118TH CONGRESS
1ST SESSION

S. 1961

To require an interagency risk assessment of the pharmaceutical supply chain to identify and mitigate health and national security risks, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 13, 2023

Mr. PETERS (for himself and Ms. ERNST) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To require an interagency risk assessment of the pharmaceutical supply chain to identify and mitigate health and national security risks, 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 ''Pharmaceutical Supply Chain Risk Assessment Act of 2023''.

SEC. 2. RISK ASSESSMENT.

(a) IN GENERAL.—The Secretary of Health and Human Services shall lead, in coordination with the Secretary of Defense, the Secretary of Homeland Security,

and the Director of the Office of Pandemic Preparedness and Response Policy, a comprehensive risk assessment of the United States pharmaceutical supply chain and report to the relevant committees of Congress on the findings of each such assessment. The assessment shall be completed not later than 18 months after the date of enactment of this Act, and shall be updated annually thereafter.

(b) CONTENTS.—At a minimum, the risk assessment under subsection (a) shall—

(1) use, as applicable, any drugs from the essential medicines list developed by the Food and Drug Administration in response to Executive Order 13944 (85 Fed. Reg. 49929) and any other relevant assessments or lists, as appropriate, to identify, in coordination with the private sector, a list of essential medicines, to be updated regularly on a timeframe that the Secretary of Health and Human Services, in coordination with the Secretary of Defense and the Secretary of Homeland Security, determines appropriate, which shall include the active pharmaceutical ingredients and drugs that—

(A) are reasonably likely to be required to respond to a public health emergency or to a chemical, biological, radiological, or nuclear threat; or

(B) the shortage of which would pose a significant threat to the United States health care system or at-risk populations;

(2) identify, for each of the active pharmaceutical ingredients and drugs that are identified under paragraph (1)—

(A) the active pharmaceutical ingredients and drugs with vulnerable supply chains;

(B) the amount manufactured by each establishment registered under section 510(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(b)), as reported under section 510(j)(3) of such Act (21 U.S.C. 360(j)(3)), or, with respect to any active pharmaceutical ingredient or drug for which such information is unavailable, an explanation for why the information is unavailable;

(C) the drugs that are sourced either exclusively or primarily from foreign establishments, including drugs manufactured domestically from active pharmaceutical ingredients sourced exclusively or primarily from foreign establishments; and

(D) the active pharmaceutical ingredients that are sourced either exclusively or primarily from foreign establishments;

(3) assess key starting materials and excipients used in manufacturing the active pharmaceutical ingredients and drugs identified under paragraph (1);

(4) assess current domestic manufacturing capabilities with respect to drugs (including key starting materials, excipients, and active pharmaceutical ingredients) identified under paragraph (1), including advanced manufacturing capabilities;

(5) identify critical vulnerabilities, including cybersecurity threats;

(6) identify the existing statutory authorities the Department of Defense, the Department of Health and Human Services, and the Department of Homeland Security have to address public health or national security risks that may arise as a result of vulnerabilities in the pharmaceutical supply chain; and

(7) identify any deficiencies, lack of authorities, or limitations in policy or process that limit the ability of any of the departments described in paragraph (6) to address vulnerabilities in the pharmaceutical supply chain identified in the risk assessment, and

describe the plans of the departments described in paragraph (6) to mitigate such vulnerabilities.

(c) PUBLICATION OF ASSESSMENT.—The risk assessment under subsection (a) (including any updates) shall be publicly available in an unclassified form but may include a classified annex containing any information that the Secretary of Health and Human Services determines to be sensitive.

(d) DEFINITIONS.—In this section:

(1) ADVANCED MANUFACTURING.—The term ''advanced manufacturing'' has the meaning given the term ''advanced and continuous pharmaceutical manufacturing'' in section 3016(h) of the 21st Century Cures Act (21 U.S.C. 399h(h)).

(2) CYBERSECURITY THREAT.—The term ''cybersecurity threat'' has the meaning given such term in section 2200 of the Homeland Security Act of 2002 (6 U.S.C. 650).

(3) DRUG.—The term ''drug'' has the meaning given such term in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)).

(4) RELEVANT COMMITTEES OF CONGRESS.—The term ''relevant committees of Congress'' means the Committee on Homeland Security and Governmental Affairs, the Committee on Health, Edu-

cation, Labor, and Pensions, and the Committee on Armed Services of the Senate and the Committee on Homeland Security, the Committee on Energy and Commerce, and the Committee on Armed Services of the House of Representatives.

(e) CLARIFICATION.—The participation of the Secretary of Health and Human Services in developing and updating the list of essential medicines under subsection (b)(1) shall be deemed to be full satisfaction of the requirements applicable to such secretary under section 3 of Executive Order 13944 (85 Fed. Reg. 49929).

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