Tuberville S.4974 Amdt. #1

TAM26874 77X S.L.C.

AMENDMENT NO._____ Calendar No._____

Purpose: To direct the Food and Drug Administration to prevent the importation of counterfeit, unapproved, misbranded, or adulterated drugs from the People's Republic of China or other foreign countries, and to establish enhanced safeguards for imported drug products.

IN THE SENATE OF THE UNITED STATES—119th Cong., 2d Sess.

S. 4974

To amend the Federal Food, Drug, and Cosmetic Act with respect to food safety.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. TUBERVILLE

Viz:

At the appropriate place, insert the following:

TITLE II—SECURE DRUG SUPPLY

SEC. 201. SHORT TITLE.

This title may be cited as the "Secure Drug Supply Act of 2026".

SEC. 202. PURPOSE.

The purposes of this title are—

(1) to prevent the unlawful importation of counterfeit, unapproved, misbranded, or adulterated drugs from the People's Republic of China and other

countries that are known to engage in intellectual property theft, forced labor, or the distribution of counterfeit and illicit pharmaceutical products that undermine the public health and economic interests of the United States;

(2) to increase visibility into the United States pharmaceutical supply chain; and

(3) to reduce the direct and indirect dependence of the United States on active pharmaceutical ingredients and key starting materials sourced from the People's Republic of China or that are of Chinese origin and sourced through third countries, in order to strengthen the resilience of the United States drug supply and protect public health and national security.

SEC. 203. PREVENTION OF IMPORTATION OF UNLAWFUL COUNTERFEIT PRESCRIPTION AND OVER-THE-COUNTER DRUGS.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this title as the "Secretary") shall utilize authorities under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) to prevent the importation of drugs, including active pharmaceutical ingredients and key starting materials, that are counterfeit, unapproved, misbranded, or adulterated and manu-

factured, prepared, propagated, compounded, and processed in a foreign establishment, with particular emphasis on preventing importation of such drugs, including active pharmaceutical ingredients and key starting materials, from the People's Republic of China and other countries that are designated as adversarial by the Secretary of State.

(b) ENFORCEMENT ACTIONS.—In carrying out subsection (a), the Secretary shall—

(1) conduct compliance and enforcement actions directed at entities involved in the manufacture, preparation, propagation, compounding, processing, or distribution of unapproved, adulterated, or misbranded drugs, including active pharmaceutical ingredients and key starting materials, that are offered for import;

(2) in cooperation with the Attorney General, initiate civil and criminal enforcement actions, including injunctions and seizures, under sections 301, 302, 303, 304, and 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 332, 333, 334, 381);

(3) refuse entry into the United States of such drugs, including active pharmaceutical ingredients or key starting materials; and

(4) conduct inspections of, or use alternative tools with respect to, as appropriate, facilities engaged in compounding to monitor for unauthorized receipt, use, or handling of drugs from the People's Republic of China and other countries designated as adversarial by the Secretary of State that were imported into the United States in violation of applicable laws and regulations.

(c) ANNUAL REPORTING.—Beginning with fiscal year 2027, not later than 180 days after the end of each fiscal year, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, detailing enforcement actions described in subsection (b) that were taken in the previous fiscal year, including information on the number and type of drugs, active pharmaceutical ingredients, and key starting materials that were the subjects of such actions during the previous fiscal year.

(d) GUIDANCE; RECOMMENDATIONS.—Not later than 180 days after the submission of each report under subsection (c), based on the information compiled in the report, the Secretary shall—

(1) issue or update guidance for importers of drugs to comply with the requirements of this title, including the amendments made by this title; and

(2) submit to Congress legislative proposals relating to resources and policies that would facilitate carrying out this title, including the amendments made by this title.

SEC. 204. SUPPLY CHAIN TRANSPARENCY AND RESILIENCE.

(a) REPORTING REQUIREMENTS FOR ACTIVE PHARMACEUTICAL INGREDIENTS AND KEY STARTING MATERIALS.—

(1) IN GENERAL.—Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)(3)) is amended—

(A) in the first sentence of subparagraph (A)—

(i) by striking "annually" and inserting "quarterly"; and

(ii) by inserting "and the information described in subparagraph (C)" before the period at the end; and

(B) by adding at the end the following:

"(C)(i) The annual report required under subparagraph (A) shall include the information de-

scribed in clause (ii) with respect to drugs, in accordance with the following:

"(I) In the 1-year period beginning on the effective date of the final regulations described in section 204(c) of the Secure Drug Supply Act of 2026, the information described in clause (ii) shall be included in the report under subparagraph (A) with respect to any drug that—

"(aa) is included on the Essential Medicines List maintained by the Food and Drug Administration pursuant to Executive Order 13944 (85 Fed. Reg. 49929); and

"(bb) is a drug for which any active pharmaceutical ingredient, key starting material, or acquired intermediate is sourced from the People's Republic of China or another foreign country of concern.

"(II) Beginning on the day after the last day of the 1-year period described in subclause (I), the information described in clause (ii) shall be included in the report under subparagraph (A) if it is a drug for which any active pharmaceutical ingredient, key starting material, or ac-

quired intermediate is sourced from the People's Republic of China or another foreign country of concern.

"(ii) The information described in this clause is the following, as applicable:

"(I) The identity of each active pharmaceutical ingredient, key starting material, and acquired intermediate used by the registrant to manufacture the listed drug.

"(II) The total amount of each such active pharmaceutical ingredient, key starting material, and acquired intermediate used by the registrant to manufacture the listed drug during the reporting period, expressed in such units as the Secretary shall specify.

"(III) The country of origin of each such active pharmaceutical ingredient, key starting material, and acquired intermediate, including the name, address, and unique facility identifier (as applicable) of each establishment at which such active pharmaceutical ingredient, key starting material, or acquired intermediate was manufactured.

"(iii) Information reported under this subparagraph shall include the country of origin without re-

gard to any distribution or shipment through a country other than the country of origin.

"(iv) A person required to report information under this subparagraph shall maintain such records and supporting documentation as the Secretary shall require to verify the accuracy and completeness of information submitted under this paragraph, for a period of not less than 5 years, and shall make such records available to the Secretary upon request.

"(D) Not later than 18 months after the 1-year period described in subparagraph (C)(i)(I) ends, and annually thereafter, the Secretary shall, based on the reports submitted under subparagraph (A), issue a confidential report to Congress that—

"(i) analyzes United States vulnerabilities arising from dependence on active pharmaceutical ingredients and key starting materials sourced from the People's Republic of China or other foreign countries of concern, including any such ingredients or materials with origins in the People's Republic of China or another foreign country of concern that are sourced through third countries;

"(ii) identifies the proportion of drugs manufactured, prepared, propagated, com-

pounded, or processed for commercial distribution in the United States that depend on active pharmaceutical ingredients and key starting materials sourced from the People's Republic of China or other foreign countries of concern, disaggregated by country of origin to the extent practicable;

"(iii) determines specific supply chain vulnerabilities, including drug classes or therapeutic categories for which dependence on active pharmaceutical ingredients and key starting materials sourced from the People's Republic of China or another foreign country of concern, poses a risk to public health or national security; and

"(iv) tracks trends over time in dependence on active pharmaceutical ingredients and key starting materials sourced from the People's Republic of China or another foreign country of concern, including anonymized aggregate data reflecting increases or decreases in such dependence.

"(E) In this paragraph:

"(i) The term 'acquired intermediate' means a material produced during steps in the

manufacture of an active pharmaceutical ingredient that undergoes further molecular change or purification before it becomes an active pharmaceutical ingredient and is manufactured at an establishment other than the establishment at which the active pharmaceutical ingredient is manufactured.

"(ii) The term 'country of origin' means, with respect to an active pharmaceutical ingredient, key starting material, or acquired intermediate, each country in which such ingredient, intermediate, or material was manufactured into its chemical identity through chemical synthesis, fermentation, extraction, purification, or other manufacturing process including each country at which such active pharmaceutical ingredient, key starting material, or acquired intermediate was repackaged, relabeled, finished, blended, or tested.

"(iii) The term 'foreign country of concern' has the meaning given such term in section 10612(a) of the Research and Development, Competition, and Innovation Act.".

(2) CONFIDENTIALITY.—Nothing in the amendment made by paragraph (1) shall be construed as

authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(b) REGULATORY GAP ANALYSIS.—Not later than 180 days after the date of enactment of this Act, the Secretary shall identify and submit to Congress a report describing—

(1) existing regulatory authorities available to the Secretary to support or incentivize the sourcing of active pharmaceutical ingredients and key starting materials from countries other than the People's Republic of China, or from sources with no People's Republic of China origin content; and

(2) any deficiencies in existing regulatory authorities that limit the ability of the Secretary to support or incentivize such sourcing, together with recommendations for legislative or administrative action to address such deficiencies.

(c) REGULATIONS.—The Secretary of Health and Human Services shall—

(1) not later than 90 days after the date of enactment of this Act, issue proposed regulations im-

plementing the amendments made by subsection (a); and

(2) not later than 180 days after issuance of the proposed regulations described in paragraph (1), finalize such regulations.

SEC. 205. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) BAN ON IMPORTS OF DRUGS FROM ESTABLISHMENTS USING FORCED LABOR OR VIOLATING SANCTIONS.—Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended, in the third sentence—

(1) by inserting "or (6) such article is a drug and the safety of such drug is based solely on information or certifications provided by a foreign government, including any inspection described in section 704(i), without routine inspections conducted by United States inspectors to verify compliance with this Act, or (7) such article is a drug and was manufactured, prepared, propagated, compounded, processed in an establishment known to have used forced labor (as defined in section 307 of the Tariff Act of 1930) or to have been in violation of sanctions imposed by the Federal Government under the International Emergency Economic Powers Act or other

applicable law, as determined by the Secretary in consultation with the Secretary of Homeland Security," after "301(cc),"; and

(2) by striking "clauses (1) through (5)" and inserting "clauses (1) through (7)".

(b) DESTRUCTION OF REFUSED ARTICLES PRESENTING SIGNIFICANT PUBLIC HEALTH CONCERNS.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), as amended by section 4, is further amended by adding at the end the following:

"(w) DESTRUCTION OF REFUSED ARTICLES PRESENTING SIGNIFICANT PUBLIC HEALTH CONCERNS.—

"(1) IN GENERAL.—If the Secretary determines that an article that has been refused admission under subsection (a) presents a significant public health concern, the Secretary may issue to the owner or consignee of the article an order to destroy the article, without the opportunity for export.

"(2) DEADLINE; COSTS.—Not later than 90 days after the issuance of an order under paragraph (1), the owner or consignee shall destroy the article. The owner or consignee shall be responsible for the costs of such destruction.

"(3) DUE PROCESS.—The Secretary shall provide to the owner or consignee of an article subject

to an order under paragraph (1) appropriate due process prior to the destruction of the article. Such due process shall include notice and an opportunity to appear before the Secretary and introduce testimony on the destruction, in combination with the notice and opportunity to appear and introduce testimony on the refusal of admission of the article under subsection (a) or separately.".

(c) PROHIBITION ON REGISTRATION OF CERTAIN FOREIGN ESTABLISHMENTS.—Section 510(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) is amended by adding at the end the following:

"(6) Notwithstanding any other provision of this section, any establishment that knowingly used, or partnered with, contracted with, or purchased from an entity that has used, forced labor (as defined in section 307 of the Tariff Act of 1930) or that knowingly violated sanctions imposed by the Federal Government under the International Emergency Economic Powers Act or other applicable law, as determined by the Secretary in consultation with the Secretary of Homeland Security, shall not be eligible for registration under this section, and the Secretary shall revoke any registration of such an establishment that was accepted prior to the date of enactment of the Secure Drug Supply Act of 2026.".

(d) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

"(jjj) The unauthorized movement, or introduction or delivery for introduction into interstate commerce, including export, of an article that is subject to an order for destruction under section 801(v).

"(kkk) The knowing provision of a materially false, fictitious, or fraudulent statement or representation to the Secretary that accompanies or relates to a drug imported or offered for import into the United States.

"(lll) The import or offering for import into the United States of a drug that previously has been refused admission under section 801(a) or exported during the pendency of a detention, unless the person reimporting or reoffering the drug affirmatively makes reference to the original refusal or detention and establishes that the drug complies with the applicable requirements of this Act, as determined by the Secretary.".

(e) MISBRANDED DRUGS.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

"(hh) If it is a drug, including an active pharmaceutical ingredient and key starting material, imported or offered for import and the drug is accompanied by a mate-

rially false, fictitious, or fraudulent statement or representation knowingly made by the person importing the drug or offering the drug for import.".

(f) ADULTERATED DRUGS.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by adding at the end the following:

"(k) If it is an active pharmaceutical ingredient that has not been approved as part of an application under section 505 of this Act or 351 of the Public Health Service Act, or otherwise approved or authorized for use in a drug or device, and it was manufactured, prepared, propagated, compounded, or processed in—

"(1) an establishment that was not inspected within the immediately preceding 3-year period; or

"(2) in the case of an establishment located in a foreign country with which the Secretary has an arrangement or agreement under section 809 to recognize the inspection of establishments by the government or an agency of the government of such country, within the immediately preceding 5-year period.

"(l) If it is a drug that was manufactured, prepared, propagated, compounded, or processed in an establishment that the Secretary, in consultation with the Secretary of Homeland Security, determines—

"(1) knowingly utilizes forced labor (as defined in section 307 of the Tariff Act of 1930; or

"(2) is in violation of sanctions imposed by the Federal Government under the International Emergency Economic Powers Act or other applicable law, including an establishment that is designated to the list of specially designated nationals and blocked persons maintained by the Office of Foreign Assets Control of the Department of the Treasury or owned 50 percent more or more, directly or indirectly, by one or more such designated persons.".

(g) REGULATIONS.—The Secretary of Health and Human Services shall—

(1) not later than 90 days after the date of enactment of this Act, issue proposed regulations implementing the amendments made by this section; and

(2) not later than 180 days after issuance of the proposed regulations described in paragraph (1), finalize such regulations.

(h) APPLICABILITY.—The amendments made by this section shall apply beginning on the date that is 180 days after the final guidance under section 206(2) is issued.

SEC. 206. DEFINING KEY STARTING MATERIAL.

The Secretary of Health and Human Services shall—

(1) not later than 90 days after the date of enactment of this Act, issue draft guidance defining the term "key starting material" for purposes of this title and the amendments made by this title; and

(2) not later than 180 days after the date of enactment of this Act, issue final guidance defining such term for such purposes.