

112TH CONGRESS
1ST SESSION

S. 296

To amend the Federal Food, Drug, and Cosmetic Act to provide the Food and Drug Administration with improved capacity to prevent drug shortages.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 7, 2011

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide the Food and Drug Administration with improved capacity to prevent drug 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 “Preserving Access to
5 Life-Saving Medications Act”.

6 **SEC. 2. DRUG SHORTAGES.**

7 (a) EXPANSION OF NOTIFICATION REQUIREMENT
8 REGARDING POTENTIAL SHORTAGES OF PRESCRIPTION

1 DRUGS.—Section 506C of the Federal Food, Drug, and
 2 Cosmetic Act (21 U.S.C. 356c) is amended—

3 (1) in the section heading, by striking “**DIS-**
 4 **CONTINUANCE OF A LIFE SAVING PRODUCT**”
 5 and inserting “**DISCONTINUANCE OR INTERRUPT-**
 6 **TION OF THE MANUFACTURE OF A PRESCRIP-**
 7 **TION DRUG**”; and

8 (2) by amending subsection (a) to read as fol-
 9 lows:

10 “(a) IN GENERAL.—

11 “(1) DEFINITION.—In this section, the terms
 12 ‘drug shortage’ and ‘shortage’, when used with re-
 13 spect to a drug, mean a period of time when the
 14 total supply of all versions of a drug available at the
 15 user level will not meet the current demand for the
 16 drug at the user level.

17 “(2) NOTIFICATION.—A manufacturer of a
 18 drug described in paragraph (3) shall notify the Sec-
 19 retary of a discontinuance, interruption, or other ad-
 20 justment of the manufacture of the drug that would
 21 likely result in a shortage of such drug—

22 “(A) in the case of a discontinuance or
 23 planned interruption or adjustment, at least 6
 24 months prior to the date of such discontinuance
 25 or planned interruption or adjustment; and

1 “(B) in the case of any other interruption
2 or adjustment, as soon as practicable after be-
3 coming aware of such interruption or adjust-
4 ment.

5 “(3) DRUGS DESCRIBED.—A drug described in
6 this paragraph is a drug—

7 “(A) for which an application has been ap-
8 proved under section 505(b) or 505(j);

9 “(B) that is described in section 503(b)(1);
10 and

11 “(C) that is not a product that was origi-
12 nally derived from human tissue and was re-
13 placed by a recombinant product.

14 “(4) TYPES OF ADJUSTMENTS.—An adjustment
15 for which a manufacturer shall submit a notification
16 under paragraph (2) includes—

17 “(A) adjustments related to the supply of
18 raw materials, including active pharmaceutical
19 ingredients;

20 “(B) adjustments to production capabili-
21 ties;

22 “(C) business decisions that may affect the
23 manufacture of the drug, such as mergers,
24 discontinuations, and a change in production
25 output; and

1 “(D) other adjustments as determined ap-
 2 propriate by the Secretary.

3 “(5) MODIFICATION OF TIME FRAMES.—The
 4 Secretary may adjust the required time frame under
 5 paragraph (2) as determined appropriate by the Sec-
 6 retary based on—

7 “(A) the type of interruption or adjust-
 8 ment at issue; and

9 “(B) any other factor, as determined by
 10 the Secretary.

11 “(6) ENFORCEMENT.—Not later than 180 days
 12 after the date of enactment of this section, the Sec-
 13 retary shall promulgate regulations establishing a
 14 schedule of civil monetary penalties for failure to
 15 submit a notification as required under this sub-
 16 section.”.

17 (b) CONFIDENTIALITY OF INFORMATION.—Section
 18 506C(c) of the Federal Food, Drug, and Cosmetic Act (21
 19 U.S.C. 356c(c)) is amended to read as follows:

20 “(c) CONFIDENTIALITY OF INFORMATION.—The Sec-
 21 retary shall ensure the confidentiality of proprietary infor-
 22 mation submitted in a notification under subsection (a).”.

23 (c) PUBLIC NOTIFICATION.—Section 506C of the
 24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c)
 25 is amended by adding at the end the following:

1 “(d) PUBLIC NOTIFICATION.—

2 “(1) NOTIFICATION OF SHORTAGES.—The Sec-
3 retary shall publish information on the types of ad-
4 justments for which a notification is required under
5 subsection (a)(4) and on actual drug shortages on
6 the Internet Web site of the Food and Drug Admin-
7 istration and, to the maximum extent practicable,
8 distribute such information to appropriate health
9 care provider and patient organizations.

10 “(2) IDENTIFICATION AND NOTIFICATION OF
11 DRUGS VULNERABLE TO DRUG SHORTAGE.—

12 “(A) IN GENERAL.—The Secretary shall
13 implement evidence-based criteria for identi-
14 fying drugs that may be vulnerable to a drug
15 shortage. Such criteria shall be based on—

16 “(i) the number of manufacturers of
17 the drug;

18 “(ii) the sources of raw material or
19 active pharmaceutical ingredients;

20 “(iii) the supply chain characteristics,
21 such as production complexities; and

22 “(iv) the availability of therapeutic al-
23 ternatives.

24 “(B) NOTIFICATION.—If the Secretary de-
25 termines using the criteria under subparagraph

1 (A) that a drug may be vulnerable to a drug
 2 shortage, the Secretary shall notify the manu-
 3 facturer of the drug of such determination and
 4 of the collaboration described under paragraph
 5 (3).

6 “(3) CONTINUITY OF OPERATIONS PLANS.—

7 The Secretary shall collaborate with manufacturers
 8 of drugs identified pursuant to paragraph (2) to es-
 9 tablish and improve continuity of operations plans
 10 with respect to medically necessary drugs, as defined
 11 by the Secretary, so that such plans include a proc-
 12 ess for addressing drug shortages.”.

13 **SEC. 3. MANUFACTURER REVIEW.**

14 Section 510(h) of the Federal Food, Drug, and Cos-
 15 metic Act (21 U.S.C. 360(h)) is amended—

16 (1) by striking “(h)” and inserting “(h)(1)”;
 17 and

18 (2) by inserting at the end the following:

19 “(2)(A) If an establishment registered with the Sec-
 20 retary pursuant to this section is subject to a reinspection
 21 due to failure to comply with a requirement of this Act,
 22 the Secretary shall conduct such reinspection not later
 23 than 90 days after the establishment certifies to the Sec-
 24 retary that the establishment has corrected the reason for
 25 such failure.

1 “(B) The Secretary shall prioritize reinspections de-
2 scribed in subparagraph (A) based on whether the estab-
3 lishment involved manufactures, propagates, compounds,
4 or processes a drug involved in a drug shortage (as defined
5 in section 506C).”.

6 **SEC. 4. REPORTS TO CONGRESS.**

7 Not later than 1 year after the date of enactment
8 of this Act, and on an annual basis thereafter, the Sec-
9 retary of Health and Human Services shall submit to Con-
10 gress a report that describes the actions taken by such
11 Secretary during the previous 1-year period to address
12 drug shortages through all aspects of the prescription
13 drug supply chain.

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