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

IN THE SENATE OF THE UNITED STATES

JANUARY 10, 2019

Mr. SANDERS (for himself, Mr. BOOKER, Mr. CASEY, Ms. BALDWIN, Mr. BLUMENTHAL, Mr. BROWN, Ms. CANTWELL, Mrs. GILLIBRAND, Ms. HARRIS, Ms. HASSAN, Mr. HEINRICH, Mr. KING, Mr. LEAHY, Ms. KLOBUCHAR, Mr. MANCHIN, Mr. MERKLEY, Mr. REED, Mrs. SHAHEEN, Ms. SMITH, Ms. STABENOW, Mr. UDALL, Mr. VAN HOLLEN, Ms. WARREN, and Mr. WHITEHOUSE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow for the importation of affordable and safe drugs 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 and Safe
5 Prescription Drug Importation Act”.

1 **SEC. 2. IMPORTING AFFORDABLE AND SAFE DRUGS.**

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

5 **“SEC. 804. IMPORTATION OF SAFE AND AFFORDABLE**
6 **DRUGS BY WHOLESALE DISTRIBUTORS,**
7 **PHARMACIES, AND INDIVIDUALS.**

8 “(a) IN GENERAL.—Not later than 180 days after
9 the date of enactment of the Affordable and Safe Prescrip-
10 tion Drug Importation Act, the Secretary shall promulgate
11 regulations permitting the importation of qualifying pre-
12 scription drugs into the United States, in accordance with
13 this section.

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

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

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

1 vider, or a repackager) engaged in wholesale dis-
2 tribution.

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

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

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

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

22 “(5) QUALIFYING PRESCRIPTION DRUG.—The
23 term ‘qualifying prescription drug’—

24 “(A) means a prescription drug that—

1 “(i) is approved for use in patients,
2 and marketed, in Canada, or subject to
3 subsection (e), approved for use in pa-
4 tients, and marketed, in another permitted
5 country;

6 “(ii) is manufactured in a facility reg-
7 istered under subsection (b)(1) or (i) of
8 section 510 that is in compliance with good
9 manufacturing practices regulations of the
10 Food and Drug Administration;

11 “(iii) has the same active ingredient
12 or ingredients, route of administration, and
13 strength as a prescription drug approved
14 under chapter V, or, for purposes of sub-
15 paragraph (B)(iv), is biosimilar to an ap-
16 proved biological product and has the same
17 route of administration and strength as the
18 approved biological product; and

19 “(iv) is labeled in accordance with—

20 “(I) the laws of Canada, or an-
21 other country from which importation
22 is permitted pursuant to subsection
23 (e); and

1 “(II) the requirements promul-
2 gated by the Secretary, which shall in-
3 clude labeling in English;

4 “(B) with respect to importers only, in-
5 cludes—

6 “(i) peritoneal dialysis solution;

7 “(ii) insulin;

8 “(iii) a drug for which a risk evalua-
9 tion and mitigation strategy is required
10 under section 505-1;

11 “(iv) biological products, as defined in
12 section 351 of the Public Health Service
13 Act that are proteins (except any chemi-
14 cally synthesized polypeptides) or analo-
15 gous products; and

16 “(v) intravenously infused drugs; and

17 “(C) does not include—

18 “(i) a controlled substance (as defined
19 in section 102 of the Controlled Sub-
20 stances Act);

21 “(ii) an anesthetic drug inhaled dur-
22 ing surgery; or

23 “(iii) a compounded drug.

24 “(6) VALID PRESCRIPTION.—The term ‘valid
25 prescription’ means a prescription that is issued for

1 a legitimate medical purpose in the usual course of
2 professional practice by—

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

6 “(B) a covering practitioner.

7 “(c) PUBLICATION OF CERTIFIED FOREIGN SELL-
8 ERS.—The Secretary shall publish on a dedicated internet
9 website a list of certified foreign sellers, including the
10 internet website address, physical address, and telephone
11 number of each such certified foreign seller.

12 “(d) ADDITIONAL CRITERIA.—

13 “(1) CERTIFIED FOREIGN SELLERS.—

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

16 “(i) be certified by the Secretary in
17 accordance with subparagraph (B);

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

20 “(iii) sell only qualifying prescription
21 drugs to importers or individuals who im-
22 port prescription drugs into the United
23 States in accordance with this section.

1 “(B) CERTIFICATION.—To be a certified
2 foreign seller, the Secretary shall certify that
3 such seller—

4 “(i) is a foreign wholesale distributor
5 or licensed foreign pharmacy operating an
6 establishment, which may include an online
7 foreign pharmacy, that is located in Can-
8 ada, or, subject to subsection (e), another
9 permitted country;

10 “(ii) is engaged in the distribution or
11 dispensing of a prescription drug that is
12 imported or offered for importation into
13 the United States;

14 “(iii) has been in existence for a pe-
15 riod of at least 5 years preceding the date
16 of such certification and has a purpose
17 other than to participate in the program
18 established under this section;

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

1 “(v) has processes established by the
2 seller, or participates in another estab-
3 lished process, to certify that the physical
4 premises and data reporting procedures
5 and licenses are in compliance with all ap-
6 plicable laws and regulations of Canada,
7 or, subject to subsection (e), the permitted
8 country in which the seller is located, and
9 has implemented policies designed to mon-
10 itor ongoing compliance with such laws
11 and regulations;

12 “(vi) conducts or commits to partici-
13 pate in ongoing and comprehensive quality
14 assurance programs and implements such
15 quality assurance measures, including
16 blind testing, to ensure the veracity and re-
17 liability of the findings of the quality as-
18 surance program;

19 “(vii) agrees that, pursuant to sub-
20 section (g), laboratories approved by the
21 Secretary may be authorized to conduct
22 product testing to determine the chemical
23 authenticity of sample pharmaceutical
24 products;

1 “(viii) agrees to notify the Secretary,
2 importers, and individuals of product re-
3 calls in Canada, or pursuant to subsection
4 (e), the permitted country in which the
5 seller is located, and agrees to cease, or re-
6 frain from, exporting such product;

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

12 “(x) except as otherwise permitted
13 under this section, does not sell products
14 that the seller could not otherwise legally
15 sell in Canada, or, subject to subsection
16 (e), the permitted country in which such
17 seller is located to customers in the United
18 States; and

19 “(xi) meets any other criteria estab-
20 lished by the Secretary.

21 “(C) CERTIFICATION FEE.—Not later than
22 30 days before the start of each fiscal year, the
23 Secretary shall establish a fee to be collected
24 from foreign sellers for such fiscal year that are
25 certified under subparagraph (B), in an amount

1 that is sufficient, and not more than necessary,
2 to pay the costs of administering the program
3 under this section, and enforcing this section
4 pursuant to section 303(h), for that fiscal year.

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

14 “(2) INDIVIDUALS.—An individual may import
15 a qualifying prescription drug described in sub-
16 section (b) from Canada or another country pursu-
17 ant to subsection (e) if such drug—

18 “(A) is dispensed, including through an
19 online pharmacy, by a certified foreign seller
20 that is a licensed foreign pharmacy;

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

24 “(C) is filled only after providing to the li-
25 censed foreign pharmacy a valid prescription

1 issued by a health care practitioner licensed to
2 practice in a State in the United States.

3 “(e) IMPORTATION FROM OTHER COUNTRIES.—Be-
4 ginning on the date that is 2 years after the date on which
5 final regulations are promulgated to carry out this section,
6 if, based on a review of the evidence obtained after such
7 effective date, including the reports submitted under sec-
8 tion 2(d) of the Affordable and Safe Prescription Drug
9 Importation Act, that importation of qualifying prescrip-
10 tion drugs from Canada under this section resulted in cost
11 savings for consumers in the United States and increased
12 access to safe medication, the Secretary shall have the au-
13 thority to permit importation of qualifying prescription
14 drugs by importers and individuals from, in addition to
15 Canada, any country that—

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

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

22 “(A) authorizes the approval of drugs only
23 if a drug has been determined to be safe and
24 effective by experts employed by or acting on
25 behalf of a governmental entity and qualified by

1 scientific training and experience to evaluate
2 the safety and effectiveness of drugs;

3 “(B) requires that any determination of
4 safety and effectiveness described in subpara-
5 graph (A) be made on the basis of adequate
6 and well-controlled investigations, including
7 clinical investigations, as appropriate, con-
8 ducted by experts qualified by scientific training
9 and experience to evaluate the safety and effec-
10 tiveness of drugs;

11 “(C) requires the methods used in, and the
12 facilities and controls used for, the manufac-
13 ture, processing, and packing of drugs in the
14 country to be adequate to preserve the identity,
15 quality, purity, and strength of the drugs; and

16 “(D) requires the reporting of adverse re-
17 actions to drugs and establish procedures to re-
18 call, and withdraw approval of, drugs found not
19 to be safe or effective.

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

24 “(g) DRUG TESTING LABORATORIES.—The Sec-
25 retary may approve one or more laboratories to conduct

1 random testing of prescription drugs sold by certified for-
2 eign sellers to assess the chemical authenticity of such
3 drugs.

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

8 “(1) to discriminate by charging a higher price
9 for a prescription drug sold to a certified foreign
10 seller that sells such drug to an importer in accord-
11 ance with this section than the price that is charged,
12 inclusive of rebates or other incentives to the coun-
13 try from which the drug is exported, to another per-
14 son that is in the same country and that does not
15 import such a drug into the United States in accord-
16 ance with this section;

17 “(2) except with respect to a prescription drug
18 on the drug shortage list under section 506E, dis-
19 criminate by denying, restricting, or delaying sup-
20 plies of a prescription drug to a certified foreign sell-
21 er, on account of such seller’s status as a certified
22 foreign seller, that sells such drug to an importer in
23 accordance with this section, or by publicly, pri-
24 vately, or otherwise refusing to do business with

1 such a certified foreign seller on account of such
2 seller's status as a certified foreign seller;

3 “(3) cause there to be a difference (including a
4 difference in active ingredient, route of administra-
5 tion, bioequivalence, strength, formulation, manufac-
6 turing establishment, manufacturing process, or per-
7 son that manufactures the drug) between a prescrip-
8 tion drug for distribution in the United States and
9 the drug for distribution in Canada or another per-
10 mitted country, subject to subsection (e), for the
11 purpose of avoiding sales by certified foreign sellers;
12 or

13 “(4) except with respect to a prescription drug
14 on the drug shortage list under section 506E, en-
15 gage in any other action to restrict, prohibit, or
16 delay the importation of a prescription drug under
17 this section.

18 “(i) INFORMATION AND RECORDS.—

19 “(1) BIENNIAL REPORTS.—Each importer shall
20 submit biennial reports to the Secretary which shall
21 contain, for each qualifying prescription drug im-
22 ported into the United States—

23 “(A) the unique facility identifier of the
24 manufacturer of the drug, described in section
25 510;

1 “(B) the transaction information described
2 in section 581(26) (other than the information
3 described in subparagraph (C)); and

4 “(C) the price paid by the importer for the
5 drug.

6 “(2) MAINTENANCE OF RECORDS BY SEC-
7 RETARY.—The Secretary shall maintain information
8 and documentation submitted under paragraph (1)
9 for such period of time as the Secretary determines
10 to be appropriate.

11 “(j) SUSPENSION OF IMPORTATION.—

12 “(1) PATTERNS OF NONCOMPLIANCE.—The
13 Secretary shall require that importation of a specific
14 qualifying prescription drug or importation by a spe-
15 cific certified foreign seller or importer pursuant to
16 this section be immediately suspended if the Sec-
17 retary determines that there is a pattern of importa-
18 tion of such specific drug or by such specific seller
19 or importer that involves counterfeit drugs, drugs
20 that have been recalled or withdrawn, or drugs in
21 violation of any requirement of this section, until an
22 investigation is completed and the Secretary deter-
23 mines that importation of such drug or by such sell-
24 er or importer does not endanger the public health.

1 “(2) TEMPORARY SUSPENSION.—The Secretary
2 may require that importation of a specific qualifying
3 prescription drug or importation by a specific cer-
4 tified foreign seller or importer pursuant to this sec-
5 tion be temporarily suspended if, with respect to
6 such drug, seller, or importer, there is a violation of
7 any requirement of this section or if the Secretary
8 determines that importation of such drug or by such
9 seller or importer might endanger the public health.
10 Such temporary suspension shall apply until the Sec-
11 retary completes an investigation and determines
12 that importation of such drug or by such seller or
13 importer does not endanger the public health.

14 “(k) SUPPLY CHAIN SECURITY.—

15 “(1) PURCHASE FROM REGISTERED FACILITIES
16 AND CERTIFIED FOREIGN SELLERS.—

17 “(A) IN GENERAL.—Except as provided in
18 subparagraph (B), certified foreign sellers who
19 sell qualifying prescription drugs for importa-
20 tion into the United States pursuant to this
21 section may purchase such drugs only from
22 manufacturers or entities registered under sec-
23 tion 510 or other certified foreign sellers.

24 “(B) EXCEPTION.—Certified foreign sellers
25 who sell qualifying prescription drugs for im-

1 portation into the United States pursuant to
2 this section may purchase such drugs from for-
3 foreign sellers in Canada or another permitted
4 country, even if such foreign seller is not a
5 manufacturer registered under section 510 or a
6 certified foreign seller, if the Secretary enters
7 into a memorandum of understanding or coop-
8 erative agreement with Canada, or such other
9 permitted country, to ensure compliance, to the
10 extent appropriate and feasible, with subchapter
11 H of chapter V. The Secretary shall seek to
12 enter into such a memorandum of under-
13 standing or cooperative agreement with Canada
14 and each country from which importation is
15 permitted under subsection (e).

16 “(2) IMPORTATION TRACING.—Certified foreign
17 sellers shall provide importers with the unique facil-
18 ity identifier associated with the manufacturer reg-
19 istered under section 510 of the qualifying prescrip-
20 tion drug and the information under paragraph
21 (25), paragraph (26) (other than subparagraph (C)),
22 and subparagraphs (D), (F), and (G) of paragraph
23 (27) of section 581. Certified foreign sellers shall
24 provide such information to individuals purchasing
25 such drugs, upon request.

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

10 “(m) CONSTRUCTION.—Nothing in this section limits
11 the authority of the Secretary relating to the importation
12 of prescription drugs, other than with respect to section
13 801(d)(1) as provided in this section.”.

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

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

21 “(1) selling, by means of the internet, with the
22 intent to defraud or mislead or with reckless dis-
23 regard for safety of the public, an adulterated or
24 counterfeit drug to an individual in the United
25 States; or

1 “(2) dispenses, by means of the internet, a drug
2 to an individual in the United States who the person
3 knows or has reasonable cause to believe, does not
4 possess a valid prescription for that drug,
5 such person shall be imprisoned for not more than
6 10 years or fined not more than \$250,000.”.

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

12 (d) REPORTS.—

13 (1) HHS.—Not later than 1 year after the date
14 on which final regulations are promulgated to carry
15 out section 804 of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 384), as amended by this Act,
17 and every 2 years thereafter, the Secretary of
18 Health and Human Services, after consultation with
19 appropriate Federal agencies, shall submit to Con-
20 gress and make public a report on the importation
21 of drugs into the United States.

22 (2) GAO REPORT.—Not later than 18 months
23 after the date on which final regulations are promul-
24 gated to carry out section 804 of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 384), as amend-

1 ed by this Act, the Comptroller General of the
2 United States shall submit to Congress a report con-
3 taining an analysis of the implementation of the
4 amendments made by this Act, including a review of
5 drug safety and cost-savings and expenses, including
6 cost-savings to consumers in the United States and
7 trans-shipment and importation tracing processes,
8 resulting from such implementation.

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