II

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2D SESSION

S. 3478

To require a report to assess, evaluate, and address the dependence of the United States on critical drugs and devices sourced or manufactured outside of the United States.

IN THE SENATE OF THE UNITED STATES

MARCH 12, 2020

Mr. DURBIN (for himself, Mr. ALEXANDER, Mrs. MURRAY, Mr. ROMNEY, Mr. JONES, Mr. BLUNT, Ms. SMITH, Ms. BALDWIN, Mr. REED, Ms. KLOBUCHAR, and Mr. BLUMENTHAL) 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 a report to assess, evaluate, and address the dependence of the United States on critical drugs and devices sourced or manufactured outside of the United States.

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 ''Commission on America's Medical Security Act''.

SEC. 2. NATIONAL ACADEMIES REPORT ON AMERICA'S MEDICAL PRODUCT SUPPLY CHAIN SECURITY.

(a) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, the Secretary of Health and Human Services shall enter into an agreement with the National Academies of Sciences, Engineering, and Medicine (referred to in this section as the ''National Academies'') to examine, and, in a manner that does not compromise national security, report on, the security of the United States medical product supply chain.

(b) PURPOSES.—The report developed under this section shall—

(1) assess and evaluate the dependence of the United States, including the private commercial sector, States, and the Federal Government, on critical drugs and devices that are sourced or manufactured outside of the United States, which may include an analysis of—

(A) the supply chain of critical drugs and devices of greatest priority to providing health care;

(B) any potential public health security or national security risks associated with reliance on critical drugs and devices sourced or manufactured outside of the United States, which

may include responses to previous or existing shortages or public health emergencies, such as infectious disease outbreaks, bioterror attacks, and other public health threats;

(C) any existing supply chain information gaps, as applicable; and

(D) potential economic impact of increased domestic manufacturing; and

(2) provide recommendations, which may include a plan to improve the resiliency of the supply chain for critical drugs and devices as described in paragraph (1), and to address any supply vulnerabilities or potential disruptions of such products that would significantly affect or pose a threat to public health security or national security, as appropriate, which may include strategies to—

(A) promote supply chain redundancy and contingency planning;

(B) encourage domestic manufacturing, including consideration of economic impacts, if any;

(C) improve supply chain information gaps;

(D) improve planning considerations for medical product supply chain capacity during public health emergencies; and

(E) promote the accessibility of such drugs and devices.

(c) INPUT.—In conducting the study and developing the report under subsection (b), the National Academies shall—

(1) consider input from the Department of Health and Human Services, the Department of Homeland Security, the Department of Defense, the Department of Commerce, the Department of State, the Department of Veterans Affairs, the Department of Justice, and any other Federal agencies as appropriate; and

(2) consult with relevant stakeholders, which may include conducting public meetings and other forms of engagement, as appropriate, with health care providers, medical professional societies, State-based societies, public health experts, State and local public health departments, State medical boards, patient groups, medical product manufacturers, health care distributors, wholesalers and group purchasing organizations, pharmacists, and other entities with

experience in health care and public health, as appropriate.

(d) DEFINITIONS.—In this section, the terms ''device'' and ''drug'' have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

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