

116TH CONGRESS
2D SESSION

S. 3343

To amend the Federal Food, Drug, and Cosmetic Act to provide enhanced security for the medical supply chain.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 27, 2020

Mr. HAWLEY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide enhanced security for the medical supply chain.

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 “Medical Supply Chain
5 Security Act”.

6 **SEC. 2. MEDICAL SUPPLY CHAIN SECURITY.**

7 (a) **ADDITIONAL MANUFACTURER REPORTING FOR**
8 **ESSENTIAL MEDICAL DEVICES.**—Section 506C of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c)
10 is amended—

1 (1) in subsection (a)—

2 (A) in the matter preceding paragraph (1),
3 by inserting “or device” after “a drug”; and

4 (B) in the flush matter by inserting “or
5 device” after “drug” each place such term ap-
6 pears;

7 (2) in subsection (c), by inserting “and devices”
8 after “drugs”;

9 (3) in subsection (g)—

10 (A) in the matter preceding paragraph (1),
11 by striking “drug shortage of a drug” and in-
12 serting “shortage of a drug or device”;

13 (B) in paragraph (1), by striking “; or”
14 and inserting a semicolon;

15 (C) by redesignating paragraph (2) as
16 paragraph (3);

17 (D) by inserting after paragraph (1) the
18 following:

19 “(2) expedite the review of a device subject to
20 premarket approval under section 515 that could
21 help mitigate or prevent such shortage; or”; and

22 (E) in paragraph (3), as so redesignated,
23 by striking “drug shortage” and inserting
24 “shortage”;

25 (4) in subsection (h)—

1 (A) by amending paragraph (2) to read as
2 follows:

3 “(2) the term ‘shortage’, with respect to a drug
4 or device, means a period of time when the demand
5 or projected demand for the drug or device within
6 the United States exceeds the supply of the drug or
7 device; and”; and

8 (B) in paragraph (3)(A), by inserting “or
9 device” after “drug”; and

10 (5) by adding at the end the following:

11 “(j) ADDITIONAL MANUFACTURER REPORTING FOR
12 ESSENTIAL DRUGS AND DEVICES.—Each manufacturer
13 of a drug or device described in subsection (a) shall pro-
14 vide to the Food and Drug Administration, on an annual
15 basis, or more frequently at the request of the Secretary,
16 information related to the manufacturing capacity of such
17 drug or device. Such information shall include—

18 “(1) details about—

19 “(A) all locations of production;

20 “(B) the sourcing of all component parts;

21 “(C) the sourcing of any active pharma-
22 ceutical ingredients; and

23 “(D) the use of any scarce raw materials;

24 and

1 “(2) any other information determined by the
 2 Secretary to be relevant to the security of the supply
 3 chain of the drug or device.”.

4 (b) PROVISION OF ADDITIONAL INFORMATION.—Sec-
 5 tion 506C–1 of the Federal Food, Drug, and Cosmetic Act
 6 (21 U.S.C. 356c–1) is amended—

7 (1) in the heading, by striking “**DRUG SHORT-**
 8 **AGES**” and inserting “**DRUG OR DEVICE SHORT-**
 9 **AGES**”;

10 (2) by striking “drug shortages” each place it
 11 appears and inserting “drug or device shortages”;

12 (3) in subsection (a)—

13 (A) in paragraph (3)(B)—

14 (i) in clause (i), by striking “section
 15 506C(g)(1)” and inserting “paragraph (1)
 16 or (2) of section 506C(g)”; and

17 (ii) in clause (ii), by striking “section
 18 506C(g)(2)” and inserting “section
 19 506C(g)(3)”; and

20 (B) in paragraph (5), by striking “drug
 21 shortage” and inserting “drug or device short-
 22 age”; and

23 (4) in subsection (c), by striking “‘drug short-
 24 age’ or”.

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