II

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, Education, Labor, and Pensions

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A BILL

To strengthen medical device supply chains.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. STRENGTHENING MEDICAL DEVICE SUPPLY CHAINS.

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

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

(A) by inserting ''or of any other circumstance that is likely to lead to a meaningful

disruption in the supply of the device or a shortage of the device, and there is no other available device that could reasonably be substituted for that device in the United States'' before the period; and

(B) by adding at the end the following: ''The Secretary shall develop and publish a list of device product codes required to comply with this subsection, and update the list every 3 years, or in response to a public health emergency.'';

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

(3) by inserting after subsection (g) the following:

''(h) RISK MANAGEMENT PLANS.—Each manufacturer of a device that is included on the list described in subsection (a), shall develop, maintain, and, as appropriate, implement a risk management plan that identifies and evaluates risks to the supply of the device, as applicable, for each establishment in which such device is manufactured. A risk management plan under this subsection—

''(1) may identify and evaluate risks to the supply of more than one device, or device category, manufactured at the same establishment; and

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

(4) in subsection (f), by inserting ''or (i)'' after ''subsection (a)''; and

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

''(i) ADDITIONAL NOTIFICATIONS.—The Secretary may receive voluntary notifications from a manufacturer of a device that is life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery, or any other device the Secretary determines to be critical to the public health, pertaining to a permanent discontinuance in the manufacture of the device (except for any discontinuance as a result of an approved modification of the device) or an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in the supply of that device in the United States, and the reasons for such discontinuance or interruption.''; and

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

(A) by striking ''shall be construed to affect'' and inserting the following: ''shall be construed—

''(1) to affect'';

(B) by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(2) to grant the Secretary the authority to—

''(A) require specific design, management, implementation, or updating of risk management plans;

''(B) assess performance or compliance with a risk management plan, under subsection (h); or

''(C) require notification under subsection (i).''.

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

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

FACTURE.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue draft guidance to facilitate voluntary notifications under subsection (i) of section 506J of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356j), as added by subsection (a). Such guidance shall include a description of circumstances in which a voluntary notification under such subsection (i) may be appropriate, recommended timeframes within which sponsors may submit such a notification, the process for receiving such notifications, and actions the Secretary may take to mitigate or prevent a shortage resulting from a discontinuance or interruption in the manufacture of a device for which such notification is received. The Secretary shall issue final guidance not later than 1 year after the close of the comment period for the draft guidance.

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