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112TH CONGRESS
1ST SESSION

H. R. 2245

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 HOUSE OF REPRESENTATIVES

JUNE 21, 2011

Ms. DEGETTE (for herself and Mr. ROONEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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 of 2011''.

SEC. 2. DISCONTINUANCE OR INTERRUPTION OF THE MANUFACTURE OF A PRESCRIPTION DRUG.

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

"SEC. 506C. DISCONTINUANCE OR INTERRUPTION OF THE MANUFACTURE OF A PRESCRIPTION DRUG.

''(a) DEFINITIONS.—In this section:

''(1) The term 'average historic demand' means the individual manufacturer's average monthly volume of sales of the drug during the last calendar year.

''(2) The term 'discontinuance' means the permanent termination of the manufacture of a drug by an individual manufacturer.

''(3) The term 'interruption' means a change that—

''(A) may result in the total supply of a drug manufactured by the individual manufacturer not meeting average historic demand; and

''(B) consists of—

''(i) a change in the supply of one or more raw materials, including active pharmaceutical ingredients;

''(ii) an unplanned interruption in ability to produce the drug;

''(iii) a business decision affecting the manufacture of the drug, such as a merger or a change in production output; or

"(iv) any other type change that could have the result described in subparagraph (A), as determined by the Secretary.

"(b) NOTIFICATIONS BY MANUFACTURERS.—

"(1) IN GENERAL.—A manufacturer of a drug that is subject to section 503(b)(1) and marketed in interstate commerce shall notify the Secretary of a discontinuance or interruption in the manufacture of such drug.

"(2) NOTIFICATION PERIOD.—A notification pursuant to paragraph (1) shall be submitted to the Secretary—

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

"(B) in the case of any other discontinuance or interruption—

"(i) at least 6 months prior to the date of such discontinuance or interruption; or

"(ii) if the manufacturer cannot provide 6 months advance notice, as soon as practicable after the manufacturer—

"(I) becomes aware of such discontinuance; or

"(II) becomes aware that such interruption may result in the total supply of the drug manufactured by the individual manufacturer not meeting average historic demand.

"(3) ADDITIONAL INFORMATION.—A manufacturer may, but is not required to, include in a notification submitted pursuant to paragraph (1) information about an alternative source of the drug or the availability of a drug with the same active ingredient.

"(4) REDUCTION IN NOTIFICATION PERIOD.—The notification period required under paragraph (2) for a manufacturer may be reduced if the manufacturer certifies to the Secretary that good cause exists for the reduction, such as a situation in which—

"(A) a public health problem may result from continuation of the manufacturing for the 6-month period;

"(B) a biomaterials shortage prevents the continuation of the manufacturing for the 6-month period;

''(C) a liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period;

''(D) continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer;

''(E) the manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code; or

''(F) the manufacturer can continue the distribution of the drug involved for 6 months.

''(5) OTHER REDUCTIONS IN NOTIFICATION PERIOD.—The Secretary may reduce the notification period required under paragraph (2) based on—

''(A) the type of discontinuance or interruption at issue; and

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

''(6) CONFIDENTIALITY OF INFORMATION.—Any information provided to the Secretary under paragraph (1) shall be treated as trade secret or confidential information subject to section 552(b)(4) of title 5 and section 1905 of title 18.

''(7) ENFORCEMENT.—

"(A) Any manufacturer that knowingly fails to submit a notification in violation of paragraph (1) shall be subject to a civil money penalty not to exceed $10,000 for each day on which the violation continues, and not to exceed $1,800,000 for all such violations adjudicated in a single proceeding.

"(B) Not later than 180 days after the date of the enactment of the Preserving Access to Life-Saving Medications Act of 2011, the Secretary shall, subject to subparagraph (A), promulgate final regulations establishing a schedule of civil monetary penalties for violations of paragraph (1).

"(C) The provisions of paragraphs (5), (6), and (7) of section 303(f) shall apply with respect to a civil penalty under this paragraph to the same extent and in the same manner as such provisions apply with respect to a civil penalty under paragraph (1), (2), (3), (4), or (9) of section 303(f).

"(c) NOTIFICATIONS BY SECRETARY.—

"(1) DRUG SHORTAGE DEFINED.—In this section, the term 'drug shortage' means, with respect to a drug, a period of time when the total supply of

such drug available at the user level will not meet the demand for such drug at the user level as determined by the Secretary.

''(2) PUBLIC NOTIFICATION.—

''(A) IN GENERAL.—Subject to subsection (b)(6), the Secretary shall—

''(i) publish on the public Internet Web site of the Food and Drug Administration information on—

''(I) the types of discontinuances and interruptions for which a notification is required under subsection (b)(1); and

''(II) actual drug shortages; and

''(ii) to the maximum extent practicable, distribute such information to appropriate health care providers and patient organizations.

''(B) DURATION.—The Secretary shall include in any publication or distribution under subparagraph (A), when possible, an estimate of the expected duration of any discontinuance or interruption or actual drug shortage.

''(3) IDENTIFICATION AND NOTIFICATION OF DRUGS VULNERABLE TO DRUG SHORTAGE.—

''(A) IN GENERAL.—If the Secretary determines using the criteria under subparagraph (B) that a drug may be vulnerable to a drug shortage, the Secretary shall notify the manufacturer of the drug of—

''(i) such determination; and

''(ii) the Secretary's duty to collaborate to improve continuity of supply plans under paragraph (4).

''(B) EVIDENCE-BASED CRITERIA.—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.

''(4) CONTINUITY OF SUPPLY PLANS.—

''(A) IN GENERAL.—With respect to drugs that are vulnerable to a drug shortage (as de-

termined under paragraph (3)), the Secretary shall collaborate with manufacturers and other stakeholders (such as distributors and health care providers) to establish and improve continuity of supply plans, so that such plans include a process for addressing drug shortages.

''(B) LIMITATION ON SECRETARY'S AUTHORITY.—The Secretary may not in any case require a manufacturer—

''(i) to manufacture a drug in the event of a discontinuance or interruption; or

''(ii) to delay or alter a discontinuance or interruption.

''(C) ALLOCATION BY MANUFACTURER.—No provision of Federal law shall be construed to prohibit a manufacturer from, or penalize a manufacturer for, allocating distribution of its products in order to manage an actual or potential drug shortage.

''(d) RULEMAKING.—The Secretary shall carry out this section pursuant to regulations promulgated after providing notice and an opportunity for comment.''.

(b) APPLICABILITY; TRANSITIONAL PERIOD.—Section 506C of the Federal Food, Drug, and Cosmetic Act,

as amended by subsection (a), applies with respect to discontinuances, interruptions, and drug shortages (as such terms are used in such section 506C) that occur on or after the day that is 1 year after the date of the enactment of this Act. Until such day, the provisions of section 506C of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the enactment of this Act, shall continue to apply.

SEC. 3. REPORTS TO CONGRESS.

The Secretary of Health and Human Services shall submit to the Congress—

(1) not later than the date that is 1 year after the date of the enactment of this Act, a report describing the actions taken by the Secretary during the previous 1-year period to address drug shortages (as defined in section 506C of the Federal Food, Drug, and Cosmetic Act, as amended by section 2) through all aspects of the prescription drug supply chain; and

(2) every 5 years thereafter, a report describing such actions taken by the Secretary during the previous 5-year period.

SEC. 4. GAO STUDY.

(a) STUDY.—The Comptroller General of the United States shall conduct a study—

(1) to examine how the Food and Drug Administration identifies and responds to drug shortages (as defined in section 506C of the Federal Food, Drug, and Cosmetic Act, as amended by section 2);

(2) to examine the possible causes of such drug shortages, including manufacturing problems, breakdown in the supply chain delivery system, changes in the supply of raw materials, stockpiling at the wholesale or provider level, and restrictive regulatory requirements;

(3) to identify if there is adequate communication between industry, the Food and Drug Administration, distributors, and end users;

(4) to analyze the effects of the enactment of this Act on the ability of the Food and Drug Administration to identify and ameliorate such drug shortages; and

(5) to identify any additional measures that need to be taken to prevent or address such drug shortages.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit a report to the Congress on the results of the study under subsection (a).

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