumers in the United States.

"(b) ADDITIONAL LIST.—In conjunction with the list described in subsection (a), the Secretary shall compile and maintain a list of drugs included on such list that are exclusively produced in, or use active or inactive ingredients produced in, the People's Republic of China.

"(c) REQUIREMENT.—The list described in subsection (a) shall, with respect to each drug included on the list, provide information about the supply chain of the drug, including each step in the supply chain that occurs prior to importation of the drug into the United States.".

(b) FEDERAL HEALTH PROGRAM PURCHASE OF DRUGS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, with respect to the purchase of a drug by the Department of Health and Human Services, the Department of Veterans Affairs, the Department of Defense, or any other Federal health

care program (as defined in section 1128B(f) of the Social Security Act (42 U.S.C. 1320a–7b(b)), the following shall apply:

(A) Beginning on January 1, 2024, such agency or program may purchase only drugs for which 60 percent or more of the active pharmaceutical ingredients are manufactured in countries described in paragraph (2).

(B) Beginning on January 1, 2026, such agency or program may purchase only drugs for which 100 percent of the active pharmaceutical ingredients are manufactured in countries described in paragraph (2).

(2) COUNTRIES DESCRIBED.—The countries described in this paragraph are countries—

(A) other than People's Republic of China; and

(B) that meet the health and safety standards of the Food and Drug Administration.

(3) WAIVERS.—The Secretary of Health and Human Services may issue waivers of the requirements under paragraph (1) for any agency or program that is unable to meet such requirements and demonstrates a need for the waiver. No waiver may

be issued under this paragraph for drugs that are purchased on or after January 1, 2027.

(c) LABELING REQUIREMENT.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

"(gg) If it is a drug and its labeling does not specify the country of origin of each active ingredient contained in the drug.".