

118TH CONGRESS  
1ST SESSION

# S. 2362

To amend the Federal Food, Drug, and Cosmetic Act to provide for notification by manufacturers of critical drugs of increased demand, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

JULY 18, 2023

Ms. KLOBUCHAR (for herself, Ms. COLLINS, Ms. SMITH, Ms. MURKOWSKI, and Ms. WARREN) 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 amend the Federal Food, Drug, and Cosmetic Act to provide for notification by manufacturers of critical drugs of increased demand, 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 “Drug Shortage Preven-  
5 tion Act of 2023”.

1 **SEC. 2. IMPROVING NOTIFICATION PROCEDURES IN CASE**  
2 **OF INCREASED DEMAND FOR CRITICAL**  
3 **DRUGS.**

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

7 (1) in the section heading, by striking “**DIS-**  
8 **CONTINUANCE OR INTERRUPTION IN THE PRO-**  
9 **DUCTION OF LIFE-SAVING DRUGS**” and inserting  
10 **“NOTIFICATION OF ISSUES AFFECTING DOMES-**  
11 **TIC SUPPLY OF CRITICAL DRUGS”**;

12 (2) by striking subsections (a), (b), and (c), and  
13 inserting the following:

14 “(a) NOTIFICATION REQUIRED.—

15 “(1) IN GENERAL.—A manufacturer of a cov-  
16 ered drug shall notify the Secretary, in accordance  
17 with subsection (b), of—

18 “(A)(i) a permanent discontinuance in the  
19 manufacture of the drug or an interruption of  
20 the manufacture of the drug that is likely to  
21 lead to a meaningful disruption in the supply of  
22 such drug in the United States;

23 “(ii) a permanent discontinuance in the  
24 manufacture of an active pharmaceutical ingre-  
25 dient of such drug, or an interruption in the  
26 manufacture of an active pharmaceutical ingre-

1           dient of such drug that is likely to lead to a  
2           meaningful disruption in the supply of the ac-  
3           tive pharmaceutical ingredient of such drug; or

4           “(iii) any other circumstance, such as an  
5           increase in demand or export restriction, that is  
6           likely to leave the manufacturer unable to meet  
7           demand for the drug without a meaningful  
8           shortfall or delay; and

9           “(B) the reasons for such discontinuance,  
10          interruption, or other circumstance, if known.

11          “(2) CONTENTS.—Notification under this sub-  
12          section with respect to a covered drug shall in-  
13          clude—

14                 “(A) with respect to the reasons for the  
15                 discontinuation, interruption, or other cir-  
16                 cumstance described in paragraph (1)(A)(iii), if  
17                 an active pharmaceutical ingredient is a reason  
18                 for, or risk factor in, such discontinuation,  
19                 interruption, or other circumstance, the source  
20                 of the active pharmaceutical ingredient and any  
21                 alternative sources for the active pharma-  
22                 ceutical ingredient known to the manufacturer;

23                 “(B) whether any associated device used  
24                 for preparation or administration included in  
25                 the drug is a reason for, or a risk factor in,

1 such discontinuation, interruption, or other cir-  
2 cumstance described in paragraph (1)(A)(iii);

3 “(C) the expected duration of the interrup-  
4 tion; and

5 “(D) such other information as the Sec-  
6 retary may require.

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

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

11 “(2) in the case of such a notice with respect  
12 to a circumstance described in subsection  
13 (a)(1)(A)(iii), as soon as practicable, or not later  
14 than 10 business days after the onset of the cir-  
15 cumstance; or

16 “(3) if compliance with paragraph (1) or (2) is  
17 not possible, as soon as practicable.

18 “(c) DISTRIBUTION.—To the maximum extent prac-  
19 ticable, the Secretary shall distribute, through such means  
20 as the Secretary determines appropriate, information on  
21 the discontinuance or interruption of the manufacture of,  
22 or other circumstance described in subsection  
23 (a)(1)(A)(iii) that is likely to lead to a shortage or mean-  
24 ingful disruption in the supply of, covered drugs to appro-

1 priate organizations, including physician, health provider,  
2 and patient organizations, as described in section 506E.”;

3 (3) in subsection (g), in the matter preceding  
4 paragraph (1), by striking “drug described in sub-  
5 section (a)” and inserting “covered drug”; and

6 (4) in subsection (j), by striking “drug de-  
7 scribed in subsection (a)” and inserting “covered  
8 drug”.

9 (b) DEFINITIONS.—Paragraph (1) of section 506C(h)  
10 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
11 356c(h)) is amended to read as follows:

12 “(1) the term ‘covered drug’ means a drug that  
13 is intended for human use and that—

14 “(A) is—

15 “(i) life-supporting;

16 “(ii) life-sustaining; or

17 “(iii) intended for use in the preven-  
18 tion or treatment of a debilitating disease  
19 or condition, including any such drug used  
20 in emergency medical care or during sur-  
21 gery or any such drug that is critical to  
22 the public health during a public health  
23 emergency declared by the Secretary under  
24 section 319 of the Public Health Service  
25 Act;

1           “(B) is not a radio pharmaceutical drug  
2           product or any other product as designated by  
3           the Secretary; and

4           “(C) is not a biological product (as defined  
5           in section 351(i) of the Public Health Service  
6           Act), unless otherwise provided by the Secretary  
7           in the regulations promulgated under subsection  
8           (i);”.

9   **SEC. 3. REPORTING ON SUPPLY CHAINS.**

10          Section 510(j)(3)(A) of the Federal Food, Drug, and  
11   Cosmetic Act (21 U.S.C. 360(j)(3)(A)) is amended—

12           (1) by striking “annually to the Secretary” in  
13           the first sentence and inserting “to the Secretary,  
14           once during the month of March each year and once  
15           during the month of September each year,”;

16           (2) by inserting “, and the legal names of, and  
17           any additional information the Secretary may re-  
18           quire, regarding suppliers of active pharmaceutical  
19           ingredients and intermediate and in-process mate-  
20           rials such person used for the manufacture, prepara-  
21           tion, propagation, compounding, or processing of  
22           such drug, and the amount of such drug manufac-  
23           tured, prepared, propagated, compounded, or proc-  
24           essed using each such active pharmaceutical ingre-  
25           dient or intermediate or in-process material sourced

1 from each such supplier” before the period at the  
2 end of the first sentence; and

3 (3) by inserting after the first sentence the fol-  
4 lowing: “In addition to the reporting required under  
5 the preceding sentence, each person who registers  
6 with the Secretary under this section with regard to  
7 a drug may voluntarily report on the information de-  
8 scribed in the preceding sentence, at such other  
9 times as the Secretary may specify.”.

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