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S. 215

To amend the Federal Food, Drug, and Cosmetic Act to permit importation in personal baggage and by mail of certain covered products for personal use from certain foreign countries and to correct impediments in implementation of the Medicine Equity and Drug Safety Act of 2000.

IN THE SENATE OF THE UNITED STATES

JANUARY 30, 2001

Ms. STABENOW introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to permit importation in personal baggage and by mail of certain covered products for personal use from certain foreign countries and to correct impediments in implementation of the Medicine Equity and Drug Safety Act of 2000.

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 “Medication Equity and
5 Drug Savings Act”.

1 **SEC. 2. IMPORTATION OF COVERED PRODUCTS FOR PER-**
 2 **SONAL USE.**

3 (a) IN GENERAL.—Chapter VIII of the Federal
 4 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)
 5 is amended by adding at the end the following:

6 **“SEC. 805. IMPORTATION OF COVERED PRODUCTS FOR**
 7 **PERSONAL USE.**

8 “(a) DEFINITIONS.—In this section:

9 “(1) COVERED PRODUCT.—The term ‘covered
 10 product’ means a prescription drug described in sec-
 11 tion 503(b)(1).

12 “(2) FOREIGN COUNTRY.—The term ‘foreign
 13 country’ means—

14 “(A) Australia, Canada, Israel, Japan,
 15 New Zealand, Switzerland, and South Africa;
 16 and

17 “(B) any other country, union, or economic
 18 area that the Secretary designates for the pur-
 19 poses of this section, subject to such limitations
 20 as the Secretary determines to be appropriate
 21 to protect the public health.

22 “(3) MARKET VALUE.—The term ‘market
 23 value’ means—

24 “(A) the price paid for a covered product
 25 in foreign country; or

1 “(B) in the case of a gift, the price at
 2 which the covered product is being sold in the
 3 foreign country from which the covered product
 4 is imported.

5 “(b) IMPORTATION IN PERSON.—

6 “(1) REGULATIONS.—Notwithstanding sub-
 7 sections (d) and (t) of section 301 and section
 8 801(a), the Secretary shall promulgate regulations
 9 permitting individuals to import into the United
 10 States from a foreign country, in personal baggage,
 11 a covered product that meets—

12 “(A) the conditions specified in paragraph
 13 (2); and

14 “(B) such additional criteria as the Sec-
 15 retary specifies to ensure the safety of patients
 16 in the United States.

17 “(2) CONDITIONS.—A covered product may be
 18 imported under the regulations if—

19 “(A) the intended use of the covered prod-
 20 uct is appropriately identified;

21 “(B) the covered product is not considered
 22 to represent a significant health risk (as deter-
 23 mined by the Secretary without any consider-
 24 ation given to the cost or availability of such a
 25 product in the United States); and

1 “(C) the individual seeking to import the
2 covered product—

3 “(i) states in writing that the covered
4 product is for the personal use of the indi-
5 vidual;

6 “(ii) seeks to import a quantity of the
7 covered product appropriate for personal
8 use, such as a 90-day supply;

9 “(iii) provides the name and address
10 of a health professional licensed to pre-
11 scribe drugs in the United States that is
12 responsible for treatment with the covered
13 product or provides evidence that the cov-
14 ered product is for the continuation of a
15 treatment begun in a foreign country;

16 “(iv) provides a detailed description of
17 the covered product being imported, includ-
18 ing the name, quantity, and market value
19 of the covered product;

20 “(v) provides the time when and the
21 place where the covered product is pur-
22 chased;

23 “(vi) provides the port of entry
24 through which the covered product is im-
25 ported;

1 “(vii) provides the name, address, and
2 telephone number of the individual who is
3 importing the covered product; and

4 “(viii) provides any other information
5 that the Secretary determines to be nec-
6 essary, including such information as the
7 Secretary determines to be appropriate to
8 identify the facility in which the covered
9 product was manufactured.

10 “(3) IMPORTATION BY AN INDIVIDUAL OTHER
11 THAN THE PATIENT.—The regulations shall permit
12 an individual who seeks to import a covered product
13 under this subsection to designate another individual
14 to effectuate the importation if the individual sub-
15 mits to the Secretary a certification by a health pro-
16 fessional licensed to prescribe drugs in the United
17 States that travelling to a foreign country to effec-
18 tuate the importation would pose a significant risk
19 to the health of the individual.

20 “(4) CONSULTATION.—In promulgating regula-
21 tions under paragraph (1), the Secretary shall con-
22 sult with the United States Trade Representative
23 and the Commissioner of Customs.

24 “(c) IMPORTATION BY MAIL.—

1 “(1) REGULATIONS.—Notwithstanding sub-
2 sections (d) and (t) of section 301 and section
3 801(a), the Secretary shall promulgate regulations
4 permitting individuals to import into the United
5 States by mail a covered product that meets such
6 criteria as the Secretary specifies to ensure the safe-
7 ty of patients in the United States.

8 “(2) CRITERIA.—In promulgating regulations
9 under paragraph (1), the Secretary shall impose the
10 conditions specified in subsection (b)(2) to the max-
11 imum extent practicable.

12 “(3) CONSULTATION.—In promulgating regula-
13 tions under paragraph (1), the Secretary shall con-
14 sult with the United States Trade Representative
15 and the Commissioner of Customs.

16 “(d) RECORDS.—Any information documenting the
17 importation of a covered product under subsections (b)
18 and (c) shall be gathered and maintained by the Secretary
19 for such period as the Secretary determines to be appro-
20 priate.

21 “(e) STUDY AND REPORT.—

22 “(1) STUDY.—The Secretary shall conduct a
23 study on the imports permitted under this section,
24 taking into consideration the information received
25 under subsections (b) and (c).

1 “(2) EVALUATIONS.—In conducting the study,
2 the Secretary shall evaluate—

3 “(A) the safety and purity of the covered
4 products imported; and

5 “(B) patent, trade, and other issues that
6 may have an effect on the safety or availability
7 of the covered products.

8 “(3) REPORT.—Not later than 5 years after the
9 date of enactment of this section, the Secretary shall
10 submit to Congress a report describing the results of
11 the study.

12 “(f) NO EFFECT ON OTHER AUTHORITY.—Nothing
13 in this section limits the statutory, regulatory, or enforce-
14 ment authority of the Secretary relating to importation
15 of covered products, other than the importation described
16 in subsections (b) and (c).

17 “(g) LIMITATION.—Information collected under this
18 section shall be subject to section 522a of title 5, United
19 States Code.”.

20 (b) CONFORMING AMENDMENT.—Section 801(d)(1)
21 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 381(d)(1)) is amended by striking “section 804” and in-
23 serting “sections 804 and 805”.

1 **SEC. 3. CORRECTION OF IMPEDIMENTS IN IMPLEMENTA-**
 2 **TION OF MEDICINE EQUITY AND DRUG SAFE-**
 3 **TY ACT OF 2000.**

4 (a) ACCESS TO LABELING TO PERMIT IMPORTA-
 5 TION.—Section 804 of the Federal Food, Drug, and Cos-
 6 metic Act (21 U.S.C. 384) is amended—

7 (1) in subsection (b)—

8 (A) in paragraph (2), by striking “and” at
 9 the end;

10 (B) in paragraph (3), by striking the pe-
 11 riod at the end and inserting “; and”; and

12 (C) by adding at the end the following
 13 paragraph:

14 “(4) specify a fair and reasonable fee that a
 15 manufacturer may charge an importer for printing
 16 and shipping labels for a covered product for use by
 17 the importer.”;

18 (2) in subsection (e)(2), by inserting after
 19 “used only for purposes of testing” the following:
 20 “or the labeling of covered products”; and

21 (3) in subsection (h)—

22 (A) by striking “No manufacturer” and in-
 23 serting the following:

24 “(1) IN GENERAL.—No manufacturer”; and

25 (B) by adding at the end the following:

1 “(2) NO CONDITIONS FOR LABELING.—No
 2 manufacturer of a covered product may impose any
 3 condition for the privilege of an importer in using la-
 4 beling for a covered product, except a requirement
 5 that the importer pay a fee for such use established
 6 by regulation under subsection (b)(4).”.

7 (b) PROHIBITION OF PRICING CONDITIONS.—Para-
 8 graph (1) of section 804(h) of the Federal Food, Drug,
 9 and Cosmetic Act (21 U.S.C. 384(h)) (as designated by
 10 subsection (a)(3)(A)) is amended by inserting before the
 11 period at the end the following: “that—

12 “(A) imposes a condition regarding the
 13 price at which an importer may resell a covered
 14 product; or

15 “(B) discriminates against a person on the
 16 basis of—

17 “(i) importation by the person of a
 18 covered product imported under subsection
 19 (a); or

20 “(ii) sale or distribution by the person
 21 of such covered products”.

22 (c) CONDITIONS FOR TAKING EFFECT.—Section 804
 23 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 24 384) is amended by striking subsection (l) and inserting
 25 the following:

1 “(l) CONDITIONS FOR TAKING EFFECT.—

2 “(1) IN GENERAL.—Except as provided in para-
3 graph (2), this section shall become effective only if
4 the Secretary certifies to Congress that there is no
5 reasonable likelihood that the implementation of this
6 section would pose any appreciable additional risk to
7 the public health or safety.

8 “(2) REGULATIONS.—Notwithstanding the fail-
9 ure of the Secretary to make a certification under
10 paragraph (1), the Secretary, not later than 30 days
11 after the date of enactment of this paragraph, shall
12 commence a rulemaking for the purpose of formu-
13 lating regulations to enable the Secretary to imple-
14 ment this section immediately upon making such a
15 certification.”.

16 (d) REPEAL OF SUNSET PROVISION.—Section 804 of
17 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 384) is amended by striking subsection (m).

19 (e) AUTHORIZATION OF APPROPRIATIONS.—Section
20 804 of the Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 384) (as amended by subsection (d)) is amended
22 by adding at the end the following:

23 “(m) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated for fiscal year 2002 and

- 1 each subsequent fiscal year such sums as are necessary
- 2 to carry out this section.”.

