II

118TH CONGRESS
2D SESSION

S. 4635

To require a report and updated guidance on continued risk management for pharmaceutical supply chains of Department of Defense.

IN THE SENATE OF THE UNITED STATES

JULY 8, 2024

Mr. PETERS (for himself and Ms. ERNST) introduced the following bill; which was read twice and referred to the Committee on Armed Services

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A BILL

To require a report and updated guidance on continued risk management for pharmaceutical supply chains of Department of Defense.

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 Risk Assessment and Mitigation Act of 2024''.

SEC. 2. REPORT AND UPDATED GUIDANCE ON CONTINUED RISK MANAGEMENT FOR PHARMACEUTICAL SUPPLY CHAINS OF DEPARTMENT OF DEFENSE.

(a) IN GENERAL.—Not later than two years after the date of the enactment of this Act, the Under Secretary of Defense for Acquisition and Sustainment shall—

(1) submit to the Committees on Armed Services of the Senate and the House of Representatives a report regarding—

(A) existing information streams within the Federal Government, if any, for excipients and key starting materials of drugs that may be used to assess the reliance by the Department of Defense on high-risk foreign suppliers analyzed in the report required under section 860(a) of the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 (Public Law 117–263; 10 U.S.C. 3241 note prec.);

(B) active pharmaceutical ingredients, final drug products, and respective excipients and key starting materials analyzed in such report that is produced by each manufacturer in a high-risk foreign country, as determined by the Secretary of Defense;

(C) any limitations on the ability of the Secretary to—

(i) obtain or analyze the information identified under subparagraphs (A) and (B); and

(ii) use data analytics to monitor vulnerabilities in the pharmaceutical supply chain of the Department;

(D) how the Secretary plans to address the limitations identified under subparagraph (C); and

(E) any recommendations of the Secretary to address those limitations; and

(2) update risk management guidance developed by the Under Secretary under section 860(a)(1) of the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 (Public Law 117–263; 10 U.S.C. 3241 note prec.) to include any relevant findings identified in paragraph (1).

(b) FDA DETERMINATIONS.—The Department of Defense shall rely upon determinations of excipients and key starting materials for final drug products that are made by the Food and Drug Administration (FDA) or that align with FDA regulations.

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