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118TH CONGRESS
1ST SESSION

H. R. 3008

To amend the Federal Food, Drug, and Cosmetic Act to provide for notification by manufacturers of critical essential medicines of increased demand of such drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 28, 2023

Ms. JACOBS (for herself, Mr. ALLRED, Ms. CLARKE of New York, Mr. DOGGETT, Mr. GARCÍA of Illinois, Mr. GRIJALVA, Mr. HUFFMAN, Mr. KHANNA, Mr. LARSON of Connecticut, Ms. LEE of California, Mr. MCGOVERN, Ms. OCASIO-CORTEZ, Ms. PRESSLEY, Mr. VEASEY, Ms. VELÁZQUEZ, Mrs. WATSON COLEMAN, Mr. CARTER of Louisiana, Ms. NORTON, Mr. COHEN, Mr. CLEAVER, Mr. SMITH of Washington, Ms. BLUNT ROCHESTER, Ms. CROCKETT, Ms. KUSTER, Ms. TOKUDA, Ms. CARAVEO, Mr. SCHIFF, Ms. JACKSON LEE, Mr. KIM of New Jersey, and Mr. MILLS) 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 for notification by manufacturers of critical essential medicines of increased demand of such drugs, and for other purposes.

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 2023''.

SEC. 2. IMPROVING NOTIFICATION PROCEDURES IN CASE OF INCREASED DEMAND FOR CRITICAL ESSENTIAL MEDICINES.

(a) IN GENERAL.—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 OR INTERRUPTION IN THE PRODUCTION OF LIFE-SAVING DRUGS**'' and inserting ''**NOTIFICATION OF ISSUES AFFECTING DOMESTIC SUPPLY OF CRITICAL ESSENTIAL MEDICINES**'';

(2) by striking subsections (a), (b), and (c), and inserting the following:

''(a) NOTIFICATION REQUIRED.—

''(1) IN GENERAL.—A manufacturer of a critical essential medicine shall notify the Secretary, in accordance with subsection (b), of—

''(A)(i) a permanent discontinuance in the manufacture of the drug or an interruption of the manufacture of the drug that is likely to lead to a meaningful disruption in the supply of such drug in the United States;

''(ii) a permanent discontinuance in the manufacture of an active pharmaceutical ingredient, an excipient, or any other input in the final dosage form of such drug or an interruption in the manufacture of the active pharmaceutical ingredient, an excipient, or any other input in the final dosage form of such drug of such drug that is likely to lead to a meaningful disruption in the supply of the active pharmaceutical ingredient of such drug;

''(iii) an increased demand (other than an anticipated seasonal surge) for such drug or an active pharmaceutical ingredient, an excipient, or any other input in the final dosage form of such drug that is likely to lead to a shortage of the drug or the active pharmaceutical ingredient, an excipient, or any other input in the final dosage form of such drug; and

''(B) the reasons for such discontinuance, interruption, or increased demand.

''(2) CONTENTS.—Notification under this subsection with respect to a critical essential medicine shall include—

''(A) with respect to the reasons for the discontinuation, interruption, or increased de-

mand referred to in paragraph (1)(C), if an active pharmaceutical ingredient, an excipient, or any other input in the final dosage form of such drug is a reason for, or risk factor in, such discontinuation, interruption, or increased demand, the source of the active pharmaceutical ingredient, excipient, or other input and any alternative sources for the an active pharmaceutical ingredient, an excipient, or any other input by the manufacturer;

"(B) whether any associated device used for preparation or administration included in the drug is a reason for, or a risk factor in, such discontinuation, interruption, or increased demand;

"(C) the expected duration of the interruption or increased demand; and

"(D) such other information as the Secretary may require.

"(b) TIMING.—

"(1) IN GENERAL.—A notice required under subsection (a) shall be submitted to the Secretary—

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

"(B) in the case of such a notice with respect to increased demand for a critical essential medicine, not later than 30 days after the submission of the initial notification under paragraph (2); or

"(C) if compliance with subparagraph (A) or (B) is not possible, as soon as practicable.

"(2) INITIAL NOTIFICATION WITH RESPECT TO INCREASED DEMAND.—In the case a notification required under subsection (a) with respect to increased demand for a critical essential medicine, the manufacturer of the drug involved shall submit to the Secretary an initial notification not later than 48 hours after the date on which there has been increased demand for the critical essential medicine for a period of at least 6 consecutive weeks.

"(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute, through such means as the Secretary deems appropriate, information on the discontinuance or interruption of the manufacture of, or the increased demand for, critical essential medicines to appropriate organizations, including physician, health provider, and patient organizations, as described in section 506E.";

(3) in subsection (g), in the matter preceding paragraph (1), by striking ''drug described in subsection (a)'' and inserting ''critical essential medicine''; and

(4) in subsection (j), by striking ''drug described in subsection (a)'' and inserting ''critical essential medicine''.

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

(1) by redesignating paragraphs (1), (2), and (3) as paragraphs (2), (3), and (4), respectively;

(2) in paragraph (2)(A) (as so redesignated), by striking ''and that is subject to section 503(b)(1)'' and inserting '', including a drug that is not subject to section 503(b)(1)''; and

(3) by inserting before paragraph (2) (as so redesignated) the following:

''(1) the term 'critical essential medicine' means a drug that—

''(A) is—

''(i) life-supporting;

''(ii) life-sustaining; or

''(iii) intended for use in the prevention or treatment of a debilitating disease

or condition, including any such drug used in emergency medical care or during surgery or any such drug that is critical to the public health during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act; and

''(B) is not a radio pharmaceutical drug product or any other product as designated by the Secretary;''.

(c) REGULATIONS.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue final regulations to implement the amendments made by subsections (a) and (b).

(d) GUIDANCE.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance on the requirements for notifications required to be submitted under section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c), as amended by subsections (a) and (b), with respect to increased demand for critical essential medicines (as defined in

such section 506C). Such guidance shall specifically address—

(A) the ways in which manufacturers of critical essential medicines can improve demand predictability;

(B) what information manufacturers of critical essential medicines should send to the Secretary; and

(C) what communications from the manufacturer the Secretary would request with respect to increases in demand following such notifications.

(2) CONSULTATION.—In developing such guidance, the Secretary shall consult with relevant stakeholders, including manufacturers of critical essential medicines and local, State, or Federal public health officials.

(3) TIMING.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue—

(A) draft guidance under paragraph (1) not later than 120 days after the date of the enactment of this Act; and

(B) final guidance under such paragraph not later than 180 days after the date of the enactment of this Act.

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