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**AMENDMENT TO H.R.**

**OFFERED BY Mr. Pallone**

**(Amendment to Medicare Modernization and Prescription Drug Act of 2002)**

**(Page & line nos. refer to Print of June 14, 2002 9:14 PM)**

Add at the end of title IX [page 252, after line 6]

the following new subtitle:

1                   **Subtitle F—Importation of**  
2                   **Prescription Drugs**

3   **SEC. 951. IMPORTATION OF PRESCRIPTION DRUGS.**

4       (a) IN GENERAL.—Chapter VIII of the Federal Food,  
5   Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended  
6   by striking section 804 and inserting the following:

7   **“SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

8       “(a) DEFINITIONS.—In this section:

9           “(1) IMPORTER.—The term ‘importer’ means a phar-  
10   macist or wholesaler.

11          “(2) PHARMACIST.—The term ‘pharmacist’ means a  
12   person licensed by a State to practice pharmacy, including  
13   the dispensing and selling of prescription drugs.

14          “(3) PRESCRIPTION DRUG.—The term ‘prescription  
15   drug’ means a drug subject to section 503(b), other than—

16           “(A) a controlled substance (as defined in section  
17   102 of the Controlled Substances Act (21 U.S.C. 802));

18           “(B) a biological product (as defined in section  
19   351 of the Public Health Service Act (42 U.S.C. 262));

20           “(C) an infused drug (including a peritoneal dialy-  
21   sis solution);

22           “(D) an intravenously injected drug; or

23           “(E) a drug that is inhaled during surgery.

24          “(4) QUALIFYING LABORATORY.—The term ‘qualifying  
25   laboratory’ means a laboratory in the United States that



1 has been approved by the Secretary for the purposes of this  
2 section.

3 "(5) WHOLESALER.—

4 "(A) IN GENERAL.—The term 'wholesaler' means  
5 a person licensed as a wholesaler or distributor of pre-  
6 scription drugs in the United States under section  
7 503(e) (2) (A).

8 "(B) EXCLUSION.—The term 'wholesaler' does not  
9 include a person authorized to import drugs under sec-  
10 tion 801(d) (1).

11 "(b) REGULATIONS.—The Secretary, after consultation  
12 with the United States Trade Representative and the Commis-  
13 sioner of Customs, shall promulgate regulations permitting  
14 pharmacists and wholesalers to import prescription drugs from  
15 Canada into the United States.

16 "(c) LIMITATION.—The regulations under subsection (b)  
17 shall—

18 "(1) require that safeguards be in place to ensure that  
19 each prescription drug imported under the regulations com-  
20 plies with section 505 (including with respect to being safe  
21 and effective for the intended use of the prescription drug),  
22 with sections 501 and 502, and with other applicable re-  
23 quirements of this Act;

24 "(2) require that an importer of a prescription drug  
25 under the regulations comply with subsections (d) (1) and  
26 (e); and

27 "(3) contain any additional provisions determined by  
28 the Secretary to be appropriate as a safeguard to protect  
29 the public health or as a means to facilitate the importation  
30 of prescription drugs.

31 "(d) INFORMATION AND RECORDS.—

32 "(1) IN GENERAL.—The regulations under subsection  
33 (b) shall require an importer of a prescription drug under  
34 subsection (b) to submit to the Secretary the following in-  
35 formation and documentation:

36 "(A) The name and quantity of the active ingre-  
37 dient of the prescription drug.



- 1           “(B) A description of the dosage form of the pre-
- 2           scription drug.
- 3           “(C) The date on which the prescription drug is
- 4           shipped.
- 5           “(D) The quantity of the prescription drug that is
- 6           shipped.
- 7           “(E) The point of origin and destination of the
- 8           prescription drug.
- 9           “(F) The price paid by the importer for the pre-
- 10          scription drug.
- 11          “(G) Documentation from the foreign seller
- 12          specifying—
- 13           “(i) the original source of the prescription
- 14          drug; and
- 15           “(ii) the quantity of each lot of the prescrip-
- 16          tion drug originally received by the seller from that
- 17          source.
- 18          “(H) The lot or control number assigned to the
- 19          prescription drug by the manufacturer of the prescrip-
- 20          tion drug.
- 21          “(I) The name, address, telephone number, and
- 22          professional license number (if any) of the importer.
- 23          “(J)(i) In the case of a prescription drug that is
- 24          shipped directly from the first foreign recipient of the
- 25          prescription drug from the manufacturer:
- 26           “(I) Documentation demonstrating that the
- 27          prescription drug was received by the recipient
- 28          from the manufacturer and subsequently shipped
- 29          by the first foreign recipient to the importer.
- 30           “(II) Documentation of the quantity of each
- 31          lot of the prescription drug received by the first
- 32          foreign recipient demonstrating that the quantity
- 33          being imported into the United States is not more
- 34          than the quantity that was received by the first for-
- 35          foreign recipient.



1                   “(III)(aa) In the case of an initial im-  
2                   ported shipment, documentation dem-  
3                   onstrating that each batch of the prescrip-  
4                   tion drug in the shipment was statistically  
5                   sampled and tested for authenticity and  
6                   degradation.

7                   “(bb) In the case of any subsequent  
8                   shipment, documentation demonstrating  
9                   that a statistically valid sample of the ship-  
10                  ment was tested for authenticity and deg-  
11                  radation.

12                  “(ii) In the case of a prescription drug  
13                  that is not shipped directly from the first for-  
14                  eign recipient of the prescription drug from the  
15                  manufacturer, documentation demonstrating  
16                  that each batch in each shipment offered for  
17                  importation into the United States was statis-  
18                  tically sampled and tested for authenticity and  
19                  degradation.

20                  “(K) Certification from the importer or  
21                  manufacturer of the prescription drug that the  
22                  prescription drug—

23                                  “(i) is approved for marketing in the  
24                                  United States; and



1                   “(ii) meets all labeling requirements  
2                   under this Act.

3                   “(L) Laboratory records, including com-  
4                   plete data derived from all tests necessary to  
5                   ensure that the prescription drug is in compli-  
6                   ance with established specifications and stand-  
7                   ards.

8                   “(M) Documentation demonstrating that  
9                   the testing required by subparagraphs (J) and  
10                  (L) was conducted at a qualifying laboratory.

11                  “(N) Any other information that the Sec-  
12                  retary determines is necessary to ensure the  
13                  protection of the public health.

14                  “(2) MAINTENANCE BY THE SECRETARY.—The  
15                  Secretary shall maintain information and docu-  
16                  mentation submitted under paragraph (1) for such  
17                  period of time as the Secretary determines to be nec-  
18                  essary.

19                  “(e) TESTING.—The regulations under subsection (b)  
20 shall require—

21                  “(1) that testing described in subparagraphs  
22                  (J) and (L) of subsection (d)(1) be conducted by the  
23                  importer or by the manufacturer of the prescription  
24                  drug at a qualified laboratory;

1           “(2) if the tests are conducted by the  
2 importer—

3           “(A) that information needed to—

4           “(i) authenticate the prescription drug  
5 being tested; and

6           “(ii) confirm that the labeling of the  
7 prescription drug complies with labeling re-  
8 quirements under this Act;

9 be supplied by the manufacturer of the pre-  
10 scription drug to the pharmacist or wholesaler;  
11 and

12           “(B) that the information supplied under  
13 subparagraph (A) be kept in strict confidence  
14 and used only for purposes of testing or other-  
15 wise complying with this Act; and

16           “(3) may include such additional provisions as  
17 the Secretary determines to be appropriate to pro-  
18 vide for the protection of trade secrets and commer-  
19 cial or financial information that is privileged or  
20 confidential.

21           “(f) REGISTRATION OF FOREIGN SELLERS.—Any es-  
22 tablishment within Canada engaged in the distribution of  
23 a prescription drug that is imported or offered for impor-  
24 tation into the United States shall register with the Sec-



1 retary the name and place of business of the establish-  
2 ment.

3       “(g) SUSPENSION OF IMPORTATION.—The Secretary  
4 shall require that importations of a specific prescription  
5 drug or importations by a specific importer under sub-  
6 section (b) be immediately suspended on discovery of a  
7 pattern of importation of the prescription drugs or by the  
8 importer that is counterfeit or in violation of any require-  
9 ment under this section, until an investigation is com-  
10 pleted and the Secretary determines that the public is ade-  
11 quately protected from counterfeit and violative prescrip-  
12 tion drugs being imported under subsection (b).

13       “(h) APPROVED LABELING.—The manufacturer of a  
14 prescription drug shall provide an importer written au-  
15 thorization for the importer to use, at no cost, the ap-  
16 proved labeling for the prescription drug.

17       “(i) PROHIBITION OF DISCRIMINATION.—

18               “(1) IN GENERAL.—It shall be unlawful for a  
19 manufacturer of a prescription drug to discriminate  
20 against, or cause any other person to discriminate  
21 against, a pharmacist or wholesaler that purchases  
22 or offers to purchase a prescription drug from the  
23 manufacturer or from any person that distributes a  
24 prescription drug manufactured by the drug manu-  
25 facturer.



1           “(2) DISCRIMINATION.—For the purposes of  
2 paragraph (1), a manufacturer of a prescription  
3 drug shall be considered to discriminate against a  
4 pharmacist or wholesaler if the manufacturer enters  
5 into a contract for sale of a prescription drug, places  
6 a limit on supply, or employs any other measure,  
7 that has the effect of—

8           “(A) providing pharmacists or wholesalers  
9 access to prescription drugs on terms or condi-  
10 tions that are less favorable than the terms or  
11 conditions provided to a foreign purchaser  
12 (other than a charitable or humanitarian orga-  
13 nization) of the prescription drug; or

14           “(B) restricting the access of pharmacists  
15 or wholesalers to a prescription drug that is  
16 permitted to be imported into the United States  
17 under this section.

18           “(j) CHARITABLE CONTRIBUTIONS.—Notwith-  
19 standing any other provision of this section, section  
20 801(d)(1) continues to apply to a prescription drug that  
21 is donated or otherwise supplied at no charge by the man-  
22 ufacturer of the drug to a charitable or humanitarian or-  
23 ganization (including the United Nations and affiliates)  
24 or to a government of a foreign country.



1       “(k) WAIVER AUTHORITY FOR IMPORTATION BY IN-  
2   DIVIDUALS.—

3       “(1) DECLARATIONS.—Congress declares that  
4   in the enforcement against individuals of the prohi-  
5   bition of importation of prescription drugs and de-  
6   vices, the Secretary should—

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

10      “(B) exercise discretion to permit individ-  
11   uals to make such importations in cir-  
12   cumstances in which—

13      “(i) the importation is clearly for per-  
14   sonal use; and

15      “(ii) the prescription drug or device  
16   imported does not appear to present an  
17   unreasonable risk to the individual.

18      “(2) WAIVER AUTHORITY.—

19      “(A) IN GENERAL.—The Secretary may  
20   grant to individuals, by regulation or on a case-  
21   by-case basis, a waiver of the prohibition of im-  
22   portation of a prescription drug or device or  
23   class of prescription drugs or devices, under  
24   such conditions as the Secretary determines to  
25   be appropriate.



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

10          “(3) DRUGS IMPORTED FROM CANADA.—In  
11          particular, the Secretary shall by regulation grant  
12          individuals a waiver to permit individuals to import  
13          into the United States a prescription drug that—

14                 “(A) is imported from a licensed pharmacy  
15                 for personal use by an individual, not for resale,  
16                 in quantities that do not exceed a 90-day sup-  
17                 ply;

18                 “(B) is accompanied by a copy of a valid  
19                 prescription;

20                 “(C) is imported from Canada, from a sell-  
21                 er registered with the Secretary;

22                 “(D) is a prescription drug approved by  
23                 the Secretary under chapter V;



1           “(E) is in the form of a final finished dos-  
2           age that was manufactured in an establishment  
3           registered under section 510; and

4           “(F) is imported under such other condi-  
5           tions as the Secretary determines to be nec-  
6           essary to ensure public safety.

7           “(I) STUDIES; REPORTS.—

8           “(1) BY THE INSTITUTE OF MEDICINE OF THE  
9           NATIONAL ACADEMY OF SCIENCES.—

10           “(A) STUDY.—

11           “(i) IN GENERAL.—The Secretary  
12           shall request that the Institute of Medicine  
13           of the National Academy of Sciences con-  
14           duct a study of—

15                   “(I) importations of prescription  
16                   drugs made under the regulations  
17                   under subsection (b); and

18                   “(II) information and docu-  
19                   mentation submitted under subsection  
20                   (d).

21           “(ii) REQUIREMENTS.—In conducting  
22           the study, the Institute of Medicine shall—

23                   “(I) evaluate the compliance of  
24                   importers with the regulations under  
25                   subsection (b);



1                   “(II) compare the number of  
2 shipments under the regulations  
3 under subsection (b) during the study  
4 period that are determined to be  
5 counterfeit, misbranded, or adulter-  
6 ated, and compare that number with  
7 the number of shipments made during  
8 the study period within the United  
9 States that are determined to be  
10 counterfeit, misbranded, or adulter-  
11 ated; and

12                   “(III) consult with the Secretary,  
13 the United States Trade Representa-  
14 tive, and the Commissioner of Patents  
15 and Trademarks to evaluate the effect  
16 of importations under the regulations  
17 under subsection (b) on trade and  
18 patent rights under Federal law.

19                   “(B) REPORT.—Not later than 2 years  
20 after the effective date of the regulations under  
21 subsection (b), the Institute of Medicine shall  
22 submit to Congress a report describing the find-  
23 ings of the study under subparagraph (A).

24                   “(2) BY THE COMPTROLLER GENERAL.—



1           “(A) STUDY.—The Comptroller General of  
2           the United States shall conduct a study to de-  
3           termine the effect of this section on the price of  
4           prescription drugs sold to consumers at retail.

5           “(B) REPORT.—Not later than 18 months  
6           after the effective date of the regulations under  
7           subsection (b), the Comptroller General of the  
8           United States shall submit to Congress a report  
9           describing the findings of the study under sub-  
10          paragraph (A).

11          “(m) CONSTRUCTION.—Nothing in this section limits  
12          the authority of the Secretary relating to the importation  
13          of prescription drugs, other than with respect to section  
14          801(d)(1) as provided in this section.

15          “(n) AUTHORIZATION OF APPROPRIATIONS.—There  
16          are authorized to be appropriated such sums as are nec-  
17          essary to carry out this section.”.

18          (b) CONFORMING AMENDMENTS.—The Federal  
19          Food, Drug, and Cosmetic Act is amended—

20                 (1) in section 301(aa) (21 U.S.C. 331(aa)), by  
21                 striking “covered product in violation of section  
22                 804” and inserting “prescription drug in violation of  
23                 section 804”;

24                 (2) in section 303(a)(6) (21 U.S.C. 333(a)(6)),  
25                 by striking “covered product pursuant to section



- 1 804(a)" and inserting "prescription drug under sec-
- 2 tion 804(b)".

