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116TH CONGRESS
1ST SESSION

H. R. 1478

To amend the Federal Food, Drug, and Cosmetic Act to allow for the importation of affordable and safe insulin by wholesale distributors, pharmacies, and individuals.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 28, 2019

Mr. WELCH (for himself and Mr. ROONEY of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow for the importation of affordable and safe insulin by wholesale distributors, pharmacies, and individuals.

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 ''Affordable Insulin Act of 2019''.

SEC. 2. IMPORTING AFFORDABLE AND SAFE INSULIN.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 804 of such Act (21 U.S.C. 384) the following:

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

''(a) IN GENERAL.—

''(1) REGULATION.—Not later than 180 days after the date of enactment of this section, the Secretary shall promulgate regulations permitting the importation of qualifying insulin into the United States, in accordance with this section.

''(2) RELATION TO SECTION 804.—Nothing in section 804 shall be construed to supercede or limit the provisions of 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 insulin 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 insulin to individuals in Canada, or, subject to subsection (e), the permitted country in which the pharmacy is located.

''(5) QUALIFYING INSULIN.—The term 'qualifying insulin' means insulin that—

''(A) 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;

''(B) 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;

''(C) has the same active ingredient or ingredients, route of administration, and strength as an insulin approved under chapter V, or is biosimilar to an approved biological product and has the same route of administration and strength as the approved biological product; and

''(D) 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;

''(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 1 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 insulin to importers or individuals who import insulin 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 Can-

ada, or, subject to subsection (e), another permitted country;

"(ii) is engaged in the distribution or dispensing of an insulin 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 qualifying insulin 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 insulin testing to determine the chemical authenticity of sample insulin products;

''(viii) agrees to notify the Secretary, importers, and individuals of insulin 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 insulin;

''(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 insulin described in subsection (b) from Canada or another country pursuant to subsection (e) if such qualifying insulin—

''(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; 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 2(d) of the Affordable Insulin Act of 2019, that importation of qualifying insulin from Canada under this section resulted in cost savings for consumers in the

United States and increased access to safe insulin, the Secretary shall have the authority to permit importation of qualifying insulin 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 insulin that are comparable to the standards in the United States and that—

''(A) authorize 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) require 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) require the methods used in, and the facilities and controls used for, the manufac-

ture, processing, and packing of drugs in the country to be adequate to preserve the identity, quality, purity, and strength of the drugs; and

''(D) require 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 insulin imported that meets the labeling requirements described in subsection (b)(5)(A)(iv) is deemed not misbranded for purposes of section 502.

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

''(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 an insulin sold to a certified foreign seller that sells such insulin 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 insulin is exported, to another person that

is in the same country and that does not import such insulin into the United States in accordance with this section;

''(2) except with respect to an insulin on the drug shortage list under section 506E, discriminate by denying, restricting, or delaying supplies of an insulin to a certified foreign seller, on account of such seller's status as a certified foreign seller, that sells such insulin 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 insulin) between an insulin for distribution in the United States and the insulin 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 an insulin on the drug shortage list under section 506E, engage in

any other action to restrict, prohibit, or delay the importation of an insulin 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 insulin imported into the United States—

''(A) the unique facility identifier of the manufacturer of the insulin, 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 insulin.

''(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 insulin or importation by a specific certified foreign seller or importer pursuant to this sec-

tion be immediately suspended if the Secretary determines that there is a pattern of importation of such specific insulin 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 insulin or importation by a specific certified foreign seller or importer pursuant to this section be temporarily suspended if, with respect to such insulin, seller, or importer, there is a violation of any requirement of this section or if the Secretary determines that importation of such insulin 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 insulin 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 insulin for importation into the United States pursuant to this section may purchase such insulin only from manufacturers or entities registered under section 510 or other certified foreign sellers.

"(B) EXCEPTION.—Certified foreign sellers who sell qualifying insulin for importation into the United States pursuant to this section may purchase such insulin 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 insulin 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 insulin, upon request.

''(l) REMS.—In the case of an importer that imports a qualifying insulin, where the insulin has the same active ingredient or ingredients, route of administration, and strength as an insulin approved under chapter V, or is biosimilar to an approved biological product and has the same route of administration and strength as the approved biological product, and where the approved product 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 insulin, 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 Act, including the amendments made by this Act, 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 804A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384), as added by this Act, 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 insulin 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 804A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384), as added by this Act, 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 Act, 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.

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