116TH CONGRESS
2D SESSION

S. 3468

To require the manufacturers of certain essential medical devices to notify the Food and Drug Administration when such manufacturers become aware of a circumstance that could lead to a shortage of such devices, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 12, 2020

Mrs. LOEFFLER (for herself and Mr. CASEY) 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 require the manufacturers of certain essential medical devices to notify the Food and Drug Administration when such manufacturers become aware of a circumstance that could lead to a shortage of such devices, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Preventing Essential Medical Device Shortages Act of 2020''.

SEC. 2. DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF ESSENTIAL MEDICAL DEVICES.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506I the following:

"SEC. 506J. DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF ESSENTIAL MEDICAL DEVICES.

''(a) IN GENERAL.—The manufacturer of an essential device shall notify the Secretary, in accordance with subsection (b), of a permanent discontinuance in the manufacture of the essential device or an interruption of the manufacture of the essential 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.

''(b) TIMING.—A notice required under subsection (a) shall be submitted to the Secretary—

''(1) at least 6 months prior to the date of the discontinuance or interruption; or

''(2) if compliance with paragraph (1) is not possible, as soon as practicable.

''(c) DISTRIBUTION.—

''(1) PUBLIC AVAILABILITY.—To the maximum extent practicable, subject to paragraph (2), the Secretary shall distribute, through such means as the

Secretary determines appropriate, information on the discontinuance or interruption of the manufacture of essential devices reported under subsection (a) to appropriate organizations, including physician, health provider, and patient organizations, as appropriate and applicable.

''(2) PUBLIC HEALTH EXCEPTION.—The Secretary may choose not to make information collected under this section publicly available pursuant to this section if the Secretary determines that disclosure of such information would adversely affect the public health, such as by increasing the possibility of hoarding or other disruption of the availability of drug products to patients.

''(d) CONFIDENTIALITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

''(e) FAILURE TO MEET REQUIREMENTS.—If a person fails to submit information required under subsection (a) in accordance with subsection (b)—

''(1) the Secretary shall issue a letter to such person informing such person of such failure;

''(2) not later than 30 calendar days after the issuance of a letter under paragraph (1), the person who receives such letter shall submit to the Secretary a written response to such letter setting forth the basis for noncompliance and providing information required under subsection (a); and

''(3) not later than 45 calendar days after the issuance of a letter under paragraph (1), the Secretary shall make such letter and any response to such letter under paragraph (2) available to the public on the internet website of the Food and Drug Administration, with appropriate redactions made to protect information described in subsection (d), except that, if the Secretary determines that the letter under paragraph (1) was issued in error or, after review of such response, the person had a reasonable basis for not notifying as required under subsection (a), the requirements of this paragraph shall not apply.

''(f) EXPEDITED INSPECTIONS AND REVIEWS.—If, based on notifications described in subsection (a) or any other relevant information, the Secretary concludes that there is, or is likely to be, a shortage of an essential device, the Secretary may—

''(1) expedite the review of an application for premarket review under section 515 or review of a notification under section 510(k) for a device that could help mitigate or prevent such shortage; or

''(2) expedite an inspection or reinspection of an establishment that could help mitigate or prevent such shortage.

''(g) DEFINITIONS.—

''(1) ESSENTIAL DEVICE.—

''(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Preventing Essential Medical Device Shortages Act of 2020, the Secretary shall, for the purposes of this section, promulgate a notice of proposed rulemaking defining the term 'essential device' and shall, not later than 1 year after such date of enactment, promulgate final regulations defining such term.

''(B) ESSENTIAL DEVICES DURING PUBLIC HEALTH EMERGENCIES.—Upon declaration by the Secretary of a public health emergency under section 319 of the Public Health Service Act, the Secretary shall issue a list of devices deemed essential devices for the purpose of en-

suring the public health and safety for the duration of the declared public health emergency.

''(2) OTHER DEFINITIONS.—In this section—

''(A) the term 'meaningful disruption'—

''(i) means a change in production that is reasonably likely to lead to a reduction in the supply of an essential device by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product; and

''(ii) does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time; and

''(B) the term 'shortage', with respect to an essential device, means a period of time when the demand or projected demand for the device within the United States exceeds the supply of the device.

''(h) ANNUAL REPORT.—The Secretary shall publish a public list, updated annually, of medical devices—

''(1) approved under section 515, cleared under section 510(k), or for which an exemption is granted under subsection (l) or (m) of section 510; and

''(2) meeting the definition of 'essential device' as described in subsection (g)(1).''.

SEC. 3. DRUG AND ESSENTIAL DEVICE SHORTAGE LIST.

Section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e) is amended—

(1) in the heading, by inserting ''**AND ESSENTIAL DEVICE**'' after ''**DRUG**'';

(2) in subsection (a), by inserting ''and essential devices (as such term is defined pursuant to section 506J(g)(1))'' after ''drugs'';

(3) in subsection (b)—

(A) in the matter preceding paragraph (1), by inserting ''and each essential device'' after ''drug'';

(B) by amending paragraph (1) to read as follows:

''(1) The name of the drug or essential device in shortage, including, with respect to a drug, the National Drug Code number, or, with respect to an essential device, the unique device identifier or national product code, if applicable.''; and

(C) in paragraph (3)—

(i) by amending subparagraph (E) to read as follows:

''(E) Discontinuance of the manufacture of the drug or essential device.''; and

(ii) in each of subparagraphs (F) and (G), by inserting ''or essential device'' before the period; and

(4) in subsection (c)(3)—

(A) by striking ''or section 506C(c)'' and inserting '', section 506C(c), or section 506J(c)''; and

(B) by inserting ''or essential devices'' after ''drug products''.

SEC. 4. GAO REPORT ON INTRA-AGENCY COORDINATION.

(a) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall 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 examining the Food and Drug Administration's intra-agency coordination, communication, and decision making in assessing device shortages and risks associated with the supply of essential devices, and any efforts by the Food and Drug Administration to

mitigate any essential device shortages or to take corrective actions.

(b) CONTENT.—The report shall include—

(1) consideration of—

(A) risks associated with violations of current good manufacturing practices;

(B) corrective and preventative actions with respect to such violations requested by the Food and Drug Administration;

(C) the effects of potential manufacturing disruptions or shut-downs on potential essential device shortages, including the discontinuance of essential device manufacturing and marketing;

(D) efforts to prioritize review of applications for essential devices that the Secretary has determined under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e) to be in shortage; and

(E) efforts to prioritize inspections of facilities necessary for approval or clearance of essential devices described in subparagraph (D);

(2) a description of how the Food and Drug Administration proactively coordinates strategies to mitigate the consequences of the violations, slow-

downs, and shut-downs described in paragraph (1) across agencies; and

(3) an evaluation of changes in relevant Food and Drug Administration practices that such agency has proposed but not yet implemented.

(c) DEFINITION.—In this section, the term ''essential device'' has the meaning given such term under section 506J(g)(1) of the Federal Food, Drug, and Cosmetic Act, as added by section 2.

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