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116TH CONGRESS
2D SESSION

H. R. 6062

To amend certain provisions in the Federal Food, Drug, and Cosmetic Act relating to the discontinuance or interruption in the production of life-saving drugs so as to apply such provisions with respect to life-saving devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 3, 2020

Mr. SCHNEIDER (for himself, Mr. HICE of Georgia, and Ms. SCHAKOWSKY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend certain provisions in the Federal Food, Drug, and Cosmetic Act relating to the discontinuance or interruption in the production of life-saving drugs so as to apply such provisions with respect to life-saving devices, 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. DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF LIFE-SAVING DEVICES.

(a) NOTIFICATION REQUIREMENT.—Section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amended—

(1) in the section heading, by striking ''**LIFE-SAVING DRUGS**'' and inserting ''**LIFE-SAVING DRUGS AND DEVICES**'';

(2) in the matter preceding paragraph (1) in subsection (a), by striking ''a drug'' and inserting ''a drug or device'';

(3) in subsection (a)(1)(C), by striking ''such drug'' and inserting ''such drug or device'';

(4) in the matter following paragraph (2) in subsection (a), by striking ''the drug'' each place it appears and inserting ''the drug or device'';

(5) in subsection (c), by striking ''the drugs'' and inserting ''the drugs or devices'';

(6) in the matter before paragraph (1) in subsection (g), by striking ''a drug shortage of a drug described in subsection (a)'' and inserting ''a drug or device shortage of a drug or device described in subsection (a)'';

(7) in subsection (g)(1), by striking ''or a supplement to such an application submitted under section 505(j), that could help mitigate or prevent such shortage'' and inserting ''a supplement to such an application submitted under section 505(j), or a submission for clearance of a device under section 510(k), classification of a device under section

513(f)(2), or approval of a device under section 515, that could help mitigate or prevent such shortage'';

(8) in subsection (g)(2), by striking ''such drug shortage'' and inserting ''such drug or device shortage'';

(9) in subsection (h), by amending paragraph (2) to read as follows:

''(2) the term 'drug or device shortage' or 'shortage', with respect to a drug or device, means a period of time when the demand or projected demand for the drug or device within the United States exceeds the supply of the drug or device; and''; and

(10) in subsection (h)(3)(A), by striking ''a drug'' and inserting ''a drug or device''.

(b) ANNUAL REPORTING ON SHORTAGES.—Section 506C–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c–1) is amended—

(1) in the section heading, by striking ''**DRUG SHORTAGES**'' and inserting ''**DRUG AND DEVICE SHORTAGES**'';

(2) in subsections (a) and (b), by striking ''drug shortages'' each place it appears and inserting ''drug and device shortages'';

(3) in subsection (a)(2), by striking ''the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program'' and inserting ''the staffs of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program and the Center for Devices and Radiological Health'';

(4) in subsection (a)(3)(B)(i), by striking ''applications and supplements'' and inserting ''applications, supplements, and submissions''; and

(5) in subsections (a)(5) and (c), by striking ''drug shortage'' and inserting ''drug or device shortage''.

SEC. 2. DEVICE SHORTAGE LIST.

(a) IN GENERAL.—Section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e) is amended—

(1) in the section heading, by striking ''**DRUG SHORTAGE LIST**'' and inserting ''**DRUG AND DEVICE SHORTAGE LIST**''; and

(2) in subsection (a), by striking ''list of drugs'' and inserting ''list of drugs and devices''.

(b) CONTENTS.—Section 506E(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e(b)) is amended—

(1) in the matter before paragraph (1), by striking ''each drug'' and inserting ''each drug and device'';

(2) by striking ''the drug'' each place it appears and inserting ''the drug or device'';

(3) in paragraph (1), by striking ''the National Drug Code number for such drug'' and inserting ''the National Drug Code number for any such drug''; and

(4) in paragraph (2), by striking ''such drug'' and inserting ''such device''.

(c) PUBLIC AVAILABILITY PUBLIC HEALTH EXCEPTION.—Section 506E(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e(b)) is amended by striking ''drug products'' and inserting ''drug products or devices''.

(d) TECHNICAL CORRECTIONS.—Effective as if included in the enactment of the 21st Century Cures Act (Public Law 114–255), section 3101(a)(2)(G) of such Act is amended, in the amendments made by such section to section 506E(b)(3)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e(b)(3)(E))—

(1) by striking ''discontinuation'' and inserting ''Discontinuation''; and

(2) by striking ''discontinuance'' and inserting ''Discontinuance''.

SEC. 3. IMPORTATION OF DEVICES IN SHORTAGE.

Section 801(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)) is amended—

(1) in paragraph (1), by adding at the end the following subparagraph:

''(C) Except as authorized by the Secretary in the case of a device that appears on the drug and device shortage list under section 506E, no device may be imported into the United States for commercial use if such device is manufactured outside the United States, unless the manufacturer has authorized the device to be marketed in the United States and has caused the device to be labeled to be marketed in the United States.''; and

(2) in paragraph (2), by striking ''drug'' each place it appears and inserting ''drug or device''.

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