

112TH CONGRESS
2D SESSION

H. R. 3839

To address critical drug shortages.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 31, 2012

Mr. CARNEY (for himself and Mr. BUCSHON) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To address critical 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 “Drug Shortage Preven-
5 tion Act of 2012”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents of this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

Sec. 3. Actions by Food and Drug Administration To Address Critical Drug Shortages.

Sec. 4. Actions by Attorney General To Address Critical Drug Shortages.

1 **SEC. 3. ACTIONS BY FOOD AND DRUG ADMINISTRATION TO**
2 **ADDRESS CRITICAL DRUG SHORTAGES.**

3 Chapter V of the Federal Food, Drug, and Cosmetic
4 Act is amended by inserting after section 506C (21 U.S.C.
5 356e) the following:

6 **“SEC. 506D. ADDRESSING CRITICAL DRUG SHORTAGES.**

7 “(a) DEFINITIONS.—In this section:

8 “(1) The term ‘biological product’ has the
9 meaning given to such term in section 351(i) of the
10 Public Health Service Act.

11 “(2) The term ‘critical drug’ has the meaning
12 given to such term by the Secretary pursuant to
13 subsection (b)(2).

14 “(3) The term ‘critical drug shortage’ has the
15 meaning given to such term by the Secretary pursu-
16 ant to subsection (c)(2).

17 “(4) The term ‘relevant stakeholders’ in-
18 cludes—

19 “(A) with respect to drugs and biological
20 products, manufacturers, distributors, and
21 group purchasing organizations; and

22 “(B) health care providers.

23 “(b) NATIONAL CRITICAL DRUG LIST.—

24 “(1) LIST.—The Secretary shall—

1 “(A) not later than 180 days after the date
2 of the enactment of this section, establish a list
3 identifying each critical drug;

4 “(B) promptly remove any drug or biological
5 product from such list if the drug or biological
6 product no longer meets the definition of a
7 critical drug established pursuant to paragraph
8 (2);

9 “(C) consider for inclusion in such list—

10 “(i) each drug and biological product
11 that is—

12 “(I) approved or licensed under
13 section 505 of this Act or section 351
14 of the Public Health Service Act; or

15 “(II) otherwise marketed pursuant
16 to regulation by the Food and
17 Drug Administration; and

18 “(ii) each such drug or biological
19 product for which a new indication is ap-
20 proved;

21 “(D) include in such list, with respect to
22 each listed critical drug, information concerning
23 the number and identity of the manufacturers
24 of such drug;

25 “(E) make such list publicly available; and

1 “(F) review and update such list semi-
2 annually.

3 “(2) DEFINITION.—Not later than 90 days
4 after the date of the enactment of this section, the
5 Secretary shall define the term ‘critical drug’ for
6 purposes of this section. In defining such term, the
7 Secretary shall—

8 “(A) solicit input from relevant stake-
9 holders through a public hearing or an oppor-
10 tunity to provide written comments;

11 “(B) take into account the medical neces-
12 sity of a drug or biological product and exclude
13 any drug or biological product that is not medi-
14 cally necessary; and

15 “(C) take into account the vulnerability of
16 a drug or biological product to shortage, includ-
17 ing because of the number of manufacturers
18 and sources of active ingredients involved.

19 “(3) REQUEST FOR REMOVAL.—

20 “(A) IN GENERAL.—The manufacturer of
21 a drug or biological product on the list estab-
22 lished under paragraph (1) may request that
23 the Secretary remove the drug or biological
24 product from the list on the basis that the drug

1 or biological product does not satisfy the defini-
2 tion of a critical drug.

3 “(B) ACTION BY THE SECRETARY.—Not
4 later than 45 days after receipt of such a re-
5 quest, the Secretary shall review the determina-
6 tion that the drug or biological product is a
7 critical drug and—

8 “(i) remove the drug or biological
9 product from the list established under
10 paragraph (1) if the Secretary determines
11 that the drug is not a critical drug; or

12 “(ii) provide to the manufacturer sub-
13 mitting such request an explanation of why
14 the drug or biological product was properly
15 determined to be a critical drug.

16 “(c) NATIONAL CRITICAL DRUG SHORTAGE LIST.—

17 “(1) LIST.—The Secretary shall—

18 “(A) not later than 1 year after the date
19 of the enactment of this section, establish and
20 make publicly available a list identifying each
21 critical drug that is in a critical drug shortage;
22 and

23 “(B) not less than monthly, review and, as
24 appropriate, update such list.

1 “(2) DEFINITION.—Not later than 180 days
2 after the date of the enactment of this section, the
3 Secretary shall define the term ‘critical drug short-
4 age’ for purposes of this section. In defining such
5 term, the Secretary shall—

6 “(A) solicit input from relevant stake-
7 holders through a public hearing or an oppor-
8 tunity to provide written comments; and

9 “(B) limit the definition to actual short-
10 ages in the United States of critical drugs.

11 “(3) CONTENTS.—The list established under
12 paragraph (1) shall, with respect to each listed crit-
13 ical drug shortage, include at a minimum access to
14 the following information:

15 “(A) Indication of the severity of the
16 shortage.

17 “(B) Each reason for the shortage.

18 “(C) An estimated date by which the crit-
19 ical drug involved will begin reaching providers
20 in quantities sufficient to meet demand.

21 “(D) Identification of alternate therapies.

22 “(E) Identification of specific regions of
23 the country particularly affected or specifically
24 not affected by the shortage.

25 “(4) REQUEST FOR REMOVAL.—

1 “(A) IN GENERAL.—The manufacturer of
2 a critical drug included on the list established
3 under paragraph (1) may request that the Sec-
4 retary remove the critical drug from the list on
5 the basis that the drug is not in a critical drug
6 shortage.

7 “(B) ACTION BY THE SECRETARY.—Not
8 later than 45 days after receipt of such a re-
9 quest, the Secretary shall review the determina-
10 tion that a critical drug shortage exists and—

11 “(i) remove the critical drug from the
12 list if the Secretary determines that the
13 drug is not in a critical drug shortage; or

14 “(ii) provide to the manufacturer sub-
15 mitting such request an explanation of why
16 the critical drug was properly determined
17 to be in a critical drug shortage.

18 “(d) SUPPLY CHAIN COMMUNICATION INFRASTRUC-
19 TURE.—

20 “(1) NOTIFICATIONS TO PUBLIC.—

21 “(A) IN GENERAL.—The Secretary shall
22 establish and implement a proactive system for
23 giving notice to the public concerning additions
24 and other modifications to the list under sub-
25 section (c)(1) regarding critical drug shortages.

1 “(B) SYSTEM REQUIREMENTS.—The sys-
2 tem under subparagraph (A) shall provide such
3 notices—

4 “(i) to any member of the public on
5 an opt-in basis; and

6 “(ii) in written form comprehensible
7 to a lay reader.

8 “(C) INITIAL IMPLEMENTATION.—The
9 Secretary shall begin implementation of the sys-
10 tem under subparagraph (A) not later than 1
11 year after the date of the enactment of this sec-
12 tion.

13 “(2) NOTIFICATIONS TO MANUFACTURERS AND
14 DISTRIBUTORS.—

15 “(A) IN GENERAL.—The Secretary shall
16 establish and implement a system for giving no-
17 tice of any imminent critical drug shortage to—

18 “(i) any manufacturer of the critical
19 drug registered under section 510;

20 “(ii) any manufacturer so registered
21 with capacity to manufacture the critical
22 drug or an alternate therapy to the critical
23 drug; and

24 “(iii) subject to subparagraph (B) and
25 at the Secretary’s discretion, any wholesale

1 distributor of the critical drug that has a
2 contractual relationship with—

3 “(I) the manufacturer of the crit-
4 ical drug; or

5 “(II) an authorized distributor of
6 record (as such term is defined in sec-
7 tion 503(e)(3)) of the critical drug.

8 “(B) WHOLESAL E DISTRIBUTORS PARTICI-
9 PATING IN UNLAWFUL ACTIVITIES.—If the At-
10 torney General determines that a wholesale dis-
11 tributor of a critical drug is participating in
12 stockpiling, price gouging, or other unlawful ac-
13 tivities related to the distribution of a critical
14 drug, the Secretary shall withhold any notifica-
15 tion that would otherwise be made to the dis-
16 tributor under subparagraph (A) with respect
17 to the critical drug until the Attorney General
18 determines that the distributor is no longer par-
19 ticipating in such activities.

20 “(C) INITIAL IMPLEMENTATION.—The
21 Secretary shall begin implementation of the sys-
22 tem under subparagraph (A) not later than 180
23 days after the date of the enactment of this sec-
24 tion.

1 “(3) NOTIFICATIONS TO ATTORNEY GEN-
2 ERAL.—The Secretary shall—

3 “(A) give notice to the Attorney General of
4 any critical drug shortage listed under sub-
5 section (c); and

6 “(B) provide such information to the At-
7 torney General as may be necessary to deter-
8 mine the extent to which it is appropriate to in-
9 crease one or more production quotas under
10 section 306(h) of the Controlled Substances Act
11 in order to address such shortage.

12 “(e) STUDY ON FEASIBILITY OF NATIONAL CONTIN-
13 GENCY PLAN.—

14 “(1) STUDY.—The Secretary shall conduct a
15 study on the feasibility of creating a national contin-
16 gency plan addressing critical drug shortages, in-
17 cluding with respect to—

18 “(A) the creation of a Federal stockpile of
19 critical drugs for the purpose of responding to
20 potential critical drug shortages; or

21 “(B) the expansion of an existing Federal
22 stockpile of drugs to include critical drugs for
23 such purpose.

1 “(2) CONSULTATION.—In conducting the study
2 under paragraph (1), the Secretary shall consult
3 with relevant stakeholders.

4 “(3) REPORT.—Not later than 1 year after the
5 date of the enactment of this Act, the Secretary
6 shall complete the study required by paragraph (1)
7 and submit to the Congress a report on the results
8 of such study.

9 “(f) APPROVAL OF DRUGS.—

10 “(1) EXPEDITED REVIEW.—The Secretary shall
11 expedite the review of—

12 “(A) any application seeking approval of a
13 critical drug under subsection (c) or (j) of sec-
14 tion 505 of this Act or licensing of a critical
15 drug under section 351 of the Public Health
16 Service Act; and

17 “(B) any request by the sponsor of a crit-
18 ical drug to approve—

19 “(i) a change to the manufacturing
20 process for a critical drug, including any
21 change in the facilities used for such proc-
22 ess; or

23 “(ii) an alternate supplier of any ac-
24 tive ingredient in a critical drug.

1 “(2) NO DELAY OF OTHER APPLICATIONS.—In
2 expediting the review of applications and requests
3 under paragraph (1), the Secretary shall not unnec-
4 essarily delay the review of applications and requests
5 for drugs and biological products that are not crit-
6 ical drugs.

7 “(3) ESTABLISHMENT OF PROCEDURES AND
8 TIMEFRAMES.—Not later than 90 days after the
9 date of the enactment of this section, the Secretary,
10 with input from relevant stakeholders, shall establish
11 procedures and timeframes for providing expedited
12 review under paragraph (1).

13 “(g) IMPROVED REGULATION.—The Secretary shall
14 review and improve the process for regulating critical
15 drugs so as to—

16 “(1) ensure that, at each stage of such process,
17 the status of such drugs as critical drugs is taken
18 into consideration;

19 “(2) improve communications between the of-
20 fices and officials of the Food and Drug Administra-
21 tion responsible for approving and regulating critical
22 drugs and the offices and officials of the Food and
23 Drug Administration responsible for identifying and
24 addressing critical drug shortages; and

1 “(3) ensure that any new regulatory concern
2 about a critical drug identified by Food and Drug
3 Administration personnel is communicated—

4 “(A) within 1 business day to the office of
5 the Food and Drug Administration responsible
6 for identifying and addressing critical drug
7 shortages; and

8 “(B) within 5 business days to the manu-
9 facturer of the critical drug.

10 “(h) CONFIDENTIALITY.—

11 “(1) IN GENERAL.—Except as described in
12 paragraph (2), in carrying out this section, the Sec-
13 retary shall not disclose—

14 “(A) any trade secret or other matter that
15 is referred to in section 1905 of title 18 of the
16 United States Code, or

17 “(B) any trade secret or other commercial
18 or financial information that is exempt from
19 disclosure under section 552(b)(4) of title 5 of
20 the United States Code.

21 “(2) DISCLOSURE TO FEDERAL OFFICERS AND
22 EMPLOYEES.—The Secretary may disclose such mat-
23 ter or information to an officer or employee of the
24 Federal Government, but only if—

1 “(A) such disclosure is for the purpose of
2 carrying out this section or section 306(h) of
3 the Controlled Substances Act; and

4 “(B) any further disclosure of such matter
5 or information by the officer and employee is
6 restricted to the same extent as disclosure of
7 such matter or information by the Secretary.

8 “(i) SENSE OF CONGRESS REGARDING INCREASE IN
9 PERSONNEL.—It is the sense of the Congress that the
10 Food and Drug Administration should increase the num-
11 ber of personnel responsible for identifying and addressing
12 critical drug shortages.”.

13 **SEC. 4. ACTIONS BY ATTORNEY GENERAL TO ADDRESS**
14 **CRITICAL DRUG SHORTAGES.**

15 Section 306 of the Controlled Substances Act (21
16 U.S.C. 826) is amended by adding at the end the fol-
17 lowing:

18 “(h) If the Secretary of Health and Human Services
19 lists a critical drug shortage under section 506D(c) of the
20 Federal Food, Drug, and Cosmetic Act, and the drug in-
21 volved or any ingredient therein is a controlled substance
22 subject to a quota under this section, then the Attorney
23 General shall increase such quota to the extent determined
24 by the Attorney General, in consultation with the Sec-

- 1 retary of Health and Human Services, to be appropriate
- 2 to address the critical drug shortage.”.

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