

116TH CONGRESS
1ST SESSION

S. _____

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

_____ introduced the following bill; which was read twice
and referred to the Committee on _____

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”.

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

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

1 **“SEC. 804. IMPORTATION OF SAFE AND AFFORDABLE**
2 **DRUGS BY WHOLESALE DISTRIBUTORS,**
3 **PHARMACIES, AND INDIVIDUALS.**

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

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

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

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

24 “(3) IMPORTER.—The term ‘importer’ means a
25 dispenser (as defined in section 581(3)) or wholesale
26 distributor registered under section 503(e) who im-

1 ports prescription drugs into the United States in
2 accordance with this section.

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

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

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

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

19 “(A) means a prescription drug that—

20 “(i) is approved for use in patients,
21 and marketed, in Canada, or subject to
22 subsection (e), approved for use in pa-
23 tients, and marketed, in another permitted
24 country;

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

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

14 “(iv) is labeled in accordance with—

15 “(I) the laws of Canada, or an-
16 other country from which importation
17 is permitted pursuant to subsection
18 (e); and

19 “(II) the requirements promul-
20 gated by the Secretary, which shall in-
21 clude labeling in English;

22 “(B) with respect to importers only, in-
23 cludes—

24 “(i) peritoneal dialysis solution;

25 “(ii) insulin;

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

4 “(iv) biological products, as defined in
5 section 351 of the Public Health Service
6 Act that are proteins (except any chemi-
7 cally synthesized polypeptides) or analo-
8 gous products; and

9 “(v) intravenously infused drugs; and
10 “(C) does not include—

11 “(i) a controlled substance (as defined
12 in section 102 of the Controlled Sub-
13 stances Act);

14 “(ii) an anesthetic drug inhaled dur-
15 ing surgery; or

16 “(iii) a compounded drug.

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

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

24 “(B) a covering practitioner.

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

6 “(d) ADDITIONAL CRITERIA.—

7 “(1) CERTIFIED FOREIGN SELLERS.—

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

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

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

14 “(iii) sell only qualifying prescription
15 drugs to importers or individuals who im-
16 port prescription drugs into the United
17 States in accordance with this section.

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

21 “(i) is a foreign wholesale distributor
22 or licensed foreign pharmacy operating an
23 establishment, which may include an online
24 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 a prescription drug that is
5 imported or offered for importation into
6 the United 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 a qualifying prescription
15 drug to an individual in the United States
16 only after receiving a valid prescription, as
17 described 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
14 product testing to determine the chemical
15 authenticity of sample pharmaceutical
16 products;

17 “(viii) agrees to notify the Secretary,
18 importers, and individuals of product re-
19 calls in Canada, or pursuant to subsection
20 (e), the permitted country in which the
21 seller is located, and agrees to cease, or re-
22 frain from, exporting such product;

23 “(ix) has established, or will establish
24 or participate in, a process for resolving
25 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 prescription drug described in sub-
7 section (b) from Canada or another country pursu-
8 ant to subsection (e) if such drug—

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, in quantities that do
14 not exceed a 90-day supply; and

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

19 “(e) IMPORTATION FROM OTHER COUNTRIES.—Be-
20 ginning on the date that is 2 years after the date on which
21 final regulations are promulgated to carry out this section,
22 if, based on a review of the evidence obtained after such
23 effective date, including the reports submitted under sec-
24 tion 2(d) of the Affordable and Safe Prescription Drug
25 Importation Act, that importation of qualifying prescrip-

1 tion drugs from Canada under this section resulted in cost
2 savings for consumers in the United States and increased
3 access to safe medication, the Secretary shall have the au-
4 thority to permit importation of qualifying prescription
5 drugs by importers and individuals from, in addition to
6 Canada, any country that—

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

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

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

19 “(B) requires that any determination of
20 safety and effectiveness described in subpara-
21 graph (A) be made on the basis of adequate
22 and well-controlled investigations, including
23 clinical investigations, as appropriate, con-
24 ducted by experts qualified by scientific training

1 and experience to evaluate the safety and effec-
2 tiveness of drugs;

3 “(C) requires the methods used in, and the
4 facilities and controls used for, the manufac-
5 ture, processing, and packing of drugs in the
6 country to be adequate to preserve the identity,
7 quality, purity, and strength of the drugs; and

8 “(D) requires the reporting of adverse re-
9 actions to drugs and establish procedures to re-
10 call, and withdraw approval of, drugs found not
11 to be safe or effective.

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

16 “(g) DRUG TESTING LABORATORIES.—The Sec-
17 retary may approve one or more laboratories to conduct
18 random testing of prescription drugs sold by certified for-
19 eign sellers to assess the chemical authenticity of such
20 drugs.

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

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

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

20 “(3) cause there to be a difference (including a
21 difference in active ingredient, route of administra-
22 tion, bioequivalence, strength, formulation, manufac-
23 turing establishment, manufacturing process, or per-
24 son that manufactures the drug) between a prescrip-
25 tion drug for distribution in the United States and

1 the drug for distribution in Canada or another per-
2 mitted country, subject to subsection (e), for the
3 purpose of avoiding sales by certified foreign sellers;
4 or

5 “(4) except with respect to a prescription drug
6 on the drug shortage list under section 506E, en-
7 gage in any other action to restrict, prohibit, or
8 delay the importation of a prescription drug under
9 this section.

10 “(i) INFORMATION AND RECORDS.—

11 “(1) BIENNIAL REPORTS.—Each importer shall
12 submit biennial reports to the Secretary which shall
13 contain, for each qualifying prescription drug im-
14 ported into the United States—

15 “(A) the unique facility identifier of the
16 manufacturer of the drug, described in section
17 510;

18 “(B) the transaction information described
19 in section 581(26) (other than the information
20 described in subparagraph (C)); and

21 “(C) the price paid by the importer for the
22 drug.

23 “(2) MAINTENANCE OF RECORDS BY SEC-
24 RETARY.—The Secretary shall maintain information
25 and documentation submitted under paragraph (1)

1 for such period of time as the Secretary determines
2 to be appropriate.

3 “(j) SUSPENSION OF IMPORTATION.—

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

17 “(2) TEMPORARY SUSPENSION.—The Secretary
18 may require that importation of a specific qualifying
19 prescription drug or importation by a specific cer-
20 tified foreign seller or importer pursuant to this sec-
21 tion be temporarily suspended if, with respect to
22 such drug, seller, or importer, there is a violation of
23 any requirement of this section or if the Secretary
24 determines that importation of such drug or by such
25 seller or importer might endanger the public health.

1 Such temporary suspension shall apply until the Sec-
2 retary completes an investigation and determines
3 that importation of such drug or by such seller or
4 importer does not endanger the public health.

5 “(k) SUPPLY CHAIN SECURITY.—

6 “(1) PURCHASE FROM REGISTERED FACILITIES
7 AND CERTIFIED FOREIGN SELLERS.—

8 “(A) IN GENERAL.—Except as provided in
9 subparagraph (B), certified foreign sellers who
10 sell qualifying prescription drugs for importa-
11 tion into the United States pursuant to this
12 section may purchase such drugs only from
13 manufacturers or entities registered under sec-
14 tion 510 or other certified foreign sellers.

15 “(B) EXCEPTION.—Certified foreign sellers
16 who sell qualifying prescription drugs for im-
17 portation into the United States pursuant to
18 this section may purchase such drugs from for-
19 eign sellers in Canada or another permitted
20 country, even if such foreign seller is not a
21 manufacturer registered under section 510 or a
22 certified foreign seller, if the Secretary enters
23 into a memorandum of understanding or coop-
24 erative agreement with Canada, or such other
25 permitted country, to ensure compliance, to the

1 extent appropriate and feasible, with subchapter
2 H of chapter V. The Secretary shall seek to
3 enter into such a memorandum of under-
4 standing or cooperative agreement with Canada
5 and each country from which importation is
6 permitted under subsection (e).

7 “(2) IMPORTATION TRACING.—Certified foreign
8 sellers shall provide importers with the unique facil-
9 ity identifier associated with the manufacturer reg-
10 istered under section 510 of the qualifying prescrip-
11 tion drug and the information under paragraph
12 (25), paragraph (26) (other than subparagraph (C)),
13 and subparagraphs (D), (F), and (G) of paragraph
14 (27) of section 581. Certified foreign sellers shall
15 provide such information to individuals purchasing
16 such drugs, upon request.

17 “(1) REMS.—In the case of an importer that imports
18 a qualifying prescription drug, where the drug with the
19 same active ingredient or ingredients (or that is biosimilar
20 to an approved biological product), route of administra-
21 tion, and strength that is approved under chapter V or
22 section 351 of the Public Health Service Act is subject
23 to elements to assure safe use under section 505–1, such
24 importer shall be subject to such elements to assure safe
25 use, as applicable and appropriate.

1 “(m) CONSTRUCTION.—Nothing in this section limits
2 the authority of the Secretary relating to the importation
3 of prescription drugs, other than with respect to section
4 801(d)(1) as provided in this section.”.

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

9 “(h) In the case of person operating an Internet
10 website, whether in the United States or in another coun-
11 try, that violates section 301(aa) by—

12 “(1) selling, by means of the Internet, with the
13 intent to defraud or mislead or with reckless dis-
14 regard for safety of the public, an adulterated or
15 counterfeit drug to an individual in the United
16 States; or

17 “(2) dispenses, by means of the Internet, a
18 drug to an individual in the United States who the
19 person knows or has reasonable cause to believe,
20 does not possess a valid prescription for that drug,
21 such person shall be imprisoned for not more than
22 10 years or fined not more than \$250,000.”.

23 (c) NO PREEMPTION.—Nothing in this Act, including
24 the amendments made by this Act, shall be construed to
25 preempt, alter, displace, abridge, or supplant any remedy

1 available under any State or Federal law, including com-
2 mon law, that provides a remedy for civil relief.

3 (d) REPORTS.—

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

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