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

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.

Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended—
(1) in the fourth sentence insert “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 ninety 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 testi-
mony, as described in the first sentence of this sub-
section, 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 destruc-
tion of a drug or device, the Secretary of Health and
Human Services shall store and, as applicable, dis-
pose of the drug or device after the issuance of the
notice, except that the owner and consignee shall re-
main liable for costs pursuant to subsection (c).”.