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H. R. 8848

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 HOUSE OF REPRESENTATIVES

JUNE 26, 2024

Ms. SCHAKOWSKY (for herself, Mr. COHEN, Mr. DOGGETT, Mr. GRIJALVA, Ms. NORTON, Ms. OMAR, Ms. PINGREE, and Mr. POCAN) 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 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 of 2024”.

6 **SEC. 2. FINDINGS; SENSE OF CONGRESS.**

7 (a) FINDINGS.—Congress finds the following:

1 (1) Prescription drug prices are, on average,
2 2.78 times more expensive in the United States com-
3 pared to comparable countries in the Organisation
4 for Economic Co-operation and Development
5 (OECD). Drugs that are still under a patent are
6 4.22 times more expensive in the United States than
7 those in comparable nations in the OECD.

8 (2) Multiple studies have demonstrated that
9 tens of millions of Americans have opted to not fill
10 a prescription due to the prohibitive cost of the pre-
11 scription.

12 (3) The Food and Drug Administration has en-
13 tered into Mutual Recognition Agreements with the
14 United Kingdom, the European Union, and Switzer-
15 land to recognize drug manufacturing inspections
16 conducted by each entity as valid and equivalent to
17 an inspection conducted by their own inspectors.

18 (4) The Food and Drug Administration, in tes-
19 timony provided to Congress, acknowledged that
20 fewer negative inspection outcomes were assessed to
21 drug manufacturers in the European Union than in
22 the United States, representing a drug manufac-
23 turing industry that is comparably safe and effective
24 to that of the United States.

1 (5) In 2022, the Food and Drug Administra-
2 tion found that 57 percent of all finished dosage
3 form manufacturing sites for drugs categorized as
4 essential medicines were located in foreign nations
5 and relied on importation to reach American pa-
6 tients.

7 (6) Millions of Americans every year already
8 benefit from safely importing their prescription
9 drugs for personal use, which Federal law permits
10 through enforcement discretion and waivers, but
11 such importation remains technically illegal under
12 most circumstances because many foreign drugs do
13 not have the exact same formulations as the Food
14 and Drug Administration-approved versions. Despite
15 Federal law recognizing that “patients and their
16 families sometimes have reason to import into the
17 United States drugs that have been approved by the
18 Food and Drug Administration” the existing restric-
19 tions mean Americans who are able to obtain relief
20 from high prescription drug costs by importing pre-
21 scription drugs for personal use may occasionally
22 lose access to these drugs as they are seized upon
23 importation.

24 (b) SENSE OF CONGRESS.—It is the sense of Con-
25 gress that—

1 (1) the cost of prescription drugs in the United
2 States represents a crisis that endangers the safety
3 of millions of Americans who must choose between
4 their health and financial stability;

5 (2) prohibitions on drug importation originally
6 intended to protect American consumers have re-
7 sulted in artificially raised prices that harm the
8 American people, even while the same drugs sell for
9 significantly less in other countries;

10 (3) since the initial prohibitions on drug impor-
11 tation were put in place, foreign nations, including
12 Canada, the United Kingdom, Switzerland, and
13 members of the European Union, have significantly
14 advanced their ability to safely approve, manufac-
15 ture, and transport prescription drugs, including
16 small molecules and biologics;

17 (4) the American pharmaceutical supply chain
18 already heavily relies on drugs that are manufac-
19 tured overseas and then imported to American pa-
20 tients, a process that has been done safely for dec-
21 ades and with exporting nations with which the
22 Food and Drug Administration does not have a Mu-
23 tual Recognition Agreement; and

24 (5) it is possible for the American people, with
25 appropriate oversight from the Secretary of Health

1 and Human Services and the Food and Drug Ad-
 2 ministration, to safely engage in a global pharma-
 3 ceutical marketplace in order to obtain prescription
 4 drugs for fair prices.

5 **SEC. 3. IMPORTING AFFORDABLE AND SAFE DRUGS.**

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

9 **“SEC. 804. IMPORTATION OF SAFE AND AFFORDABLE**
 10 **DRUGS BY WHOLESALE DISTRIBUTORS,**
 11 **PHARMACIES, AND INDIVIDUALS.**

12 “(a) IN GENERAL.—Not later than 1 year after the
 13 date of enactment of the Affordable and Safe Prescription
 14 Drug Importation Act of 2024, the Secretary shall pro-
 15 mulgate regulations permitting the importation of quali-
 16 fying prescription drugs into the United States, in accord-
 17 ance with this section.

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

19 “(1) CERTIFIED FOREIGN SELLER.—The term
 20 ‘certified foreign seller’ means a licensed foreign
 21 pharmacy or foreign wholesale distributor that the
 22 Secretary certifies under subsection (d)(1)(B), that
 23 pays the fee required under subsection (d)(1)(C),
 24 and that is included on the list described in sub-
 25 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, the United Kingdom, a member
15 state of the European Union, Switzerland, or subject
16 to subsection (e), another applicable country, that—

17 “(A) operates in accordance with applica-
18 ble pharmacy standards set forth by the phar-
19 macy laws and regulations of the country in
20 which the pharmacy is located; and

21 “(B) is licensed to operate and dispense
22 prescription drugs to individuals in the country
23 in which the pharmacy is located.

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

1 “(A) means a prescription drug that—

2 “(i) is approved for use in patients,
3 and marketed, in Canada, the United
4 Kingdom, a member state of the European
5 Union, Switzerland, or subject to sub-
6 section (e), in another permitted country;

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

15 “(iii) is labeled in accordance with—

16 “(I) the laws of Canada, the
17 United Kingdom, a member state of
18 the European Union, Switzerland, or
19 another country from which importa-
20 tion is permitted pursuant to sub-
21 section (e); and

22 “(II) the requirements promul-
23 gated by the Secretary, which shall in-
24 clude labeling in English;

1 “(B) with respect to importers only, in-
2 cludes—

3 “(i) peritoneal dialysis solution;

4 “(ii) insulin;

5 “(iii) a drug for which a risk evalua-
6 tion and mitigation strategy is required
7 under section 505–1;

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

13 “(v) intravenously infused drugs; and

14 “(C) does not include—

15 “(i) a controlled substance (as defined
16 in section 102 of the Controlled Sub-
17 stances Act);

18 “(ii) an anesthetic drug inhaled dur-
19 ing surgery; or

20 “(iii) a compounded drug.

21 “(6) VALID PRESCRIPTION.—The term ‘valid
22 prescription’ means a prescription that is issued for
23 a legitimate medical purpose in the usual course of
24 professional practice by a practitioner who has con-

1 ducted at least one in-person medical evaluation of
2 the patient.

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

8 “(d) ADDITIONAL CRITERIA.—

9 “(1) CERTIFIED FOREIGN SELLERS.—

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

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

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

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

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

23 “(i) is a foreign wholesale distributor
24 or licensed foreign pharmacy operating an
25 establishment, which may include an online

1 foreign pharmacy, that is located in Can-
2 ada, the United Kingdom, a member state
3 of the European Union, Switzerland, or,
4 subject to subsection (e), another per-
5 mitted country;

6 “(ii) is engaged in the distribution or
7 dispensing of a prescription drug that is
8 imported or offered for importation into
9 the United States;

10 “(iii) 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 “(iv) 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 the coun-
22 try in which the seller is located and has
23 implemented policies designed to monitor
24 ongoing compliance with such laws and
25 regulations;

1 “(v) 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 “(vi) agrees that, pursuant to sub-
9 section (g), 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 “(vii) agrees to notify the Secretary,
15 importers, and individuals of product re-
16 calls in the country in which the seller is
17 located, and agrees to cease, or refrain
18 from, exporting such product;

19 “(viii) has established, or will estab-
20 lish or participate in, a process for resolv-
21 ing grievances, as defined by the Secretary,
22 and will be held accountable for violations
23 of established guidelines and rules;

24 “(ix) except as otherwise permitted
25 under this section, does not sell products

1 that the seller could not otherwise legally
2 sell in the country in which the seller is lo-
3 cated to customers in the United States;
4 and

5 “(x) meets any other criteria estab-
6 lished by the Secretary.

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

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

1 “(2) INDIVIDUALS.—An individual may import
2 a qualifying prescription drug described in sub-
3 section (b) from Canada, the United Kingdom, a
4 member state of the European Union, Switzerland,
5 or another country pursuant to subsection (e) if
6 such drug—

7 “(A) is dispensed, including a drug ordered
8 from an online pharmacy, by a certified foreign
9 seller that is a licensed foreign pharmacy;

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

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

17 “(e) IMPORTATION FROM OTHER COUNTRIES.—Be-
18 ginning on the date that is 1 year after the date on which
19 final regulations are promulgated to carry out this section,
20 if, based on a review of the evidence obtained after such
21 effective date, including the reports submitted under sec-
22 tion 2(d) of the Affordable and Safe Prescription Drug
23 Importation Act of 2024, that importation of qualifying
24 prescription drugs from Canada, the United Kingdom, a
25 member state of the European Union, and Switzerland

1 under this section was conducted safely, the Secretary
2 shall have the authority to permit importation of quali-
3 fying prescription drugs by importers and individuals
4 from, in addition to Canada, the United Kingdom, a mem-
5 ber state of the European Union, and Switzerland, any
6 country that—

7 “(1) has statutory or regulatory standards for
8 the approval and sale of prescription drugs that
9 would enable safe importation of prescription drugs
10 into the United States;

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

17 “(3) requires that any determination of safety
18 and effectiveness described in paragraph (2) be
19 made on the basis of adequate and well-controlled
20 investigations, including clinical investigations, as
21 appropriate, conducted by experts qualified by sci-
22 entific training and experience to evaluate the safety
23 and effectiveness of drugs;

24 “(4) requires the methods used in, and the fa-
25 cilities and controls used for, the manufacture, proc-

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

4 “(5) requires the reporting of adverse reactions
5 to drugs and establish procedures to recall, and
6 withdraw approval of, drugs found not to be safe or
7 effective.

8 “(f) LABELING.—Any qualifying prescription drug
9 imported that meets the labeling requirements described
10 in subsection (b)(5)(A)(iii) is deemed not misbranded for
11 purposes of section 502.

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

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

21 “(1) to discriminate by charging a higher price
22 for a prescription drug sold to a certified foreign
23 seller that sells such drug to an importer in accord-
24 ance with this section than the price that is charged,
25 inclusive of rebates or other incentives to the coun-

1 try from which the drug is exported, to another per-
2 son that is in the same country and that does not
3 import such a drug into the United States in accord-
4 ance with this section;

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

15 “(3) cause there to be a difference (including a
16 difference in active ingredient, route of administra-
17 tion, bioequivalence, strength, formulation, manufac-
18 turing establishment, manufacturing process, or per-
19 son that manufactures the drug) between a prescrip-
20 tion drug for distribution in the United States and
21 the drug for distribution in Canada, the United
22 Kingdom, a member state of the European Union,
23 Switzerland, or another permitted country, subject
24 to subsection (e), for the purpose of avoiding sales
25 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 “(i) ENFORCEMENT DISCRETION AND WAIVER AU-
7 THORITY FOR IMPORTATION BY INDIVIDUALS.—

8 “(1) DECLARATIONS.—Congress declares that
9 in the enforcement against individuals of the prohi-
10 bition of importation of prescription drugs and de-
11 vices, the Secretary should—

12 “(A) focus enforcement on cases in which
13 the importation by an individual poses a signifi-
14 cant threat to public health; and

15 “(B) exercise discretion to permit individ-
16 uals to make such importations in cir-
17 cumstances in which—

18 “(i) the importation is clearly for per-
19 sonal use; and

20 “(ii) the prescription drug or device
21 imported does not appear to present an
22 unreasonable risk to the individual.

23 “(2) WAIVER AUTHORITY.—

24 “(A) IN GENERAL.—The Secretary may
25 grant to individuals, by regulation or on a case-

1 by-case basis, a waiver of the prohibition of im-
2 portation of a prescription drug or device or
3 class of prescription drugs or devices, under
4 such conditions as the Secretary determines to
5 be appropriate.

6 “(B) GUIDANCE ON CASE-BY-CASE WAIV-
7 ERS.—The Secretary shall publish, and update
8 as necessary, guidance that accurately describes
9 circumstances in which the Secretary will con-
10 sistently grant waivers on a case-by-case basis
11 under subparagraph (A), so that individuals
12 may know with the greatest practicable degree
13 of certainty whether a particular importation
14 for personal use will be permitted.

15 “(j) INFORMATION AND RECORDS.—

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

20 “(A) the unique facility identifier of the
21 manufacturer of the drug, described in section
22 510;

23 “(B) the transaction information described
24 in section 581(26) (other than the information
25 described in subparagraph (C)); and

1 “(C) the price paid by the importer for the
2 drug.

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

8 “(k) SUSPENSION OF IMPORTATION.—

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

22 “(2) TEMPORARY SUSPENSION.—The Secretary
23 may require that importation of a specific qualifying
24 prescription drug or importation by a specific cer-
25 tified foreign seller or importer pursuant to this sec-

tion be temporarily suspended if, with respect to such drug, seller, or importer, there is a violation of any requirement of this section or if the Secretary determines that importation of such drug or by such seller or importer might endanger the public health. Such temporary suspension shall apply until the Secretary completes an investigation and determines that importation of such drug or by such seller or importer does not endanger the public health.

“(l) SUPPLY CHAIN SECURITY.—

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

“(A) IN GENERAL.—Except as provided in subparagraph (B), certified foreign sellers who sell qualifying prescription drugs for importation into the United States pursuant to this section may purchase such drugs only from manufacturers or entities registered under section 510 or other certified foreign sellers.

“(B) EXCEPTION.—Certified foreign sellers who sell qualifying prescription drugs for importation into the United States pursuant to this section may purchase such drugs from foreign sellers in Canada, the United Kingdom, a member state of the European Union, Switzer-

land, or another permitted country, subject to subsection (e), even if such foreign seller is not a manufacturer registered under section 510 or a certified foreign seller, if the Secretary enters into a memorandum of understanding or cooperative agreement with the respective country, to ensure compliance, to the extent appropriate and feasible, with subchapter H of chapter V. The Secretary shall seek to enter into such a memorandum of understanding or cooperative agreement with Canada, the United Kingdom, the European Union, Switzerland, and each country from which importation is permitted under subsection (e).

“(2) IMPORTATION TRACING.—Certified foreign sellers shall provide importers with the name and address of the manufacturer registered under section 510 of the qualifying prescription drug and the information under paragraph (25), paragraph (26) (other than subparagraph (C)), and subparagraphs (D), (F), and (G) of paragraph (27) of section 581. Certified foreign sellers shall provide such information to individuals purchasing such drugs, upon request.

1 “(m) REMS.—In the case of an importer that im-
2 ports a qualifying prescription drug, where the drug with
3 the same active ingredient or ingredients (or that is bio-
4 similar to an approved biological product), route of admin-
5 istration, and strength that is approved under chapter V
6 or 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 “(n) 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
15 SALES.—Section 303 of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 333) is amended by adding at the
17 end the following:

18 “(h) In the case of person operating or utilizing an
19 internet website, whether in the United States or in an-
20 other country, 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 10
6 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.

○