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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

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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.

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 ''Preserving Access to Life-Saving Medications Act''.

SEC. 2. DRUG SHORTAGES.

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

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

(1) in the section heading, by striking "**DISCONTINUANCE OF A LIFE SAVING PRODUCT**" and inserting "**DISCONTINUANCE OR INTERRUPTION OF THE MANUFACTURE OF A PRESCRIPTION DRUG**"; and

(2) by amending subsection (a) to read as follows:

"(a) IN GENERAL.—

"(1) DEFINITION.—In this section, the terms 'drug shortage' and 'shortage', when used with respect to a drug, mean a period of time when the total supply of all versions of a drug available at the user level will not meet the current demand for the drug at the user level.

"(2) NOTIFICATION.—A manufacturer of a drug described in paragraph (3) shall notify the Secretary of a discontinuance, interruption, or other adjustment of the manufacture of the drug that would likely result in a shortage of such drug—

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

"(B) in the case of any other interruption or adjustment, as soon as practicable after becoming aware of such interruption or adjustment.

"(3) DRUGS DESCRIBED.—A drug described in this paragraph is a drug—

"(A) for which an application has been approved under section 505(b) or 505(j);

"(B) that is described in section 503(b)(1); and

"(C) that is not a product that was originally derived from human tissue and was replaced by a recombinant product.

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

"(A) adjustments related to the supply of raw materials, including active pharmaceutical ingredients;

"(B) adjustments to production capabilities;

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

"(D) other adjustments as determined appropriate by the Secretary.

"(5) MODIFICATION OF TIME FRAMES.—The Secretary may adjust the required time frame under paragraph (2) as determined appropriate by the Secretary based on—

"(A) the type of interruption or adjustment at issue; and

"(B) any other factor, as determined by the Secretary.

"(6) ENFORCEMENT.—Not later than 180 days after the date of enactment of this section, the Secretary shall promulgate regulations establishing a schedule of civil monetary penalties for failure to submit a notification as required under this subsection.".

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

"(c) CONFIDENTIALITY OF INFORMATION.—The Secretary shall ensure the confidentiality of proprietary information submitted in a notification under subsection (a).".

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

"(d) PUBLIC NOTIFICATION.—

"(1) NOTIFICATION OF SHORTAGES.—The Secretary shall publish information on the types of adjustments for which a notification is required under subsection (a)(4) and on actual drug shortages on the Internet Web site of the Food and Drug Administration and, to the maximum extent practicable, distribute such information to appropriate health care provider and patient organizations.

"(2) IDENTIFICATION AND NOTIFICATION OF DRUGS VULNERABLE TO DRUG SHORTAGE.—

"(A) IN GENERAL.—The Secretary shall implement evidence-based criteria for identifying drugs that may be vulnerable to a drug shortage. Such criteria shall be based on—

"(i) the number of manufacturers of the drug;

"(ii) the sources of raw material or active pharmaceutical ingredients;

"(iii) the supply chain characteristics, such as production complexities; and

"(iv) the availability of therapeutic alternatives.

"(B) NOTIFICATION.—If the Secretary determines using the criteria under subparagraph

(A) that a drug may be vulnerable to a drug shortage, the Secretary shall notify the manufacturer of the drug of such determination and of the collaboration described under paragraph (3).

"(3) CONTINUITY OF OPERATIONS PLANS.—The Secretary shall collaborate with manufacturers of drugs identified pursuant to paragraph (2) to establish and improve continuity of operations plans with respect to medically necessary drugs, as defined by the Secretary, so that such plans include a process for addressing drug shortages.".

SEC. 3. MANUFACTURER REVIEW.

Section 510(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)) is amended—

(1) by striking "(h)" and inserting "(h)(1)"; and

(2) by inserting at the end the following:

"(2)(A) If an establishment registered with the Secretary pursuant to this section is subject to a reinspection due to failure to comply with a requirement of this Act, the Secretary shall conduct such reinspection not later than 90 days after the establishment certifies to the Secretary that the establishment has corrected the reason for such failure.

"(B) The Secretary shall prioritize reinspections described in subparagraph (A) based on whether the establishment involved manufactures, propagates, compounds, or processes a drug involved in a drug shortage (as defined in section 506C).".

SEC. 4. REPORTS TO CONGRESS.

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

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