

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.

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## 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.

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 “Preventing Essential  
5       Medical Device Shortages Act of 2020”.

1 **SEC. 2. DISCONTINUANCE OR INTERRUPTION IN THE PRO-**  
2 **DUCTION OF ESSENTIAL MEDICAL DEVICES.**

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

6 **“SEC. 506J. DISCONTINUANCE OR INTERRUPTION IN THE**  
7 **PRODUCTION OF ESSENTIAL MEDICAL DE-**  
8 **VICES.**

9 “(a) **IN GENERAL.**—The manufacturer of an essen-  
10 tial device shall notify the Secretary, in accordance with  
11 subsection (b), of a permanent discontinuance in the man-  
12 ufacture of the essential device or an interruption of the  
13 manufacture of the essential device that is likely to lead  
14 to a meaningful disruption in the supply of that device  
15 in the United States, and the reasons for such discontinu-  
16 ance or interruption.

17 “(b) **TIMING.**—A notice required under subsection (a)  
18 shall be submitted to the Secretary—

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

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

23 “(c) **DISTRIBUTION.**—

24 “(1) **PUBLIC AVAILABILITY.**—To the maximum  
25 extent practicable, subject to paragraph (2), the Sec-  
26 retary shall distribute, through such means as the

1 Secretary determines appropriate, information on  
2 the discontinuance or interruption of the manufac-  
3 ture of essential devices reported under subsection  
4 (a) to appropriate organizations, including physician,  
5 health provider, and patient organizations, as appro-  
6 priate and applicable.

7 “(2) PUBLIC HEALTH EXCEPTION.—The Sec-  
8 retary may choose not to make information collected  
9 under this section publicly available pursuant to this  
10 section if the Secretary determines that disclosure of  
11 such information would adversely affect the public  
12 health, such as by increasing the possibility of  
13 hoarding or other disruption of the availability of  
14 drug products to patients.

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

21 “(e) FAILURE TO MEET REQUIREMENTS.—If a per-  
22 son fails to submit information required under subsection  
23 (a) in accordance with subsection (b)—

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

1           “(2) not later than 30 calendar days after the  
2           issuance of a letter under paragraph (1), the person  
3           who receives such letter shall submit to the Sec-  
4           retary a written response to such letter setting forth  
5           the basis for noncompliance and providing informa-  
6           tion required under subsection (a); and

7           “(3) not later than 45 calendar days after the  
8           issuance of a letter under paragraph (1), the Sec-  
9           retary shall make such letter and any response to  
10          such letter under paragraph (2) available to the pub-  
11          lic on the internet website of the Food and Drug Ad-  
12          ministration, with appropriate redactions made to  
13          protect information described in subsection (d), ex-  
14          cept that, if the Secretary determines that the letter  
15          under paragraph (1) was issued in error or, after re-  
16          view of such response, the person had a reasonable  
17          basis for not notifying as required under subsection  
18          (a), the requirements of this paragraph shall not  
19          apply.

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

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

5           “(2) expedite an inspection or reinspection of  
6 an establishment that could help mitigate or prevent  
7 such shortage.

8           “(g) DEFINITIONS.—

9           “(1) ESSENTIAL DEVICE.—

10           “(A) IN GENERAL.—Not later than 180  
11 days after the date of enactment of the Pre-  
12 venting Essential Medical Device Shortages Act  
13 of 2020, the Secretary shall, for the purposes of  
14 this section, promulgate a notice of proposed  
15 rulemaking defining the term ‘essential device’  
16 and shall, not later than 1 year after such date  
17 of enactment, promulgate final regulations de-  
18 fining such term.

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

1           suring the public health and safety for the du-  
2           ration of the declared public health emergency.

3           “(2) OTHER DEFINITIONS.—In this section—

4                   “(A) the term ‘meaningful disruption’—

5                           “(i) means a change in production  
6                           that is reasonably likely to lead to a reduc-  
7                           tion in the supply of an essential device by  
8                           a manufacturer that is more than neg-  
9                           ligible and affects the ability of the manu-  
10                          facturer to fill orders or meet expected de-  
11                          mand for its product; and

12                          “(ii) does not include interruptions in  
13                          manufacturing due to matters such as rou-  
14                          tine maintenance or insignificant changes  
15                          in manufacturing so long as the manufac-  
16                          turer expects to resume operations in a  
17                          short period of time; and

18                          “(B) the term ‘shortage’, with respect to  
19                          an essential device, means a period of time  
20                          when the demand or projected demand for the  
21                          device within the United States exceeds the  
22                          supply of the device.

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

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

4           “(2) meeting the definition of ‘essential device’  
5           as described in subsection (g)(1).”.

6 **SEC. 3. DRUG AND ESSENTIAL DEVICE SHORTAGE LIST.**

7           Section 506E of the Federal Food, Drug, and Cos-  
8           metic Act (21 U.S.C. 356e) is amended—

9           (1) in the heading, by inserting “**AND ESSEN-**  
10           **TIAL DEVICE**” after “**DRUG**”;

11           (2) in subsection (a), by inserting “and essen-  
12           tial devices (as such term is defined pursuant to sec-  
13           tion 506J(g)(1))” after “drugs”;

14           (3) in subsection (b)—

15           (A) in the matter preceding paragraph (1),  
16           by inserting “and each essential device” after  
17           “drug”;

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

20           “(1) The name of the drug or essential device  
21           in shortage, including, with respect to a drug, the  
22           National Drug Code number, or, with respect to an  
23           essential device, the unique device identifier or na-  
24           tional product code, if applicable.”; and

25           (C) in paragraph (3)—

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

3 “(E) Discontinuance of the manufacture of  
4 the drug or essential device.”; and

5 (ii) in each of subparagraphs (F) and  
6 (G), by inserting “or essential device” be-  
7 fore the period; and

8 (4) in subsection (c)(3)—

9 (A) by striking “or section 506C(c)” and  
10 inserting “, section 506C(c), or section  
11 506J(c)”; and

12 (B) by inserting “or essential devices”  
13 after “drug products”.

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

15 (a) IN GENERAL.—Not later than 18 months after  
16 the date of enactment of this Act, the Comptroller General  
17 of the United States shall submit to the Committee on  
18 Health, Education, Labor, and Pensions of the Senate and  
19 the Committee on Energy and Commerce of the House  
20 of Representatives a report examining the Food and Drug  
21 Administration’s intra-agency coordination, communica-  
22 tion, and decision making in assessing device shortages  
23 and risks associated with the supply of essential devices,  
24 and any efforts by the Food and Drug Administration to

1 mitigate any essential device shortages or to take correc-  
2 tive actions.

3 (b) CONTENT.—The report shall include—

4 (1) consideration of—

5 (A) risks associated with violations of cur-  
6 rent good manufacturing practices;

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

10 (C) the effects of potential manufacturing  
11 disruptions or shut-downs on potential essential  
12 device shortages, including the discontinuance  
13 of essential device manufacturing and mar-  
14 keting;

15 (D) efforts to prioritize review of applica-  
16 tions for essential devices that the Secretary  
17 has determined under section 506E of the Fed-  
18 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
19 356e) to be in shortage; and

20 (E) efforts to prioritize inspections of fa-  
21 cilities necessary for approval or clearance of  
22 essential devices described in subparagraph (D);

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

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

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

6       (c) DEFINITION.—In this section, the term “essential  
7       device” has the meaning given such term under section  
8       506J(g)(1) of the Federal Food, Drug, and Cosmetic Act,  
9       as added by section 2.

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