

116TH CONGRESS
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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Commission on Amer-
5 ica’s Medical Security Act”.

1 **SEC. 2. NATIONAL ACADEMIES REPORT ON AMERICA'S**
2 **MEDICAL PRODUCT SUPPLY CHAIN SECU-**
3 **RITY.**

4 (a) IN GENERAL.—Not later than 60 days after the
5 date of enactment of this Act, the Secretary of Health and
6 Human Services shall enter into an agreement with the
7 National Academies of Sciences, Engineering, and Medi-
8 cine (referred to in this section as the “National Acad-
9 emies”) to examine, and, in a manner that does not com-
10 promise national security, report on, the security of the
11 United States medical product supply chain.

12 (b) PURPOSES.—The report developed under this sec-
13 tion shall—

14 (1) assess and evaluate the dependence of the
15 United States, including the private commercial sec-
16 tor, States, and the Federal Government, on critical
17 drugs and devices that are sourced or manufactured
18 outside of the United States, which may include an
19 analysis of—

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

23 (B) any potential public health security or
24 national security risks associated with reliance
25 on critical drugs and devices sourced or manu-
26 factured outside of the United States, which

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

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

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

9 (2) provide recommendations, which may in-
10 clude a plan to improve the resiliency of the supply
11 chain for critical drugs and devices as described in
12 paragraph (1), and to address any supply vulnerabil-
13 ities or potential disruptions of such products that
14 would significantly affect or pose a threat to public
15 health security or national security, as appropriate,
16 which may include strategies to—

17 (A) promote supply chain redundancy and
18 contingency planning;

19 (B) encourage domestic manufacturing, in-
20 cluding consideration of economic impacts, if
21 any;

22 (C) improve supply chain information
23 gaps;

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

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

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

9 (1) consider input from the Department of
10 Health and Human Services, the Department of
11 Homeland Security, the Department of Defense, the
12 Department of Commerce, the Department of State,
13 the Department of Veterans Affairs, the Department
14 of Justice, and any other Federal agencies as appro-
15 priate; and

16 (2) consult with relevant stakeholders, which
17 may include conducting public meetings and other
18 forms of engagement, as appropriate, with health
19 care providers, medical professional societies, State-
20 based societies, public health experts, State and local
21 public health departments, State medical boards, pa-
22 tient groups, medical product manufacturers, health
23 care distributors, wholesalers and group purchasing
24 organizations, pharmacists, and other entities with

1 experience in health care and public health, as ap-
2 propriate.

3 (d) DEFINITIONS.—In this section, the terms “de-
4 vice” and “drug” have the meanings given such terms in
5 section 201 of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 321).

○