

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

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.

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. DISCONTINUANCE OR INTERRUPTION IN THE**
4 **PRODUCTION OF LIFE-SAVING DEVICES.**

5 (a) NOTIFICATION REQUIREMENT.—Section 506C of
6 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 356c) is amended—

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

4 (2) in the matter preceding paragraph (1) in
5 subsection (a), by striking “a drug” and inserting “a
6 drug or device”;

7 (3) in subsection (a)(1)(C), by striking “such
8 drug” and inserting “such drug or device”;

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

12 (5) in subsection (c), by striking “the drugs”
13 and inserting “the drugs or devices”;

14 (6) in the matter before paragraph (1) in sub-
15 section (g), by striking “a drug shortage of a drug
16 described in subsection (a)” and inserting “a drug
17 or device shortage of a drug or device described in
18 subsection (a)”;

19 (7) in subsection (g)(1), by striking “or a sup-
20 plement to such an application submitted under sec-
21 tion 505(j), that could help mitigate or prevent such
22 shortage” and inserting “a supplement to such an
23 application submitted under section 505(j), or a sub-
24 mission for clearance of a device under section
25 510(k), classification of a device under section

1 513(f)(2), or approval of a device under section 515,
2 that could help mitigate or prevent such shortage”;

3 (8) in subsection (g)(2), by striking “such drug
4 shortage” and inserting “such drug or device short-
5 age”;

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

8 “(2) the term ‘drug or device shortage’ or
9 ‘shortage’, with respect to a drug or device, means
10 a period of time when the demand or projected de-
11 mand for the drug or device within the United
12 States exceeds the supply of the drug or device;
13 and”; and

14 (10) in subsection (h)(3)(A), by striking “a
15 drug” and inserting “a drug or device”.

16 (b) ANNUAL REPORTING ON SHORTAGES.—Section
17 506C–1 of the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 356c–1) is amended—

19 (1) in the section heading, by striking “**DRUG**
20 **SHORTAGES**” and inserting “**DRUG AND DEVICE**
21 **SHORTAGES**”;

22 (2) in subsections (a) and (b), by striking
23 “drug shortages” each place it appears and inserting
24 “drug and device shortages”;

1 (3) in subsection (a)(2), by striking “the staff
2 of the Center for Drug Evaluation and Research’s
3 Office of Compliance and Drug Shortage Program”
4 and inserting “the staffs of the Center for Drug
5 Evaluation and Research’s Office of Compliance and
6 Drug Shortage Program and the Center for Devices
7 and Radiological Health”;

8 (4) in subsection (a)(3)(B)(i), by striking “ap-
9 plications and supplements” and inserting “applica-
10 tions, supplements, and submissions”; and

11 (5) in subsections (a)(5) and (c), by striking
12 “drug shortage” and inserting “drug or device
13 shortage”.

14 **SEC. 2. DEVICE SHORTAGE LIST.**

15 (a) IN GENERAL.—Section 506E of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 356e) is amend-
17 ed—

18 (1) in the section heading, by striking “**DRUG**
19 **SHORTAGE LIST**” and inserting “**DRUG AND DE-**
20 **VICE SHORTAGE LIST**”; and

21 (2) in subsection (a), by striking “list of drugs”
22 and inserting “list of drugs and devices”.

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

1 (1) in the matter before paragraph (1), by
2 striking “each drug” and inserting “each drug and
3 device”;

4 (2) by striking “the drug” each place it appears
5 and inserting “the drug or device”;

6 (3) in paragraph (1), by striking “the National
7 Drug Code number for such drug” and inserting
8 “the National Drug Code number for any such
9 drug”; and

10 (4) in paragraph (2), by striking “such drug”
11 and inserting “such device”.

12 (c) PUBLIC AVAILABILITY PUBLIC HEALTH EXCEP-
13 TION.—Section 506E(c) of the Federal Food, Drug, and
14 Cosmetic Act (21 U.S.C. 356e(b)) is amended by striking
15 “drug products” and inserting “drug products or devices”.

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

22 (1) by striking “discontinuation” and inserting
23 “Discontinuation”; and

24 (2) by striking “discontinuance” and inserting
25 “Discontinuance”.

1 **SEC. 3. IMPORTATION OF DEVICES IN SHORTAGE.**

2 Section 801(d) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 381(d)) is amended—

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

6 “(C) Except as authorized by the Secretary in the
7 case of a device that appears on the drug and device short-
8 age list under section 506E, no device may be imported
9 into the United States for commercial use if such device
10 is manufactured outside the United States, unless the
11 manufacturer has authorized the device to be marketed
12 in the United States and has caused the device to be la-
13 beled to be marketed in the United States.”; and

14 (2) in paragraph (2), by striking “drug” each
15 place it appears and inserting “drug or device”.

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