

117TH CONGRESS
2D SESSION

S. 3834

To strengthen medical device supply chains.

IN THE SENATE OF THE UNITED STATES

MARCH 14, 2022

Mr. BRAUN (for himself and Mr. MARSHALL) introduced the following bill;
which was read twice and referred to the Committee on Health, Edu-
cation, Labor, and Pensions

A BILL

To strengthen medical device supply chains.

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. STRENGTHENING MEDICAL DEVICE SUPPLY**
4 **CHAINS.**

5 (a) IN GENERAL.—Section 506J of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 356j) is amend-
7 ed—

8 (1) in the flush text at the end of subsection
9 (a)—

10 (A) by inserting “or of any other cir-
11 cumstance that is likely to lead to a meaningful

1 disruption in the supply of the device or a
2 shortage of the device, and there is no other
3 available device that could reasonably be sub-
4 stituted for that device in the United States”
5 before the period; and

6 (B) by adding at the end the following:
7 “The Secretary shall develop and publish a list
8 of device product codes required to comply with
9 this subsection, and update the list every 3
10 years, or in response to a public health emer-
11 gency.”;

12 (2) by redesignating subsections (h) and (i) as
13 subsections (j) and (k), respectively;

14 (3) by inserting after subsection (g) the fol-
15 lowing:

16 “(h) RISK MANAGEMENT PLANS.—Each manufac-
17 turer of a device that is included on the list described in
18 subsection (a), shall develop, maintain, and, as appro-
19 priate, implement a risk management plan that identifies
20 and evaluates risks to the supply of the device, as applica-
21 ble, for each establishment in which such device is manu-
22 factured. A risk management plan under this subsection—

23 “(1) may identify and evaluate risks to the sup-
24 ply of more than one device, or device category,
25 manufactured at the same establishment; and

1 “(2) shall be subject to inspection and copying
2 by the Secretary pursuant to section 704 or at the
3 request of the Secretary.”;

4 (4) in subsection (f), by inserting “or (i)” after
5 “subsection (a)”; and

6 (5) by inserting after subsection (h), as added
7 by paragraph (3), the following:

8 “(i) **ADDITIONAL NOTIFICATIONS.**—The Secretary
9 may receive voluntary notifications from a manufacturer
10 of a device that is life-supporting, life-sustaining, or in-
11 tended for use in emergency medical care or during sur-
12 gery, or any other device the Secretary determines to be
13 critical to the public health, pertaining to a permanent dis-
14 continuance in the manufacture of the device (except for
15 any discontinuance as a result of an approved modification
16 of the device) or an interruption of the manufacture of
17 the device that is likely to lead to a meaningful disruption
18 in the supply of that device in the United States, and the
19 reasons for such discontinuance or interruption.”; and

20 (6) in subsection (j) (as so redesignated by
21 paragraph (2))—

22 (A) by striking “shall be construed to af-
23 fect” and inserting the following: “shall be con-
24 strued—

25 “(1) to affect”;

1 (B) by striking the period at the end and
2 inserting “; or”; and

3 (C) by adding at the end the following:

4 “(2) to grant the Secretary the authority to—

5 “(A) require specific design, management,
6 implementation, or updating of risk manage-
7 ment plans;

8 “(B) assess performance or compliance
9 with a risk management plan, under subsection
10 (h); or

11 “(C) require notification under subsection
12 (i).”.

13 (b) REPORT.—Not later than 2 years after the date
14 of enactment of this Act, and annually thereafter, the Sec-
15 retary of Health and Human Services shall prepare and
16 submit to the Committee on Health, Education, Labor,
17 and Pensions of the Senate and the Committee on Energy
18 and Commerce of the House of Representatives a report
19 on the use of information manufacturers submit pursuant
20 to section 506J of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 356j) and applicable guidance issued with
22 respect to such section, and any actions taken by the Sec-
23 retary to mitigate or prevent a device shortage.

24 (c) GUIDANCE ON VOLUNTARY NOTIFICATIONS OF
25 DISCONTINUANCE OR INTERRUPTION OF DEVICE MANU-

1 FACTURE.—Not later than 1 year after the date of enact-
2 ment of this Act, the Secretary shall issue draft guidance
3 to facilitate voluntary notifications under subsection (i) of
4 section 506J of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 356j), as added by subsection (a). Such
6 guidance shall include a description of circumstances in
7 which a voluntary notification under such subsection (i)
8 may be appropriate, recommended timeframes within
9 which sponsors may submit such a notification, the proc-
10 ess for receiving such notifications, and actions the Sec-
11 retary may take to mitigate or prevent a shortage result-
12 ing from a discontinuance or interruption in the manufac-
13 ture of a device for which such notification is received.
14 The Secretary shall issue final guidance not later than 1
15 year after the close of the comment period for the draft
16 guidance.

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