Bernie Sanders
Sanders #1

AMENDMENT NO._____ Calendar No._____

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

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 4348

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 _____

Viz:

Strike section 906 and insert the following:

SEC. 906. IMPORTING AFFORDABLE AND SAFE DRUGS.

(a) IN GENERAL.—

(1) AMENDMENT.—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 Food and Drug Administration Safety and Landmark Advancements Act of 2022, the Secretary shall promulgate regulations, to replace the regulations described in section 906(a)(2)(A) of such Act, 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 (c).

"(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, the United Kingdom, 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, the United Kingdom, 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, the United Kingdom, 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, the United Kingdom, 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, the United Kingdom, 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 website a list of certified foreign sellers, including the internet website 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, the United Kingdom, 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, the United Kingdom, 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, the United Kingdom, 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, the United Kingdom, 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 violations of section 301(aa), 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 subsection (b) from Canada, the United Kingdom, 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 906(c) of the Food and Drug Administration Safety and Landmark Advancements Act of 2022, that importation of qualifying prescription drugs from Canada or the United Kingdom 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 and the United Kingdom, 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.—

"(1) IN GENERAL.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing agreement or other agreement)—

"(A) 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;

"(B) to 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, the United Kingdom, or another permitted country, subject to subsection (e), for the purpose of avoiding sales by certified foreign sellers; or

"(C) except with respect to a prescription drug on the drug shortage list under section 506E, to engage in any other action to restrict, prohibit, or delay the importation of a prescription drug under this section.

"(2) DENYING, RESTRICTING, OR DELAYING SUPPLIES TO CERTIFIED FOREIGN SELLERS.—A certified foreign seller may utilize remedies available under contract law to prevent a manufacturer from denying, restricting, or delaying supplies of a prescription drug to the seller on account of the seller's status as a certified foreign seller.

"(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, as required under subsection (d)(1)(F) of this section as in effect on the day before the date of enactment of the Food and Drug Administration Safety and Landmark Advancements Act of 2022.

"(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 Sec-

retary 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.

"(3) PROCEDURE FOR INVESTIGATIONS.—The Secretary shall—

"(A) initiate any investigation—

"(i) under paragraph (1) not later than 30 days after the date on which the Secretary makes the determination described in such paragraph; and

"(ii) as applicable, under paragraph (2) not later than 30 days after the date on which the Secretary orders the suspension described in such paragraph; and

"(B) subject to paragraph (5), complete any investigation under paragraph (1) or (2) not later than 90 days after the date on which the Secretary initiates such investigation.

"(4) WRITTEN DECISION.—Upon the conclusion of an investigation under paragraph (1) or (2), the Secretary shall issue a decision in writing to the affected parties. Such decision shall—

"(A) permit the seller or importer to resume importation activities under this section; or

"(B) provide specific reasons for why the seller or importer may not resume importation activities under this section and what actions the seller can take, if applicable, to comply with the requirements under this section.

"(5) EXTENSION.—The Secretary may extend an investigation under paragraph (1) or (2) past the required completion date under paragraph (3)(B) if the Secretary provides specific reasons to Congress for the need to extend the investigation. In the case of such an extension, the Secretary shall issue a decision under paragraph (4) to the affected parties not later than 90 days after the date on which the Secretary issues the reasons for the extension.

"(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, the United Kingdom, 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, the United Kingdom, 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, the United Kingdom, 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.".

(2) APPLICABILITY OF EXISTING REGULATIONS.—

(A) IN GENERAL.—The regulations published at part 251 of title 21 of the Code of Federal Regulations, as in effect on the day before the date of enactment of this Act, shall be deemed promulgated under section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384), as amended by paragraph (1), and remain in effect until the date on which regulations are promulgated under subsection (a) of such section.

(B) PREVIOUSLY AUTHORIZED PROGRAMS.—Any program of a State or Indian Tribe that, on the day before the date of enact-

ment of this Act, was authorized, or was pending authorization pursuant to an application submitted for such authorization, under section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384), as in effect on the day before such date of enactment, may, at the discretion of the Secretary of Health and Human Services, be authorized under section 804 of such Act, as amended by paragraph (1), subject to any requirements or conditions for such authorization under such section as in effect on the day before such date of enactment (including the regulations described in subparagraph (A)), through the 2-year period of such authorization.

(b) 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.

(c) REPORTS.—

(1) HHS.—Not later than 1 year after the date on which final regulations are promulgated under 804(a) of the Federal Food, Drug, and Cosmetic Act

(21 U.S.C. 384(a)), 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 under section 804(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(a)), 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.