

AMENDMENT TO COMMITTEE PRINT OF H.R. 2430
OFFERED BY MR. WELCH OF VERMONT

At the end of title V of the committee print, insert
the following new section:

1 **SEC. 505. IMPORTING AFFORDABLE AND SAFE DRUGS**
2 **FROM CANADA.**

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

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

9 “(a) IN GENERAL.—Not later than 180 days after
10 the date of enactment of the FDA Reauthorization Act
11 of 2017, the Secretary shall promulgate regulations per-
12 mitting the importation of qualifying prescription drugs
13 into the United States, in accordance with 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),

1 and that is included on the list described in sub-
2 section (c).

3 “(2) FOREIGN WHOLESALE DISTRIBUTOR.—
4 The term ‘foreign wholesale distributor’ means a
5 person (other than a manufacturer, a manufactur-
6 er’s co-licensed partner, a third-party logistics pro-
7 vider, or a repackager) engaged in wholesale dis-
8 tribution.

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

14 “(4) LICENSED FOREIGN PHARMACY.—The
15 term ‘licensed foreign pharmacy’ means a pharmacy
16 located in Canada that—

17 “(A) operates in accordance with applica-
18 ble pharmacy standards set forth by the provin-
19 cial pharmacy rules and regulations enacted in
20 Canada; and

21 “(B) is licensed to operate and dispense
22 prescription drugs to individuals in Canada.

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

25 “(A) means a prescription drug that—

1 “(i) is approved for use in patients,
2 and marketed, in Canada;

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

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

16 “(iv) is labeled in accordance with—

17 “(I) the laws of Canada; and

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

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

23 “(i) peritoneal dialysis solution;

24 “(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-
25 ada;

1 “(ii) is engaged in the distribution or
2 dispensing of a prescription drug that is
3 imported or offered for importation into
4 the United States;

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

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

16 “(v) has processes established by the
17 seller, or participates in another estab-
18 lished process, to certify that the physical
19 premises and data reporting procedures
20 and licenses are in compliance with all ap-
21 plicable laws and regulations of Canada
22 and has implemented policies designed to
23 monitor ongoing compliance with such laws
24 and regulations;

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

8 “(vii) agrees that, pursuant to sub-
9 section (f), laboratories approved by the
10 Secretary may be authorized to conduct
11 product testing to determine the chemical
12 authenticity of sample pharmaceutical
13 products;

14 “(viii) agrees to notify the Secretary,
15 importers, and individuals of product re-
16 calls in Canada and agrees to cease, or re-
17 frain from, exporting such product;

18 “(ix) has established, or will establish
19 or participate in, a process for resolving
20 grievances, as defined by the Secretary,
21 and will be held accountable for violations
22 of established guidelines and rules;

23 “(x) except as otherwise permitted
24 under this section, does not sell products
25 that the seller could not otherwise legally

1 sell in Canada to customers in the United
2 States; and

3 “(xi) meets any other criteria estab-
4 lished by the Secretary.

5 “(C) CERTIFICATION FEE.—Not later than
6 30 days before the start of each fiscal year, the
7 Secretary shall establish a fee to be collected
8 from foreign sellers for such fiscal year that are
9 certified under subparagraph (B), in an amount
10 that is sufficient, and not more than necessary,
11 to pay the costs of administering the program
12 under this section, and enforcing this section
13 pursuant to section 303(h), for that fiscal year.

14 “(D) RECERTIFICATION.—A certification
15 under subparagraph (B) shall be in effect for a
16 period of 2 years, or until there is a material
17 change in the circumstances under which the
18 foreign seller meets the requirements under
19 such subparagraph, whichever occurs earlier. A
20 foreign seller may reapply for certification
21 under such subparagraph (B), in accordance
22 with a process established by the Secretary.

23 “(2) INDIVIDUALS.—An individual may import
24 a qualifying prescription drug described in sub-
25 section (b) from Canada if such drug—

1 “(A) is dispensed, including through an
2 online pharmacy, by a certified foreign seller
3 that is a licensed foreign pharmacy;

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

7 “(C) is filled only after providing to the li-
8 censed foreign pharmacy a valid prescription
9 issued by a health care practitioner licensed to
10 practice in a State in the United States.

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

15 “(f) DRUG TESTING LABORATORIES.—The Secretary
16 may approve one or more laboratories to conduct random
17 testing of prescription drugs sold by certified foreign sell-
18 ers to assess the chemical authenticity of such drugs.

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

23 “(1) to discriminate by charging a higher price
24 for a prescription drug sold to a certified foreign
25 seller that sells such drug to an importer in accord-

1 ance with this section than the price that is charged,
2 inclusive of rebates or other incentives to the coun-
3 try from which the drug is exported, to another per-
4 son that is in the same country and that does not
5 import such a drug into the United States in accord-
6 ance with this section;

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

17 “(3) cause there to be a difference (including a
18 difference in active ingredient, route of administra-
19 tion, bioequivalence, strength, formulation, manufac-
20 turing establishment, manufacturing process, or per-
21 son that manufactures the drug) between a prescrip-
22 tion drug for distribution in the United States and
23 the drug for distribution in Canada, for the purpose
24 of avoiding sales by certified foreign sellers; or

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

6 “(h) INFORMATION AND RECORDS.—

7 “(1) BIENNIAL REPORTS.—Each importer shall
8 submit biannual reports to the Secretary which shall
9 contain, for each qualifying prescription drug im-
10 ported into the United States—

11 “(A) the unique facility identifier of the
12 manufacturer of the drug, described in section
13 510;

14 “(B) the transaction information described
15 in section 581(26) (other than the information
16 described in subparagraph (C)); and

17 “(C) the price paid by the importer for the
18 drug.

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

24 “(i) SUSPENSION OF IMPORTATION.—

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

14 “(2) TEMPORARY SUSPENSION.—The Secretary
15 may require that importation of a specific qualifying
16 prescription drug or importation by a specific cer-
17 tified foreign seller or importer pursuant to this sec-
18 tion be temporarily suspended if, with respect to
19 such drug, seller, or importer, there is a violation of
20 any requirement of this section or if the Secretary
21 determines that importation of such drug or by such
22 seller or importer might endanger the public health.
23 Such temporary suspension shall apply until the Sec-
24 retary completes an investigation and determines

1 that importation of such drug or by such seller or
2 importer does not endanger the public health.

3 “(j) SUPPLY CHAIN SECURITY.—

4 “(1) PURCHASE FROM REGISTERED FACILITIES
5 AND CERTIFIED FOREIGN SELLERS.—

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

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

1 enter into such a memorandum of under-
2 standing or cooperative agreement with Canada.

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

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

22 “(l) CONSTRUCTION.—Nothing in this section limits
23 the authority of the Secretary relating to the importation
24 of prescription drugs, other than with respect to section
25 801(d)(1) 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
14 drug to an individual in the United States who the
15 person knows or has reasonable cause to believe,
16 does not 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 section, in-
20 cluding the amendments made by this section, shall be
21 construed to preempt, alter, displace, abridge, or supplant
22 any remedy available under any State or Federal law, in-
23 cluding common law, that provides a remedy for civil re-
24 lief.

25 (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 804 of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 384), as amended by this sec-
5 tion, 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 drugs 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 804 of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 384), as amend-
14 ed by this section, 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 section, including a review
18 of drug safety and cost-savings and expenses, includ-
19 ing cost-savings to consumers in the United States
20 and trans-shipment and importation tracing proc-
21 esses, resulting from such implementation.

