

116TH CONGRESS
2D SESSION

S. 4225

To establish authority to destroy counterfeit devices offered for import, and
for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 20, 2020

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

A BILL

To establish authority to destroy counterfeit devices offered
for import, 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. SHORT TITLE.**

4 This Act may be cited as the “Safeguarding Thera-
5 peutics Act of 2020”.

6 **SEC. 2. AUTHORITY TO DESTROY COUNTERFEIT DEVICES.**

7 (a) IN GENERAL.—Section 801(a) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is
9 amended—

1 (1) in the fourth sentence, by inserting “or
2 counterfeit device” after “counterfeit drug”; and

3 (2) by striking “The Secretary of the Treasury
4 shall cause the destruction of” and all that follows
5 through “liable for costs pursuant to subsection
6 (c).” and inserting the following: “The Secretary of
7 the Treasury shall cause the destruction of any such
8 article refused admission unless such article is ex-
9 ported, under regulations prescribed by the Sec-
10 retary of the Treasury, within 90 days of the date
11 of notice of such refusal or within such additional
12 time as may be permitted pursuant to such regula-
13 tions, except that the Secretary of Health and
14 Human Services may destroy, without the oppor-
15 tunity for export, any drug or device refused admis-
16 sion under this section, if such drug or device is val-
17 ued at an amount that is \$2,500 or less (or such
18 higher amount as the Secretary of the Treasury may
19 set by regulation pursuant to section 498(a)(1) of
20 the Tariff Act of 1930 (19 U.S.C. 1498(a)(1))) and
21 was not brought into compliance as described under
22 subsection (b). The Secretary of Health and Human
23 Services shall issue regulations providing for notice
24 and an opportunity to appear before the Secretary
25 of Health and Human Services and introduce testi-

1 mony, as described in the first sentence of this sub-
2 section, on destruction of a drug or device under the
3 seventh sentence of this subsection. The regulations
4 shall provide that prior to destruction, appropriate
5 due process is available to the owner or consignee
6 seeking to challenge the decision to destroy the drug
7 or device. Where the Secretary of Health and
8 Human Services provides notice and an opportunity
9 to appear and introduce testimony on the destruc-
10 tion of a drug or device, the Secretary of Health and
11 Human Services shall store and, as applicable, dis-
12 pose of the drug or device after the issuance of the
13 notice, except that the owner and consignee shall re-
14 main liable for costs pursuant to subsection (c).”.

15 (b) DEFINITION.—Section 201(h) of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is
17 amended—

18 (1) by redesignating subparagraphs (1), (2),
19 and (3) as clauses (A), (B), and (C), respectively;
20 and

21 (2) after making such redesignations—

22 (A) by striking “(h) The term” and insert-
23 ing “(h)(1) The term”; and

24 (B) by adding at the end the following:

1 “(2) The term ‘counterfeit device’ means a device
2 which, or the container, packaging, or labeling of which,
3 without authorization, bears a trademark, trade name, or
4 other identifying mark, imprint, or symbol, or any likeness
5 thereof, or is manufactured using a design, of a device
6 manufacturer, packer, or distributor other than the person
7 or persons who in fact manufactured, packed, or distrib-
8 uted such device and which thereby falsely purports or is
9 represented to be the product of, or to have been packed
10 or distributed by, such other device manufacturer, packer,
11 or distributor.

12 “(3) For purposes of subparagraph (2)—

13 “(A) the term ‘manufactured’ refers to any of
14 the following activities: manufacture, preparation,
15 propagation, compounding, assembly, or processing;
16 and

17 “(B) the term ‘manufacturer’ means a person
18 who is engaged in any of the activities listed in
19 clause (A).”.

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