Union Calendar No.

116TH CONGRESS
2D SESSION

H. R. 5663

[Report No. 116–]

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.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 21, 2020

Mr. GUTHRIE (for himself and Mr. ENGEL) introduced the following bill; which was referred to the Committee on Energy and Commerce

JULY --, 2020

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on January 21, 2020]

A BILL

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Safeguarding Therapeutics Act".

SEC. 2. AUTHORITY TO DESTROY COUNTERFEIT DEVICES.

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

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

(2) by striking "The Secretary of the Treasury shall cause the destruction of" and all that follows through "liable for costs pursuant to subsection (c)." and inserting the following: "The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations, except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug or device refused admission under this section, if such drug or device is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the

Treasury may set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930 (19 U.S.C. 1498(a)(1))) and was not brought into compliance as described under subsection (b). The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of a drug or device under the seventh sentence of this subsection. The regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug or device. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of a drug or device, the Secretary of Health and Human Services shall store and, as applicable, dispose of the drug or device after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c).".

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

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

(2) after making such redesignations—

(A) by striking "(h) The term" and inserting "(h)(1) The term"; and

(B) by adding at the end the following:

"(2) The term 'counterfeit device' means a device which, or the container, packaging, or labeling of which, without authorization, bears a trademark, trade name, or other identifying mark, imprint, or symbol, or any likeness thereof, or is manufactured using a design, of a device manufacturer, packer, or distributor other than the person or persons who in fact manufactured, packed, or distributed such device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other device manufacturer, packer, or distributor.

"(3) For purposes of subparagraph (2)—

"(A) the term 'manufactured' refers to any of the following activities: manufacture, preparation, propagation, compounding, assembly, or processing; and

"(B) the term 'manufacturer' means a person who is engaged in any of the activities listed in clause (A).".