

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Affordable Insulin Act
5 of 2019”.

6 **SEC. 2. IMPORTING AFFORDABLE AND SAFE INSULIN.**

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

1 **“SEC. 804A. IMPORTATION OF SAFE AND AFFORDABLE IN-**
2 **SULIN BY WHOLESALE DISTRIBUTORS, PHAR-**
3 **MACIES, AND INDIVIDUALS.**

4 “(a) IN GENERAL.—

5 “(1) REGULATION.—Not later than 180 days
6 after the date of enactment of this section, the Sec-
7 retary shall promulgate regulations permitting the
8 importation of qualifying insulin into the United
9 States, in accordance with this section.

10 “(2) RELATION TO SECTION 804.—Nothing in
11 section 804 shall be construed to supercede or limit
12 the provisions of this section.

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

14 “(1) CERTIFIED FOREIGN SELLER.—The term
15 ‘certified foreign seller’ means a licensed foreign
16 pharmacy or foreign wholesale distributor that the
17 Secretary certifies under subsection (d)(1)(B), that
18 pays the fee required under subsection (d)(1)(C),
19 and that is included on the list described in sub-
20 section (c).

21 “(2) FOREIGN WHOLESALE DISTRIBUTOR.—
22 The term ‘foreign wholesale distributor’ means a
23 person (other than a manufacturer, a manufactur-
24 er’s co-licensed partner, a third-party logistics pro-
25 vider, or a repackager) engaged in wholesale dis-
26 tribution.

1 “(3) IMPORTER.—The term ‘importer’ means a
2 dispenser (as defined in section 581(3)) or wholesale
3 distributor registered under section 503(e) who im-
4 ports insulin into the United States in accordance
5 with this section.

6 “(4) LICENSED FOREIGN PHARMACY.—The
7 term ‘licensed foreign pharmacy’ means a pharmacy
8 located in Canada, or subject to subsection (e), an-
9 other applicable country, that—

10 “(A) operates in accordance with applica-
11 ble pharmacy standards set forth by the provin-
12 cial pharmacy rules and regulations enacted in
13 Canada, or, subject to subsection (e), such ap-
14 plicable rules and regulations of the permitted
15 country in which such seller is located; and

16 “(B) is licensed to operate and dispense in-
17 sulin to individuals in Canada, or, subject to
18 subsection (e), the permitted country in which
19 the pharmacy is located.

20 “(5) QUALIFYING INSULIN.—The term ‘quali-
21 fying insulin’ means insulin that—

22 “(A) is approved for use in patients, and
23 marketed, in Canada, or subject to subsection
24 (e), approved for use in patients, and marketed,
25 in another permitted country;

1 “(B) is manufactured in a facility reg-
2 istered under subsection (b)(1) or (i) of section
3 510 that is in compliance with good manufac-
4 turing practices regulations of the Food and
5 Drug Administration;

6 “(C) has the same active ingredient or in-
7 gredients, route of administration, and strength
8 as an insulin approved under chapter V, or is
9 biosimilar to an approved biological product and
10 has the same route of administration and
11 strength as the approved biological product; and

12 “(D) is labeled in accordance with—

13 “(i) the laws of Canada, or another
14 country from which importation is per-
15 mitted pursuant to subsection (e); and

16 “(ii) the requirements promulgated by
17 the Secretary, which shall include labeling
18 in English;

19 “(6) VALID PRESCRIPTION.—The term ‘valid
20 prescription’ means a prescription that is issued for
21 a legitimate medical purpose in the usual course of
22 professional practice by—

23 “(A) a practitioner who has conducted at
24 least 1 in-person medical evaluation of the pa-
25 tient; or

1 “(B) a covering practitioner.

2 “(c) PUBLICATION OF CERTIFIED FOREIGN SELL-
3 ERS.—The Secretary shall publish on a dedicated internet
4 website a list of certified foreign sellers, including the
5 internet website address, physical address, and telephone
6 number of each such certified foreign seller.

7 “(d) ADDITIONAL CRITERIA.—

8 “(1) CERTIFIED FOREIGN SELLERS.—

9 “(A) IN GENERAL.—To be a certified for-
10 eign seller, such seller shall—

11 “(i) be certified by the Secretary in
12 accordance with subparagraph (B);

13 “(ii) pay the registration fee estab-
14 lished under subparagraph (C); and

15 “(iii) sell only qualifying insulin to im-
16 porters or individuals who import insulin
17 into the United States in accordance with
18 this section.

19 “(B) CERTIFICATION.—To be a certified
20 foreign seller, the Secretary shall certify that
21 such seller—

22 “(i) is a foreign wholesale distributor
23 or licensed foreign pharmacy operating an
24 establishment, which may include an online
25 foreign pharmacy, that is located in Can-

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

3 “(ii) is engaged in the distribution or
4 dispensing of an insulin that is imported or
5 offered for importation into the United
6 States;

7 “(iii) has been in existence for a pe-
8 riod of at least 5 years preceding the date
9 of such certification and has a purpose
10 other than to participate in the program
11 established under this section;

12 “(iv) in the case of a certified foreign
13 seller that is a licensed foreign pharmacy,
14 agrees to dispense qualifying insulin to an
15 individual in the United States only after
16 receiving a valid prescription, as described
17 in paragraph (2)(C);

18 “(v) has processes established by the
19 seller, or participates in another estab-
20 lished process, to certify that the physical
21 premises and data reporting procedures
22 and licenses are in compliance with all ap-
23 plicable laws and regulations of Canada,
24 or, subject to subsection (e), the permitted
25 country in which the seller is located, and

1 has implemented policies designed to mon-
2 itor ongoing compliance with such laws
3 and regulations;

4 “(vi) conducts or commits to partici-
5 pate in ongoing and comprehensive quality
6 assurance programs and implements such
7 quality assurance measures, including
8 blind testing, to ensure the veracity and re-
9 liability of the findings of the quality as-
10 surance program;

11 “(vii) agrees that, pursuant to sub-
12 section (g), laboratories approved by the
13 Secretary may be authorized to conduct in-
14 sulin testing to determine the chemical au-
15 thenticity of sample insulin products;

16 “(viii) agrees to notify the Secretary,
17 importers, and individuals of insulin recalls
18 in Canada, or pursuant to subsection (e),
19 the permitted country in which the seller is
20 located, and agrees to cease, or refrain
21 from, exporting such insulin;

22 “(ix) has established, or will establish
23 or participate in, a process for resolving
24 grievances, as defined by the Secretary,

1 and will be held accountable for violations
2 of established guidelines and rules;

3 “(x) except as otherwise permitted
4 under this section, does not sell products
5 that the seller could not otherwise legally
6 sell in Canada, or, subject to subsection
7 (e), the permitted country in which such
8 seller is located to customers in the United
9 States; and

10 “(xi) meets any other criteria estab-
11 lished by the Secretary.

12 “(C) CERTIFICATION FEE.—Not later than
13 30 days before the start of each fiscal year, the
14 Secretary shall establish a fee to be collected
15 from foreign sellers for such fiscal year that are
16 certified under subparagraph (B), in an amount
17 that is sufficient, and not more than necessary,
18 to pay the costs of administering the program
19 under this section, and enforcing this section
20 pursuant to section 303(h), for that fiscal year.

21 “(D) RECERTIFICATION.—A certification
22 under subparagraph (B) shall be in effect for a
23 period of 2 years, or until there is a material
24 change in the circumstances under which the
25 foreign seller meets the requirements under

1 such subparagraph, whichever occurs earlier. A
2 foreign seller may reapply for certification
3 under such subparagraph (B), in accordance
4 with a process established by the Secretary.

5 “(2) INDIVIDUALS.—An individual may import
6 a qualifying insulin described in subsection (b) from
7 Canada or another country pursuant to subsection
8 (e) if such qualifying insulin—

9 “(A) is dispensed, including through an
10 online pharmacy, by a certified foreign seller
11 that is a licensed foreign pharmacy;

12 “(B) is purchased for personal use by the
13 individual, not for resale; and

14 “(C) is filled only after providing to the li-
15 censed foreign pharmacy a valid prescription
16 issued by a health care practitioner licensed to
17 practice in a State in the United States.

18 “(e) IMPORTATION FROM OTHER COUNTRIES.—Be-
19 ginning on the date that is 2 years after the date on which
20 final regulations are promulgated to carry out this section,
21 if, based on a review of the evidence obtained after such
22 effective date, including the reports submitted under sec-
23 tion 2(d) of the Affordable Insulin Act of 2019, that im-
24 portation of qualifying insulin from Canada under this
25 section resulted in cost savings for consumers in the

1 United States and increased access to safe insulin, the
2 Secretary shall have the authority to permit importation
3 of qualifying insulin by importers and individuals from,
4 in addition to Canada, any country that—

5 “(1) is a member of the Organisation for Eco-
6 nomic Co-operation and Development; and

7 “(2) has statutory or regulatory standards for
8 the approval and sale of insulin that are comparable
9 to the standards in the United States and that—

10 “(A) authorize the approval of drugs only
11 if a drug has been determined to be safe and
12 effective by experts employed by or acting on
13 behalf of a governmental entity and qualified by
14 scientific training and experience to evaluate
15 the safety and effectiveness of drugs;

16 “(B) require that any determination of
17 safety and effectiveness described in subpara-
18 graph (A) be made on the basis of adequate
19 and well-controlled investigations, including
20 clinical investigations, as appropriate, con-
21 ducted by experts qualified by scientific training
22 and experience to evaluate the safety and effec-
23 tiveness of drugs;

24 “(C) require the methods used in, and the
25 facilities and controls used for, the manufac-

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

4 “(D) require the reporting of adverse reac-
5 tions to drugs and establish procedures to re-
6 call, and withdraw approval of, drugs found not
7 to be safe or effective.

8 “(f) LABELING.—Any qualifying insulin imported
9 that meets the labeling requirements described in sub-
10 section (b)(5)(A)(iv) is deemed not misbranded for pur-
11 poses of section 502.

12 “(g) INSULIN TESTING LABORATORIES.—The Sec-
13 retary may approve one or more laboratories to conduct
14 random testing of insulin sold by certified foreign sellers
15 to assess the chemical authenticity of such insulin.

16 “(h) UNFAIR AND DISCRIMINATORY ACTS AND PRAC-
17 TICES.—It is unlawful for a manufacturer, directly or indi-
18 rectly (including by being a party to a licensing agreement
19 or other agreement)—

20 “(1) to discriminate by charging a higher price
21 for an insulin sold to a certified foreign seller that
22 sells such insulin to an importer in accordance with
23 this section than the price that is charged, inclusive
24 of rebates or other incentives to the country from
25 which the insulin is exported, to another person that

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

4 “(2) except with respect to an insulin on the
5 drug shortage list under section 506E, discriminate
6 by denying, restricting, or delaying supplies of an in-
7 sulin to a certified foreign seller, on account of such
8 seller’s status as a certified foreign seller, that sells
9 such insulin to an importer in accordance with this
10 section, or by publicly, privately, or otherwise refus-
11 ing to do business with such a certified foreign seller
12 on account of such seller’s status as a certified for-
13 eign seller;

14 “(3) cause there to be a difference (including a
15 difference in active ingredient, route of administra-
16 tion, bioequivalence, strength, formulation, manufac-
17 turing establishment, manufacturing process, or per-
18 son that manufactures the insulin) between an insu-
19 lin for distribution in the United States and the in-
20 sulin for distribution in Canada or another per-
21 mitted country, subject to subsection (e), for the
22 purpose of avoiding sales by certified foreign sellers;
23 or

24 “(4) except with respect to an insulin on the
25 drug shortage list under section 506E, engage in

1 any other action to restrict, prohibit, or delay the
2 importation of an insulin under this section.

3 “(i) INFORMATION AND RECORDS.—

4 “(1) BIENNIAL REPORTS.—Each importer shall
5 submit biennial reports to the Secretary which shall
6 contain, for each qualifying insulin imported into the
7 United States—

8 “(A) the unique facility identifier of the
9 manufacturer of the insulin, described in sec-
10 tion 510;

11 “(B) the transaction information described
12 in section 581(26) (other than the information
13 described in subparagraph (C)); and

14 “(C) the price paid by the importer for the
15 insulin.

16 “(2) MAINTENANCE OF RECORDS BY SEC-
17 RETARY.—The Secretary shall maintain information
18 and documentation submitted under paragraph (1)
19 for such period of time as the Secretary determines
20 to be appropriate.

21 “(j) SUSPENSION OF IMPORTATION.—

22 “(1) PATTERNS OF NONCOMPLIANCE.—The
23 Secretary shall require that importation of a specific
24 qualifying insulin or importation by a specific cer-
25 tified foreign seller or importer pursuant to this sec-

1 tion be immediately suspended if the Secretary de-
2 termines that there is a pattern of importation of
3 such specific insulin or by such specific seller or im-
4 porter that involves counterfeit drugs, drugs that
5 have been recalled or withdrawn, or drugs in viola-
6 tion of any requirement of this section, until an in-
7 vestigation is completed and the Secretary deter-
8 mines that importation of such drug or by such sell-
9 er or importer does not endanger the public health.

10 “(2) TEMPORARY SUSPENSION.—The Secretary
11 may require that importation of a specific qualifying
12 insulin or importation by a specific certified foreign
13 seller or importer pursuant to this section be tempo-
14 rarily suspended if, with respect to such insulin, sell-
15 er, or importer, there is a violation of any require-
16 ment of this section or if the Secretary determines
17 that importation of such insulin or by such seller or
18 importer might endanger the public health. Such
19 temporary suspension shall apply until the Secretary
20 completes an investigation and determines that im-
21 portation of such insulin or by such seller or im-
22 porter does not endanger the public health.

23 “(k) SUPPLY CHAIN SECURITY.—

24 “(1) PURCHASE FROM REGISTERED FACILITIES
25 AND CERTIFIED FOREIGN SELLERS.—

1 “(A) IN GENERAL.—Except as provided in
2 subparagraph (B), certified foreign sellers who
3 sell qualifying insulin for importation into the
4 United States pursuant to this section may pur-
5 chase such insulin only from manufacturers or
6 entities registered under section 510 or other
7 certified foreign sellers.

8 “(B) EXCEPTION.—Certified foreign sellers
9 who sell qualifying insulin for importation into
10 the United States pursuant to this section may
11 purchase such insulin from foreign sellers in
12 Canada or another permitted country, even if
13 such foreign seller is not a manufacturer reg-
14 istered under section 510 or a certified foreign
15 seller, if the Secretary enters into a memo-
16 randum of understanding or cooperative agree-
17 ment with Canada, or such other permitted
18 country, to ensure compliance, to the extent ap-
19 propriate and feasible, with subchapter H of
20 chapter V. The Secretary shall seek to enter
21 into such a memorandum of understanding or
22 cooperative agreement with Canada and each
23 country from which importation is permitted
24 under subsection (e).

1 “(2) IMPORTATION TRACING.—Certified foreign
2 sellers shall provide importers with the unique facil-
3 ity identifier associated with the manufacturer reg-
4 istered under section 510 of the qualifying insulin
5 and the information under paragraph (25), para-
6 graph (26) (other than subparagraph (C)), and sub-
7 paragraphs (D), (F), and (G) of paragraph (27) of
8 section 581. Certified foreign sellers shall provide
9 such information to individuals purchasing such in-
10 sulin, upon request.

11 “(l) REMS.—In the case of an importer that imports
12 a qualifying insulin, where the insulin has the same active
13 ingredient or ingredients, route of administration, and
14 strength as an insulin approved under chapter V, or is
15 biosimilar to an approved biological product and has the
16 same route of administration and strength as the approved
17 biological product, and where the approved product is sub-
18 ject to elements to assure safe use under section 505–1,
19 such importer shall be subject to such elements to assure
20 safe use, as applicable and appropriate.

21 “(m) CONSTRUCTION.—Nothing in this section limits
22 the authority of the Secretary relating to the importation
23 of insulin, other than with respect to section 801(d)(1)
24 as provided in this section.”.

1 (b) PENALTIES WITH RESPECT TO ONLINE PHAR-
2 MACIES.—Section 303 of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 333) is amended by adding at
4 the end the following:

5 “(h) In the case of person operating an internet
6 website, whether in the United States or in another coun-
7 try, that violates section 301(aa) by—

8 “(1) selling, by means of the internet, with the
9 intent to defraud or mislead or with reckless dis-
10 regard for safety of the public, an adulterated or
11 counterfeit drug to an individual in the United
12 States; or

13 “(2) dispenses, by means of the internet, a drug
14 to an individual in the United States who the person
15 knows or has reasonable cause to believe, does not
16 possess a valid prescription for that drug,
17 such person shall be imprisoned for not more than 10
18 years or fined not more than \$250,000.”.

19 (c) NO PREEMPTION.—Nothing in this Act, including
20 the amendments made by this Act, shall be construed to
21 preempt, alter, displace, abridge, or supplant any remedy
22 available under any State or Federal law, including com-
23 mon law, that provides a remedy for civil relief.

24 (d) REPORTS.—

1 (1) HHS.—Not later than 1 year after the date
2 on which final regulations are promulgated to carry
3 out section 804A of the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 384), as added by this Act,
5 and every 2 years thereafter, the Secretary of
6 Health and Human Services, after consultation with
7 appropriate Federal agencies, shall submit to Con-
8 gress and make public a report on the importation
9 of insulin into the United States.

10 (2) GAO REPORT.—Not later than 18 months
11 after the date on which final regulations are promul-
12 gated to carry out section 804A of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 384), as
14 added by this Act, the Comptroller General of the
15 United States shall submit to Congress a report con-
16 taining an analysis of the implementation of the
17 amendments made by this Act, including a review of
18 drug safety and cost-savings and expenses, including
19 cost-savings to consumers in the United States and
20 trans-shipment and importation tracing processes,
21 resulting from such implementation.

○