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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

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A BILL

To address critical 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 ''Drug Shortage Prevention Act of 2012''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

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

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

"SEC. 506D. ADDRESSING CRITICAL DRUG SHORTAGES.

"(a) DEFINITIONS.—In this section:

"(1) The term 'biological product' has the meaning given to such term in section 351(i) of the Public Health Service Act.

"(2) The term 'critical drug' has the meaning given to such term by the Secretary pursuant to subsection (b)(2).

"(3) The term 'critical drug shortage' has the meaning given to such term by the Secretary pursuant to subsection (c)(2).

"(4) The term 'relevant stakeholders' includes—

"(A) with respect to drugs and biological products, manufacturers, distributors, and group purchasing organizations; and

"(B) health care providers.

"(b) NATIONAL CRITICAL DRUG LIST.—

"(1) LIST.—The Secretary shall—

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

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

''(C) consider for inclusion in such list—

''(i) each drug and biological product that is—

''(I) approved or licensed under section 505 of this Act or section 351 of the Public Health Service Act; or

''(II) otherwise marketed pursuant to regulation by the Food and Drug Administration; and

''(ii) each such drug or biological product for which a new indication is approved;

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

''(E) make such list publicly available; and

"(F) review and update such list semi-annually.

"(2) DEFINITION.—Not later than 90 days after the date of the enactment of this section, the Secretary shall define the term 'critical drug' for purposes of this section. In defining such term, the Secretary shall—

"(A) solicit input from relevant stakeholders through a public hearing or an opportunity to provide written comments;

"(B) take into account the medical necessity of a drug or biological product and exclude any drug or biological product that is not medically necessary; and

"(C) take into account the vulnerability of a drug or biological product to shortage, including because of the number of manufacturers and sources of active ingredients involved.

"(3) REQUEST FOR REMOVAL.—

"(A) IN GENERAL.—The manufacturer of a drug or biological product on the list established under paragraph (1) may request that the Secretary remove the drug or biological product from the list on the basis that the drug

or biological product does not satisfy the definition of a critical drug.

''(B) ACTION BY THE SECRETARY.—Not later than 45 days after receipt of such a request, the Secretary shall review the determination that the drug or biological product is a critical drug and—

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

''(ii) provide to the manufacturer submitting such request an explanation of why the drug or biological product was properly determined to be a critical drug.

''(c) NATIONAL CRITICAL DRUG SHORTAGE LIST.—

''(1) LIST.—The Secretary shall—

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

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

''(2) DEFINITION.—Not later than 180 days after the date of the enactment of this section, the Secretary shall define the term 'critical drug shortage' for purposes of this section. In defining such term, the Secretary shall—

''(A) solicit input from relevant stakeholders through a public hearing or an opportunity to provide written comments; and

''(B) limit the definition to actual shortages in the United States of critical drugs.

''(3) CONTENTS.—The list established under paragraph (1) shall, with respect to each listed critical drug shortage, include at a minimum access to the following information:

''(A) Indication of the severity of the shortage.

''(B) Each reason for the shortage.

''(C) An estimated date by which the critical drug involved will begin reaching providers in quantities sufficient to meet demand.

''(D) Identification of alternate therapies.

''(E) Identification of specific regions of the country particularly affected or specifically not affected by the shortage.

''(4) REQUEST FOR REMOVAL.—

"(A) IN GENERAL.—The manufacturer of a critical drug included on the list established under paragraph (1) may request that the Secretary remove the critical drug from the list on the basis that the drug is not in a critical drug shortage.

"(B) ACTION BY THE SECRETARY.—Not later than 45 days after receipt of such a request, the Secretary shall review the determination that a critical drug shortage exists and—

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

"(ii) provide to the manufacturer submitting such request an explanation of why the critical drug was properly determined to be in a critical drug shortage.

"(d) SUPPLY CHAIN COMMUNICATION INFRASTRUCTURE.—

"(1) NOTIFICATIONS TO PUBLIC.—

"(A) IN GENERAL.—The Secretary shall establish and implement a proactive system for giving notice to the public concerning additions and other modifications to the list under subsection (c)(1) regarding critical drug shortages.

''(B) SYSTEM REQUIREMENTS.—The system under subparagraph (A) shall provide such notices—

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

''(ii) in written form comprehensible to a lay reader.

''(C) INITIAL IMPLEMENTATION.—The Secretary shall begin implementation of the system under subparagraph (A) not later than 1 year after the date of the enactment of this section.

''(2) NOTIFICATIONS TO MANUFACTURERS AND DISTRIBUTORS.—

''(A) IN GENERAL.—The Secretary shall establish and implement a system for giving notice of any imminent critical drug shortage to—

''(i) any manufacturer of the critical drug registered under section 510;

''(ii) any manufacturer so registered with capacity to manufacture the critical drug or an alternate therapy to the critical drug; and

''(iii) subject to subparagraph (B) and at the Secretary's discretion, any wholesale

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

"(I) the manufacturer of the critical drug; or

"(II) an authorized distributor of record (as such term is defined in section 503(e)(3)) of the critical drug.

"(B) WHOLESALE DISTRIBUTORS PARTICIPATING IN UNLAWFUL ACTIVITIES.—If the Attorney General determines that a wholesale distributor of a critical drug is participating in stockpiling, price gouging, or other unlawful activities related to the distribution of a critical drug, the Secretary shall withhold any notification that would otherwise be made to the distributor under subparagraph (A) with respect to the critical drug until the Attorney General determines that the distributor is no longer participating in such activities.

"(C) INITIAL IMPLEMENTATION.—The Secretary shall begin implementation of the system under subparagraph (A) not later than 180 days after the date of the enactment of this section.

''(3) NOTIFICATIONS TO ATTORNEY GENERAL.—The Secretary shall—

''(A) give notice to the Attorney General of any critical drug shortage listed under subsection (c); and

''(B) provide such information to the Attorney General as may be necessary to determine the extent to which it is appropriate to increase one or more production quotas under section 306(h) of the Controlled Substances Act in order to address such shortage.

''(e) STUDY ON FEASIBILITY OF NATIONAL CONTINGENCY PLAN.—

''(1) STUDY.—The Secretary shall conduct a study on the feasibility of creating a national contingency plan addressing critical drug shortages, including with respect to—

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

''(B) the expansion of an existing Federal stockpile of drugs to include critical drugs for such purpose.

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

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

''(f) APPROVAL OF DRUGS.—

''(1) EXPEDITED REVIEW.—The Secretary shall expedite the review of—

''(A) any application seeking approval of a critical drug under subsection (c) or (j) of section 505 of this Act or licensing of a critical drug under section 351 of the Public Health Service Act; and

''(B) any request by the sponsor of a critical drug to approve—

''(i) a change to the manufacturing process for a critical drug, including any change in the facilities used for such process; or

''(ii) an alternate supplier of any active ingredient in a critical drug.

''(2) NO DELAY OF OTHER APPLICATIONS.—In expediting the review of applications and requests under paragraph (1), the Secretary shall not unnecessarily delay the review of applications and requests for drugs and biological products that are not critical drugs.

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

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

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

''(2) improve communications between the offices and officials of the Food and Drug Administration responsible for approving and regulating critical drugs and the offices and officials of the Food and Drug Administration responsible for identifying and addressing critical drug shortages; and

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

''(A) within 1 business day to the office of the Food and Drug Administration responsible for identifying and addressing critical drug shortages; and

''(B) within 5 business days to the manufacturer of the critical drug.

''(h) CONFIDENTIALITY.—

''(1) IN GENERAL.—Except as described in paragraph (2), in carrying out this section, the Secretary shall not disclose—

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

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

''(2) DISCLOSURE TO FEDERAL OFFICERS AND EMPLOYEES.—The Secretary may disclose such matter or information to an officer or employee of the Federal Government, but only if—

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

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

''(i) SENSE OF CONGRESS REGARDING INCREASE IN PERSONNEL.—It is the sense of the Congress that the Food and Drug Administration should increase the number of personnel responsible for identifying and addressing critical drug shortages.''.

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

Section 306 of the Controlled Substances Act (21 U.S.C. 826) is amended by adding at the end the following:

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

retary of Health and Human Services, to be appropriate to address the critical drug shortage.''.

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