

117TH CONGRESS
1ST SESSION

S. 3416

To expand the enforcement authority of the Food and Drug Administration
with respect to counterfeit devices.

IN THE SENATE OF THE UNITED STATES

DECEMBER 16, 2021

Mr. MURPHY (for himself and Mr. BRAUN) introduced the following bill; which
was read twice and referred to the Committee on Health, Education,
Labor, and Pensions

A BILL

To expand the enforcement authority of the Food and Drug
Administration with respect to counterfeit devices.

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 “Protecting Patients
5 from Counterfeit Medical Devices Act”.

6 **SEC. 2. EXPANDING ENFORCEMENT AUTHORITY AND PEN-**
7 **ALTIES FOR COUNTERFEIT DEVICES.**

8 (a) PROHIBITED ACTS.—Section 301 of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
10 ed by adding at the end the following:

1 “(fff)(1) Forging, counterfeiting, simulating, or false-
2 ly representing, or without proper authority using any
3 mark, stamp, tag, label, or other identification device upon
4 any device or container, packaging, or labeling thereof so
5 as to render such device a counterfeit device.

6 “(2) Making, selling, disposing of, or keeping in pos-
7 session, control, or custody, or concealing any punch, die,
8 plate, stone, or other thing designed to print, imprint, or
9 reproduce the trademark, trade name, or other identifying
10 mark, imprint, or device of another or any likeness of any
11 of the foregoing upon any device or container, packaging,
12 or labeling thereof so as to render such device a counter-
13 feit device.

14 “(3) The doing of any act which causes a device to
15 be a counterfeit device, or the sale or dispensing, or the
16 holding for sale or dispensing, of a counterfeit device.”.

17 (b) PENALTIES.—Section 303 of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 333) is amended—

19 (1) in subsection (b)(8), by inserting “, or who
20 violates section 301(fff)(3) by knowingly making,
21 selling or dispensing, or holding for sale or dis-
22 pensing, a counterfeit device,” after “a counterfeit
23 drug”; and

24 (2) in subsection (c), by inserting “; or (6) for
25 having violated section 301(fff)(2) if such person

1 acted in good faith and had no reason to believe that
2 use of the punch, die, plate, stone, or other thing in-
3 volved would result in a device being a counterfeit
4 device, or for having violated section 301(fff)(3) if
5 the person doing the act or causing it to be done
6 acted in good faith and had no reason to believe that
7 the device was a counterfeit device” before the pe-
8 riod.

9 (c) SEIZURE.—Section 304(a)(2) of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 334(a)(2)) is
11 amended—

12 (1) by striking “, and (E)” and inserting “,
13 (E)”;

14 (2) by inserting “, (F) Any device that is a
15 counterfeit device, (G) Any container, packaging, or
16 labeling of a counterfeit device, and (H) Any punch,
17 die, plate, stone, labeling, container, or other thing
18 used or designed for use in making a counterfeit de-
19 vice or devices” before the period.

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