Bernie Sanders

TAM17935 S.L.C.

Amendment #1

AMENDMENT NO._____ Calendar No._____

Purpose: To allow for the importation of safe and affordable drugs by wholesale distributors, pharmacies, and individuals.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

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. SANDERS

Viz:

At the end of title XVIII, add the following:

SEC. 807. IMPORTING AFFORDABLE AND SAFE DRUGS.

(a) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) is amended to read as follows:

"SEC. 804. IMPORTATION OF SAFE AND AFFORDABLE DRUGS BY WHOLESALE DISTRIBUTORS, PHARMACIES, AND INDIVIDUALS.

"(a) IN GENERAL.—Not later than 180 days after the date of enactment of the FDA Reauthorization Act

of 2017, the Secretary shall promulgate regulations permitting the importation of qualifying prescription drugs into the United States, in accordance with this section.

"(b) DEFINITIONS.—For purposes of this section:

"(1) CERTIFIED FOREIGN SELLER.—The term 'certified foreign seller' means a licensed foreign pharmacy or foreign wholesale distributor that the Secretary certifies under subsection (d)(1)(B), that pays the fee required under subsection (d)(1)(C), and that is included on the list described in subsection (e).

"(2) FOREIGN WHOLESALE DISTRIBUTOR.—The term 'foreign wholesale distributor' means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager) engaged in wholesale distribution.

"(3) IMPORTER.—The term 'importer' means a dispenser (as defined in section 581(3)) or wholesale distributor registered under section 503(e) who imports prescription drugs into the United States in accordance with this section.

"(4) LICENSED FOREIGN PHARMACY.—The term 'licensed foreign pharmacy' means a pharmacy

located in Canada, or subject to subsection (e), another applicable country, that—

"(A) operates in accordance with applicable pharmacy standards set forth by the provincial pharmacy rules and regulations enacted in Canada, or, subject to subsection (e), such applicable rules and regulations of the permitted country in which such seller is located; and

"(B) is licensed to operate and dispense prescription drugs to individuals in Canada, or, subject to subsection (e), the permitted country in which the pharmacy is located.

"(5) QUALIFYING PRESCRIPTION DRUG.—The term 'qualifying prescription drug'—

"(A) means a prescription drug that—

"(i) is approved for use in patients, and marketed, in Canada, or subject to subsection (e), approved for use in patients, and marketed, in another permitted country;

"(ii) is manufactured in a facility registered under subsection (b)(1) or (i) of section 510 that is in compliance with good manufacturing practices regulations of the Food and Drug Administration;

"(iii) has the same active ingredient or ingredients, route of administration, and strength as a prescription drug approved under chapter V, or, for purposes of subparagraph (B)(iv), is biosimilar to an approved biological product and has the same route of administration and strength as the approved biological product; and

"(iv) is labeled in accordance with—

"(I) the laws of Canada, or another country from which importation is permitted pursuant to subsection (e); and

"(II) the requirements promulgated by the Secretary, which shall include labeling in English;

"(B) with respect to importers only, includes—

"(i) peritoneal dialysis solution;

"(ii) insulin;

"(iii) a drug for which a risk evaluation and mitigation strategy is required under section 505–1;

"(iv) biological products, as defined in section 351 of the Public Health Service

Act that are proteins (except any chemically synthesized polypeptides) or analogous products; and

"(v) intravenously infused drugs; and

"(C) does not include—

"(i) a controlled substance (as defined in section 102 of the Controlled Substances Act);

"(ii) an anesthetic drug inhaled during surgery; or

"(iii) a compounded drug.

"(6) VALID PRESCRIPTION.—The term 'valid prescription' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—

"(A) a practitioner who has conducted at least one in-person medical evaluation of the patient; or

"(B) a covering practitioner.

"(c) PUBLICATION OF CERTIFIED FOREIGN SELLERS.—The Secretary shall publish on a dedicated Internet Web site a list of certified foreign sellers, including the Internet Web site address, physical address, and telephone number of each such certified foreign seller.

"(d) ADDITIONAL CRITERIA.—

"(1) CERTIFIED FOREIGN SELLERS.—

"(A) IN GENERAL.—To be a certified foreign seller, such seller shall—

"(i) be certified by the Secretary in accordance with subparagraph (B);

"(ii) pay the registration fee established under subparagraph (C); and

"(iii) sell only qualifying prescription drugs to importers or individuals who import prescription drugs into the United States in accordance with this section.

"(B) CERTIFICATION.—To be a certified foreign seller, the Secretary shall certify that such seller—

"(i) is a foreign wholesale distributor or licensed foreign pharmacy operating an establishment, which may include an online foreign pharmacy, that is located in Canada, or, subject to subsection (e), another permitted country;

"(ii) is engaged in the distribution or dispensing of a prescription drug that is imported or offered for importation into the United States;

"(iii) has been in existence for a period of at least 5 years preceding the date of such certification and has a purpose other than to participate in the program established under this section;

"(iv) in the case of a certified foreign seller that is a licensed foreign pharmacy, agrees to dispense a qualifying prescription drug to an individual in the United States only after receiving a valid prescription, as described in paragraph (2)(C);

"(v) has processes established by the seller, or participates in another established process, to certify that the physical premises and data reporting procedures and licenses are in compliance with all applicable laws and regulations of Canada, or, subject to subsection (e), the permitted country in which the seller is located, and has implemented policies designed to monitor ongoing compliance with such laws and regulations;

"(vi) conducts or commits to participate in ongoing and comprehensive quality assurance programs and implements such

quality assurance measures, including blind testing, to ensure the veracity and reliability of the findings of the quality assurance program;

"(vii) agrees that, pursuant to subsection (g), laboratories approved by the Secretary may be authorized to conduct product testing to determine the chemical authenticity of sample pharmaceutical products;

"(viii) agrees to notify the Secretary, importers, and individuals of product recalls in Canada, or pursuant to subsection (e), the permitted country in which the seller is located, and agrees to cease, or refrain from, exporting such product;

"(ix) has established, or will establish or participate in, a process for resolving grievances, as defined by the Secretary, and will be held accountable for violations of established guidelines and rules;

"(x) except as otherwise permitted under this section, does not sell products that the seller could not otherwise legally sell in Canada, or, subject to subsection

(e), the permitted country in which such seller is located to customers in the United States; and

"(xi) meets any other criteria established by the Secretary.

"(C) CERTIFICATION FEE.—Not later than 30 days before the start of each fiscal year, the Secretary shall establish a fee to be collected from foreign sellers for such fiscal year that are certified under subparagraph (B), in an amount that is sufficient, and not more than necessary, to pay the costs of administering the program under this section, and enforcing this section pursuant to section 303(h), for that fiscal year.

"(D) RECERTIFICATION.—A certification under subparagraph (B) shall be in effect for a period of 2 years, or until there is a material change in the circumstances under which the foreign seller meets the requirements under such subparagraph, whichever occurs earlier. A foreign seller may reapply for certification under such subparagraph (B), in accordance with a process established by the Secretary.

"(2) INDIVIDUALS.—An individual may import a qualifying prescription drug described in sub-

section (b) from Canada or another country pursuant to subsection (e) if such drug—

"(A) is dispensed, including through an online pharmacy, by a certified foreign seller that is a licensed foreign pharmacy;

"(B) is purchased for personal use by the individual, not for resale, in quantities that do not exceed a 90-day supply; and

"(C) is filled only after providing to the licensed foreign pharmacy a valid prescription issued by a health care practitioner licensed to practice in a State in the United States.

"(e) IMPORTATION FROM OTHER COUNTRIES.—Beginning on the date that is 2 years after the date on which final regulations are promulgated to carry out this section, if, based on a review of the evidence obtained after such effective date, including the reports submitted under section 807(d) of the FDA Reauthorization Act of 2017, that importation of qualifying prescription drugs from Canada under this section resulted in cost savings for consumers in the United States and increased access to safe medication, the Secretary shall have the authority to permit importation of qualifying prescription drugs by importers and individuals from, in addition to Canada, any country that—

"(1) is a member of the Organisation for Economic Co-operation and Development; and

"(2) has statutory or regulatory standards for the approval and sale of prescription drugs that are comparable to the standards in the United States and that—

"(A) authorizes the approval of drugs only if a drug has been determined to be safe and effective by experts employed by or acting on behalf of a governmental entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs;

"(B) requires that any determination of safety and effectiveness described in subparagraph (A) be made on the basis of adequate and well-controlled investigations, including clinical investigations, as appropriate, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs;

"(C) requires the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of drugs in the country to be adequate to preserve the identity, quality, purity, and strength of the drugs; and

"(D) requires the reporting of adverse reactions to drugs and establish procedures to recall, and withdraw approval of, drugs found not to be safe or effective.

"(f) LABELING.—Any qualifying prescription drug imported that meets the labeling requirements described in subsection (b)(5)(A)(iv) is deemed not misbranded for purposes of section 502.

"(g) DRUG TESTING LABORATORIES.—The Secretary may approve one or more laboratories to conduct random testing of prescription drugs sold by certified foreign sellers to assess the chemical authenticity of such drugs.

"(h) UNFAIR AND DISCRIMINATORY ACTS AND PRACTICES.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing agreement or other agreement)—

"(1) to discriminate by charging a higher price for a prescription drug sold to a certified foreign seller that sells such drug to an importer in accordance with this section than the price that is charged, inclusive of rebates or other incentives to the country from which the drug is exported, to another person that is in the same country and that does not

import such a drug into the United States in accordance with this section;

"(2) except with respect to a prescription drug on the drug shortage list under section 506E, discriminate by denying, restricting, or delaying supplies of a prescription drug to a certified foreign seller, on account of such seller's status as a certified foreign seller, that sells such drug to an importer in accordance with this section, or by publicly, privately, or otherwise refusing to do business with such a certified foreign seller on account of such seller's status as a certified foreign seller;

"(3) cause there to be a difference (including a difference in active ingredient, route of administration, bioequivalence, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and the drug for distribution in Canada or another permitted country, subject to subsection (e), for the purpose of avoiding sales by certified foreign sellers; or

"(4) except with respect to a prescription drug on the drug shortage list under section 506E, engage in any other action to restrict, prohibit, or

delay the importation of a prescription drug under this section.

"(i) INFORMATION AND RECORDS.—

"(1) BIANNUAL REPORTS.—Each importer shall submit biannual reports to the Secretary which shall contain, for each qualifying prescription drug imported into the United States—

"(A) the unique facility identifier of the manufacturer of the drug, described in section 510;

"(B) the transaction information described in section 581(26) (other than the information described in subparagraph (C)); and

"(C) the price paid by the importer for the drug.

"(2) MAINTENANCE OF RECORDS BY SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be appropriate.

"(j) SUSPENSION OF IMPORTATION.—

"(1) PATTERNS OF NONCOMPLIANCE.—The Secretary shall require that importation of a specific qualifying prescription drug or importation by a specific certified foreign seller or importer pursuant to

this section be immediately suspended if the Secretary determines that there is a pattern of importation of such specific drug or by such specific seller or importer that involves counterfeit drugs, drugs that have been recalled or withdrawn, or drugs in violation of any requirement of this section, until an investigation is completed and the Secretary determines that importation of such drug or by such seller or importer does not endanger the public health.

"(2) TEMPORARY SUSPENSION.—The Secretary may require that importation of a specific qualifying prescription drug or importation by a specific certified foreign seller or importer pursuant to this section be temporarily suspended if, with respect to such drug, seller, or importer, there is a violation of any requirement of this section or if the Secretary determines that importation of such drug or by such seller or importer might endanger the public health. Such temporary suspension shall apply until the Secretary completes an investigation and determines that importation of such drug or by such seller or importer does not endanger the public health.

"(k) SUPPLY CHAIN SECURITY.—

"(1) PURCHASE FROM REGISTERED FACILITIES AND CERTIFIED FOREIGN SELLERS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), certified foreign sellers who sell qualifying prescription drugs for importation into the United States pursuant to this section may purchase such drugs only from manufacturers or entities registered under section 510 or other certified foreign sellers.

"(B) EXCEPTION.—Certified foreign sellers who sell qualifying prescription drugs for importation into the United States pursuant to this section may purchase such drugs from foreign sellers in Canada or another permitted country, even if such foreign seller is not a manufacturer registered under section 510 or a certified foreign seller, if the Secretary enters into a memorandum of understanding or cooperative agreement with Canada, or such other permitted country, to ensure compliance, to the extent appropriate and feasible, with subchapter H of chapter V. The Secretary shall seek to enter into such a memorandum of understanding or cooperative agreement with Canada and each country from which importation is permitted under subsection (e).

"(2) IMPORTATION TRACING.—Certified foreign sellers shall provide importers with the unique facility identifier associated with the manufacturer registered under section 510 of the qualifying prescription drug and the information under paragraph (25), paragraph (26) (other than subparagraph (C)), and subparagraphs (D), (F), and (G) of paragraph (27) of section 581. Certified foreign sellers shall provide such information to individuals purchasing such drugs, upon request.

"(l) REMS.—In the case of an importer that imports a qualifying prescription drug, where the drug with the same active ingredient or ingredients (or that is biosimilar to an approved biological product), route of administration, and strength that is approved under chapter V or section 351 of the Public Health Service Act is subject to elements to assure safe use under section 505–1, such importer shall be subject to such elements to assure safe use, as applicable and appropriate.

"(m) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.".

(b) PENALTIES WITH RESPECT TO ONLINE PHARMACIES.—Section 303 of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

"(h) In the case of person operating an Internet website, whether in the United States or in another country, that violates section 301(aa) by—

"(1) selling, by means of the Internet, with the intent to defraud or mislead or with reckless disregard for safety of the public, an adulterated or counterfeit drug to an individual in the United States; or

"(2) dispenses, by means of the Internet, a drug to an individual in the United States who the person knows or has reasonable cause to believe, does not possess a valid prescription for that drug, such person shall be imprisoned for not more than 10 years or fined not more than $250,000.".

(c) NO PREEMPTION.—Nothing in this section, including the amendments made by this section, shall be construed to preempt, alter, displace, abridge, or supplant any remedy available under any State or Federal law, including common law, that provides a remedy for civil relief.

(d) REPORTS.—

(1) HHS.—Not later than 1 year after the date on which final regulations are promulgated to carry

out section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384), as amended by this section, and every 2 years thereafter, the Secretary of Health and Human Services, after consultation with appropriate Federal agencies, shall submit to Congress and make public a report on the importation of drugs into the United States.

(2) GAO REPORT.—Not later than 18 months after the date on which final regulations are promulgated to carry out section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384), as amended by this section, the Comptroller General of the United States shall submit to Congress a report containing an analysis of the implementation of the amendments made by this section, including a review of drug safety and cost-savings and expenses, including cost-savings to consumers in the United States and trans-shipment and importation tracing processes, resulting from such implementation.