

117TH CONGRESS
2D SESSION

S. 3477

To improve the program for reporting on device shortages.

IN THE SENATE OF THE UNITED STATES

JANUARY 11 (legislative day, JANUARY 10), 2022

Mr. CASEY (for himself and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To improve the program for reporting on device shortages.

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 “Planning, Reporting,
5 and Enabling Voluntary Expansion of Notifications Tar-
6 geting Medical Device Shortages Act of 2022” or the
7 “PREVENT Medical Device Shortages Act of 2022”.

8 **SEC. 2. PREVENTING MEDICAL DEVICE SHORTAGES.**

9 (a) NOTIFICATIONS.—

1 (1) IN GENERAL.—Section 506J of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 356j) is
3 amended—

4 (A) in the flush text at the end of sub-
5 section (a), by inserting “or of any other cir-
6 cumstance that is likely to lead to a meaningful
7 disruption in the supply of the device or a
8 shortage of the device and other devices that
9 could reasonably be substituted for that device
10 in the United States” before the period;

11 (B) in subsection (f), by inserting “or (h)”
12 after “subsection (a)”;

13 (C) by redesignating subsections (h) and
14 (i) as subsections (j) and (k), respectively; and

15 (D) by inserting after subsection (g) the
16 following:

17 “(h) ADDITIONAL NOTIFICATIONS.—The Secretary
18 may receive notifications from a manufacturer of a device
19 that is life-supporting, life-sustaining, or intended for use
20 in emergency medical care or during surgery, or any other
21 device the Secretary determines to be critical to the public
22 health, pertaining to a permanent discontinuance in the
23 manufacture of the device (except for any discontinuance
24 as a result of an approved modification of the device) or
25 an interruption of the manufacture of the device that is

1 likely to lead to a meaningful disruption in the supply of
2 that device in the United States, and the reasons for such
3 discontinuance or interruption.

4 “(i) RISK MANAGEMENT PLANS.—Each manufac-
5 turer of a device that is critical to the public health, in-
6 cluding devices that are life-supporting, life-sustaining, or
7 intended for use in emergency medical care or during sur-
8 gery, shall develop, maintain, and, as appropriate, imple-
9 ment a redundancy risk management plan that identifies
10 and evaluates risks to the supply of the device, as applica-
11 ble, for each establishment in which such device is manu-
12 factured. A risk management plan under this subsection—

13 “(1) may identify and evaluate risks to the sup-
14 ply of more than 1 device manufactured at the same
15 establishment; and

16 “(2) shall be subject to inspection and copying,
17 both remotely and physically, by the Secretary pur-
18 suant to section 704 or at the request of the Sec-
19 retary.”.

20 (2) REPORT.—Not later than 1 year after the
21 date of enactment of this Act, and annually for 4
22 years thereafter, the Secretary of Health and
23 Human Services (referred to in this section as the
24 “Secretary”) shall prepare and submit to the Com-
25 mittee on Health, Education, Labor, and Pensions

1 of the Senate and the Committee on Energy and
2 Commerce of the House of Representatives a report
3 on the use of information manufacturers submit pur-
4 suant to section 506J of the Federal Food, Drug,
5 and Cosmetic Act (21 U.S.C. 356j) or applicable
6 guidance.

7 (3) GUIDANCE ON VOLUNTARY NOTIFICATIONS
8 OF DISCONTINUANCE OR INTERRUPTION OF DEVICE
9 MANUFACTURE.—Not later than 1 year after the
10 date of enactment of this Act, the Secretary shall
11 issue draft guidance to facilitate voluntary notifica-
12 tions under subsection (h) of section 506J of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 356j), as added by paragraph (1). Such guidance
15 shall include a description of circumstances in which
16 a voluntary notification under such subsection (h)
17 may be appropriate, recommended timeframes within
18 which sponsors should submit such a notification,
19 the process for receiving such notifications, and ac-
20 tions the Secretary may take to mitigate or prevent
21 a shortage resulting from a discontinuance or inter-
22 ruption in the manufacture of a device for which
23 such notification is received. The Secretary shall

- 1 issue final guidance not later than 1 year after the
- 2 close of the comment period for the draft guidance.

