

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

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 of 2011”.

6 **SEC. 2. DISCONTINUANCE OR INTERRUPTION OF THE MAN-**
7 **UFACTURE OF A PRESCRIPTION DRUG.**

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

1 **“SEC. 506C. DISCONTINUANCE OR INTERRUPTION OF THE**
2 **MANUFACTURE OF A PRESCRIPTION DRUG.**

3 “(a) DEFINITIONS.—In this section:

4 “(1) The term ‘average historic demand’ means
5 the individual manufacturer’s average monthly vol-
6 ume of sales of the drug during the last calendar
7 year.

8 “(2) The term ‘discontinuance’ means the per-
9 manent termination of the manufacture of a drug by
10 an individual manufacturer.

11 “(3) The term ‘interruption’ means a change
12 that—

13 “(A) may result in the total supply of a
14 drug manufactured by the individual manufac-
15 turer not meeting average historic demand; and

16 “(B) consists of—

17 “(i) a change in the supply of one or
18 more raw materials, including active phar-
19 maceutical ingredients;

20 “(ii) an unplanned interruption in
21 ability to produce the drug;

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

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

4 “(b) NOTIFICATIONS BY MANUFACTURERS.—

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

10 “(2) NOTIFICATION PERIOD.—A notification
11 pursuant to paragraph (1) shall be submitted to the
12 Secretary—

13 “(A) in the case of a planned discontinu-
14 ance, at least 6 months prior to the date of
15 such discontinuance; and

16 “(B) in the case of any other discontinu-
17 ance or interruption—

18 “(i) at least 6 months prior to the
19 date of such discontinuance or interrup-
20 tion; or

21 “(ii) if the manufacturer cannot pro-
22 vide 6 months advance notice, as soon as
23 practicable after the manufacturer—

24 “(I) becomes aware of such dis-
25 continuance; or

1 “(II) becomes aware that such
2 interruption may result in the total
3 supply of the drug manufactured by
4 the individual manufacturer not meet-
5 ing average historic demand.

6 “(3) ADDITIONAL INFORMATION.—A manufac-
7 turer may, but is not required to, include in a notifi-
8 cation submitted pursuant to paragraph (1) infor-
9 mation about an alternative source of the drug or
10 the availability of a drug with the same active ingre-
11 dient.

12 “(4) REDUCTION IN NOTIFICATION PERIOD.—
13 The notification period required under paragraph
14 (2) for a manufacturer may be reduced if the manu-
15 facturer certifies to the Secretary that good cause
16 exists for the reduction, such as a situation in
17 which—

18 “(A) a public health problem may result
19 from continuation of the manufacturing for the
20 6-month period;

21 “(B) a biomaterials shortage prevents the
22 continuation of the manufacturing for the 6-
23 month period;

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

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

7 “(E) the manufacturer has filed for bank-
8 ruptcy under chapter 7 or 11 of title 11, United
9 States Code; or

10 “(F) the manufacturer can continue the
11 distribution of the drug involved for 6 months.

12 “(5) OTHER REDUCTIONS IN NOTIFICATION PE-
13 RIOD.—The Secretary may reduce the notification
14 period required under paragraph (2) based on—

15 “(A) the type of discontinuance or inter-
16 ruption at issue; and

17 “(B) any other factor, as determined by
18 the Secretary.

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

24 “(7) ENFORCEMENT.—

1 “(A) Any manufacturer that knowingly
2 fails to submit a notification in violation of
3 paragraph (1) shall be subject to a civil money
4 penalty not to exceed \$10,000 for each day on
5 which the violation continues, and not to exceed
6 \$1,800,000 for all such violations adjudicated
7 in a single proceeding.

8 “(B) Not later than 180 days after the
9 date of the enactment of the Preserving Access
10 to Life-Saving Medications Act of 2011, the
11 Secretary shall, subject to subparagraph (A),
12 promulgate final regulations establishing a
13 schedule of civil monetary penalties for viola-
14 tions of paragraph (1).

15 “(C) The provisions of paragraphs (5), (6),
16 and (7) of section 303(f) shall apply with re-
17 spect to a civil penalty under this paragraph to
18 the same extent and in the same manner as
19 such provisions apply with respect to a civil
20 penalty under paragraph (1), (2), (3), (4), or
21 (9) of section 303(f).

22 “(c) NOTIFICATIONS BY SECRETARY.—

23 “(1) DRUG SHORTAGE DEFINED.—In this sec-
24 tion, the term ‘drug shortage’ means, with respect to
25 a drug, a period of time when the total supply of

1 such drug available at the user level will not meet
2 the demand for such drug at the user level as deter-
3 mined by the Secretary.

4 “(2) PUBLIC NOTIFICATION.—

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

7 “(i) publish on the public Internet
8 Web site of the Food and Drug Adminis-
9 tration information on—

10 “(I) the types of discontinuances
11 and interruptions for which a notifica-
12 tion is required under subsection
13 (b)(1); and

14 “(II) actual drug shortages; and

15 “(ii) to the maximum extent prac-
16 ticable, distribute such information to ap-
17 propriate health care providers and patient
18 organizations.

19 “(B) DURATION.—The Secretary shall in-
20 clude in any publication or distribution under
21 subparagraph (A), when possible, an estimate
22 of the expected duration of any discontinuance
23 or interruption or actual drug shortage.

24 “(3) IDENTIFICATION AND NOTIFICATION OF
25 DRUGS VULNERABLE TO DRUG SHORTAGE.—

1 “(A) IN GENERAL.—If the Secretary deter-
2 mines using the criteria under subparagraph
3 (B) that a drug may be vulnerable to a drug
4 shortage, the Secretary shall notify the manu-
5 facturer of the drug of—

6 “(i) such determination; and

7 “(ii) the Secretary’s duty to collabo-
8 rate to improve continuity of supply plans
9 under paragraph (4).

10 “(B) EVIDENCE-BASED CRITERIA.—The
11 Secretary shall implement evidence-based cri-
12 teria for identifying drugs that may be vulner-
13 able to a drug shortage. Such criteria shall be
14 based on—

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

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

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

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

23 “(4) CONTINUITY OF SUPPLY PLANS.—

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

1 terminated under paragraph (3)), the Secretary
2 shall collaborate with manufacturers and other
3 stakeholders (such as distributors and health
4 care providers) to establish and improve con-
5 tinuity of supply plans, so that such plans in-
6 clude a process for addressing drug shortages.

7 “(B) LIMITATION ON SECRETARY’S AU-
8 THORITY.—The Secretary may not in any case
9 require a manufacturer—

10 “(i) to manufacture a drug in the
11 event of a discontinuance or interruption;
12 or

13 “(ii) to delay or alter a discontinuance
14 or interruption.

15 “(C) ALLOCATION BY MANUFACTURER.—
16 No provision of Federal law shall be construed
17 to prohibit a manufacturer from, or penalize a
18 manufacturer for, allocating distribution of its
19 products in order to manage an actual or poten-
20 tial drug shortage.

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

24 (b) APPLICABILITY; TRANSITIONAL PERIOD.—Sec-
25 tion 506C of the Federal Food, Drug, and Cosmetic Act,

1 as amended by subsection (a), applies with respect to
2 discontinuances, interruptions, and drug shortages (as
3 such terms are used in such section 506C) that occur on
4 or after the day that is 1 year after the date of the enact-
5 ment of this Act. Until such day, the provisions of section
6 506C of the Federal Food, Drug, and Cosmetic Act, as
7 in effect on the day before the enactment of this Act, shall
8 continue to apply.

9 **SEC. 3. REPORTS TO CONGRESS.**

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

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

20 (2) every 5 years thereafter, a report describing
21 such actions taken by the Secretary during the pre-
22 vious 5-year period.

23 **SEC. 4. GAO STUDY.**

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

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

5 (2) to examine the possible causes of such drug
6 shortages, including manufacturing problems, break-
7 down in the supply chain delivery system, changes in
8 the supply of raw materials, stockpiling at the
9 wholesale or provider level, and restrictive regulatory
10 requirements;

11 (3) to identify if there is adequate communica-
12 tion between industry, the Food and Drug Adminis-
13 tration, distributors, and end users;

14 (4) to analyze the effects of the enactment of
15 this Act on the ability of the Food and Drug Admin-
16 istration to identify and ameliorate such drug short-
17 ages; and

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

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

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