

116TH CONGRESS
2D SESSION

H. R. 5663

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 22, 2020

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to give authority to the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to destroy counterfeit devices.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Safeguarding Thera-
3 peutics Act”.

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

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

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

10 (2) by striking “The Secretary of the Treasury
11 shall cause the destruction of” and all that follows
12 through “liable for costs pursuant to subsection
13 (c).” and inserting the following: “The Secretary of
14 the Treasury shall cause the destruction of any such
15 article refused admission unless such article is ex-
16 ported, under regulations prescribed by the Sec-
17 retary of the Treasury, within 90 days of the date
18 of notice of such refusal or within such additional
19 time as may be permitted pursuant to such regula-
20 tions, except that the Secretary of Health and
21 Human Services may destroy, without the oppor-
22 tunity for export, any drug or device refused admis-
23 sion under this section, if such drug or device is val-
24 ued at an amount that is \$2,500 or less (or such
25 higher amount as the Secretary of the Treasury may
26 set by regulation pursuant to section 498(a)(1) of

1 the Tariff Act of 1930 (19 U.S.C. 1498(a)(1))) and
2 was not brought into compliance as described under
3 subsection (b). The Secretary of Health and Human
4 Services shall issue regulations providing for notice
5 and an opportunity to appear before the Secretary
6 of Health and Human Services and introduce testi-
7 mony, as described in the first sentence of this sub-
8 section, on destruction of a drug or device under the
9 seventh sentence of this subsection. The regulations
10 shall provide that prior to destruction, appropriate
11 due process is available to the owner or consignee
12 seeking to challenge the decision to destroy the drug
13 or device. Where the Secretary of Health and
14 Human Services provides notice and an opportunity
15 to appear and introduce testimony on the destruc-
16 tion of a drug or device, the Secretary of Health and
17 Human Services shall store and, as applicable, dis-
18 pose of the drug or device after the issuance of the
19 notice, except that the owner and consignee shall re-
20 main liable for costs pursuant to subsection (c).”.

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

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

4 (2) after making such redesignations—

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

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

8 “(2) The term ‘counterfeit device’ means a de-
9 vice which, or the container, packaging, or labeling
10 of which, without authorization, bears a trademark,
11 trade name, or other identifying mark, imprint, or
12 symbol, or any likeness thereof, or is manufactured
13 using a design, of a device manufacturer, packer, or
14 distributor other than the person or persons who in
15 fact manufactured, packed, or distributed such de-
16 vice and which thereby falsely purports or is rep-
17 resented to be the product of, or to have been
18 packed or distributed by, such other device manufac-
19 turer, packer, or distributor.

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

21 “(A) the term ‘manufactured’ refers to any
22 of the following activities: manufacture, prepa-
23 ration, propagation, compounding, assembly, or
24 processing; and

