118TH CONGRESS
1ST SESSION

S. 2364

To map the United States pharmaceutical supply chain and use data analytics to identify supply chain vulnerabilities and other national security threats.

IN THE SENATE OF THE UNITED STATES

JULY 18, 2023

Mr. PETERS (for himself, Mr. LANKFORD, and Mr. BRAUN) 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 map the United States pharmaceutical supply chain and use data analytics to identify supply chain vulnerabilities and other national security threats.

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 ''Mapping America's Pharmaceutical Supply Act'' or the ''MAPS Act''.

SEC. 2. FEDERAL U.S. PHARMACEUTICAL SUPPLY CHAIN MAPPING.

(a) IN GENERAL.—The Secretary of Health and Human Services, in coordination with the heads of other

relevant agencies, including the Secretary of Defense and the Secretary of Homeland Security, shall support efforts, including through public-private partnerships, to map the entire United States pharmaceutical supply chain, from inception to distribution, and use data analytics to identify supply chain vulnerabilities and other national security threats. Such activities shall include, at minimum—

(1) defining agency roles in monitoring the pharmaceutical supply chain and communicating supply chain vulnerabilities;

(2) establishing a database of drugs selected 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 and published 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 drugs and the active pharmaceutical ingredients of such 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; and

(3) with respect to drugs selected for inclusion in the database pursuant to paragraph (2), identifying—

(A) the location of establishments registered under subsection (b), (c), or (i) of section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) involved in the production of active pharmaceutical ingredients and finished dosage forms, and the amount of such ingredients and finished dosage forms produced at each such establishment;

(B) to the extent available, the location of establishments so registered involved in the production of the key starting materials and excipients needed to produce the active pharmaceutical ingredients and finished dosage forms, and the amount of such materials and excipients produced at each such establishment; and

(C) any regulatory actions with respect to the establishments manufacturing such drugs, including with respect to labeling requirements, registration and listing information required to be submitted under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), inspections and related regulatory activities conducted under section 704 of such Act (21 U.S.C. 374), the seizure of such a drug pursuant to section 304 of such Act (21 U.S.C. 334), any recalls of such a drug; inclusion of such a drug on the drug shortage list under section 506E of such Act (21 U.S.C. 356e), or prior drug shortages reports of a discontinuance or interruption in the production of such a drug under 506C of such Act (21 U.S.C. 355d).

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, and annually thereafter, the Secretary of Health and Human Services, in consultation with the heads of agencies with which such Secretary coordinates under subsection (a), shall submit a report to Congress on—

(1) progress on implementing subsection (a), including any timelines for full implementation, if any;

(2) gaps in data needed for full implementation of such subsection;

(3) how the database established under subsection (a)(2) increases Federal visibility into the pharmaceutical supply chain;

(4) how Federal agencies are able to use data analytics to conduct predictive modeling of anticipated drug shortages or national security threats; and

(5) the extent to which industry has cooperated in mapping the pharmaceutical supply chain and building the database described in subsection (a)(2).

(c) CONFIDENTIAL COMMERCIAL INFORMATION.—The exchange of information among the Secretary of Health and Human Services and the heads of other relevant agencies, including the Secretary of Defense and the Secretary of Homeland Security, for purposes of carrying out this section shall not be a violation of section 1905 of title 18, United States Code.

(d) CLARIFICATION.—The database established under this section shall not be publicly disclosed. Nothing this subsection shall be construed to relieve the Secretary of Health and Human Services from its obligation to provide information to Congress.

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