

*Amendment to the Amendment  
in the Nature of a Substitute*

**TO H.R. 1101**

**OFFERED BY MR. POLIS OF COLORADO**

Add at the end of the bill the following:

1 **SEC. 7. 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 this section, the Secretary shall  
10 promulgate regulations permitting the importation of  
11 qualifying prescription drugs into the United States, in ac-  
12 cordance with 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).

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

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

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

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

22                 “(B) is licensed to operate and dispense  
23                 prescription drugs to individuals in Canada, or,  
24                 subject to subsection (e), the permitted country  
25                 in which the pharmacy is located.

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

3           “(A) means a prescription drug that—

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

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

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

22                  “(iv) is labeled in accordance with—

23                          “(I) the laws of Canada, or an-  
24                          other country from which importation

1 is permitted pursuant to subsection  
2 (e); and

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

6 “(B) with respect to importers only, in-  
7 cludes—

8 “(i) peritoneal dialysis solution;

9 “(ii) insulin;

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

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

18 “(v) intravenously infused drugs; and

19 “(C) does not include—

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

23 “(ii) an anesthetic drug inhaled dur-  
24 ing surgery; or

25 “(iii) a compounded drug.

1           “(6) VALID PRESCRIPTION.—The term ‘valid  
2           prescription’ means a prescription that is issued for  
3           a legitimate medical purpose in the usual course of  
4           professional practice by—

5                   “(A) a practitioner who has conducted at  
6                   least 1 in-person medical evaluation of the pa-  
7                   tient; or

8                   “(B) a covering practitioner.

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

14          “(d) ADDITIONAL CRITERIA.—

15                   “(1) CERTIFIED FOREIGN SELLERS.—

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

18                                   “(i) be certified by the Secretary in  
19                                   accordance with subparagraph (B);

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

22                                   “(iii) sell only qualifying prescription  
23                                   drugs to importers or individuals who im-  
24                                   port prescription drugs into the United  
25                                   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 Web  
19 site, whether in the United States or in another country,  
20 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  
2           drug to an individual in the United States who the  
3           person knows or has reasonable cause to believe,  
4           does not 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.

