118TH CONGRESS
2D SESSION

S. _____

To require the Secretary of Health and Human Services to maintain a list of the country of origin of certain critical drugs marketed in the United States, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. COTTON (for himself and Mr. KAINE) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To require the Secretary of Health and Human Services to maintain a list of the country of origin of certain critical drugs marketed in the United States, 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 ''Protecting Our Essential Medicines Act''.

SEC. 2. LIST OF CRITICAL DRUGS PRODUCED OUTSIDE THE UNITED STATES.

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. 524C. LIST OF CRITICAL DRUGS PRODUCED OUTSIDE THE UNITED STATES.

''(a) LIST OF CRITICAL DRUGS.—

''(1) IN GENERAL.—For purposes of strengthening the public health supply chain and industrial base, and increasing the manufacture of essential drugs, including biological products, and critical inputs of such drugs in the United States, the Secretary shall compile and maintain a list of each drug that is—

''(A) 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;

''(B) imported into the United States; and

''(C)(i) determined by the interagency task force established under subsection (e) to be critical to the health and safety of consumers in the United States;

''(ii) determined by such task force to be a drug the shortage of which would have an ad-

verse health outcome on patients with chronic conditions; or

''(iii) a qualified countermeasure, as defined in section 319F–1(a)(2) of the Public Health Service Act, a qualified pandemic or epidemic product, as defined in section 319F–3(i) of such Act, or a security countermeasure, as defined in section 319F–2(c) of such Act.

''(2) SUPPLY CHAIN INFORMATION.—The list required by paragraph (1) shall, with respect to each drug included on the list, provide information about each facility registered under section 510 that is involved in the manufacture, preparation, propagation, compounding, or processing of the drug or an ingredient of the drug.

''(3) NO PUBLIC DISCLOSURE.—The list required by paragraph (1), and any portion thereof, shall not be publicly disclosed, and nothing in paragraph (1) or (2) shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

''(4) PERMISSIBLE DISCLOSURE TO NATIONAL SECURITY AGENCIES OF THE FEDERAL GOVERN-

MENT.—The list required by paragraph (1) (and any portion thereof) may be disclosed by the Secretary only—

"(A) within the Department of Health and Human Services and pursuant to reporting under subsection (e); and

"(B) for purposes of evaluating supply chain vulnerabilities and other national security issues, with national security agencies of the Federal Government, including all elements of the Department of Defense and national intelligence agencies.

"(5) DEFINITION.—In this subsection, the term 'critical inputs' means active pharmaceutical ingredients, starting material for active pharmaceutical ingredients, and other ingredients of drugs that the Commissioner of Food and Drugs determines to be critical in assessing the safety and effectiveness of drugs described in paragraph (1).

"(b) ADDITIONAL LISTS.—

"(1) IN GENERAL.—In conjunction with the list under subsection (a), the Secretary shall, in consultation with the interagency task force established under subsection (e), compile and maintain—

"(A) a list of drugs included on the list under subsection (a) that are exclusively produced in, or use active pharmaceutical ingredients produced in, a foreign entity of concern (as defined in section 9901(8) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021); and

"(B) a list identifying the top 3 countries from which the United States imports drugs described in subsection (a)(1).

"(2) DISCLOSURE.—

"(A) LIST OF DRUGS.—

"(i) NO PUBLIC DISCLOSURE.—The list required by paragraph (1)(A) (and any portion thereof) shall not be publicly disclosed.

"(ii) PERMISSIBLE DISCLOSURE TO NATIONAL SECURITY AGENCIES OF THE FEDERAL GOVERNMENT.—The list required by paragraph (1)(A), and any portion thereof, may be disclosed by the Secretary only—

"(I) within the Department of Health and Human Services, and pur-

suant to reporting under subsection (f); and

"(II) for purposes of evaluating supply chain vulnerabilities and other national security issues, with national security agencies of the Federal Government.

"(B) LIST OF TOP 3 COUNTRIES.—The Secretary shall publicly disclose the list required by paragraph (1)(B), but may not include in any such disclosure—

"(i) information about an identifiable drug or active pharmaceutical ingredient; or

"(ii) proprietary information regarding a drug or active pharmaceutical ingredient, including information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

"(c) TIMELINES.—

"(1) INITIAL LIST.—The Secretary shall compile the initial lists of drugs under subsections (a) and (b) not later than 180 days after the date of en-

actment of the Protecting Our Essential Medicines Act.

''(2) UPDATES.—The Secretary shall update the lists of drugs under subsections (a) and (b), as the Secretary determines necessary and appropriate, and not less frequently than every 2 years.

''(d) CYBERSECURITY MEASURES.— Prior to sharing of any lists required by subsection (a) or (b), within the Department of Health and Human Services or to national security agencies, the Secretary shall ensure that robust cybersecurity measures are in place to prevent inappropriate access to, or unauthorized disclosure of, the list or any information related to the list.

''(e) INTERAGENCY TASK FORCE.—

''(1) ESTABLISHMENT.—Not later than 30 days after the date of enactment of the Protecting Our Essential Medicines Act, the Secretary shall establish an interagency task force for purposes of identifying drugs to include in the list of critical drugs, as described in subsection (a)(1)(C) and consulting with the Secretary with respect to compiling, maintaining, and updating the list under subsection (b). The task force shall be comprised of representatives of the Federal Government as the Secretary, in consultation with the Commissioner of Food and Drugs,

the Director of the Centers for Disease Control and Prevention, the Secretary of Defense, the Assistant Secretary for Preparedness and Response, the Secretary of Homeland Security, the Commissioner of U.S. Customs and Border Protection, and the Director of National Intelligence, determines appropriate.

''(2) PROCEDURES.—Not later than 60 days after the date of enactment of the Protecting Our Essential Medicines Act, the task force established under paragraph (1) shall submit a report on the procedures such task force will follow in making determinations with respect to drugs as described in clauses (i) and (ii) of subsection (a)(1)(C) to—

''(A) the Committee on Health, Education, Labor, and Pensions, the Committee on Finance, and the Committee on Armed Services of the Senate; and

''(B) the Committee on Energy and Commerce, the Committee on Ways and Means, and the Committee on Armed Services of the House of Representatives.

''(f) REPORTING.—Upon compiling the initial list of drugs as required under subsections (a) and (b), and upon making each update to such lists as described in sub-

section (c)(2), the Secretary shall submit the list of drugs to—

''(1) the Secretary of Defense;

''(2) the Attorney General; and

''(3) the Director of National Intelligence.''.