

108TH CONGRESS
1ST SESSION

S. 1781

To authorize the Secretary of Health and Human Services to promulgate regulations for the reimportation of prescription drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 23, 2003

Mr. DORGAN (for himself, Ms. SNOWE, Ms. STABENOW, Mr. JOHNSON, Mr. PRYOR, Mr. DAYTON, Mr. LEAHY, Mr. LEVIN, Mr. FEINGOLD, Mr. MCCAIN, and Mr. JEFFORDS) introduced the following bill; which was read the first time

OCTOBER 24, 2003

Read the second time and placed on the calendar

OCTOBER 24, 2003

Referred to the Committee on Health, Education, Labor, and Pensions, by unanimous consent

A BILL

To authorize the Secretary of Health and Human Services to promulgate regulations for the reimportation of prescription drugs, and for other purposes.

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 “Pharmaceutical Mar-
5 ket Access Act of 2003”.

1 **SEC. 2. FINDINGS.**

2 Congress finds that—

3 (1) Americans unjustly pay up to 1000 percent
4 more to fill their prescriptions than consumers in
5 other countries;

6 (2) the United States is the largest market for
7 pharmaceuticals in the world, yet American con-
8 sumers pay the highest prices for pharmaceuticals in
9 the world;

10 (3) an unaffordable drug is neither safe nor ef-
11 fective;

12 (4) allowing and structuring the importation of
13 prescription drugs ensures access to affordable
14 drugs, thus providing a level of safety to American
15 consumers that consumers do not currently enjoy;

16 (5) according to the Congressional Budget Of-
17 fice, American seniors alone will spend
18 \$1,800,000,000,000 on pharmaceuticals over the
19 next 10 years; and

20 (6) allowing open pharmaceutical markets could
21 save American consumers at least \$635,000,000,000
22 each year.

23 **SEC. 3. PURPOSES.**

24 The purposes of this Act are—

25 (1) to give all Americans immediate relief from
26 the outrageously high cost of pharmaceuticals;

1 (2) to reverse the perverse economics of Amer-
2 ican pharmaceutical markets;

3 (3) to allow the importation of drugs (excluding
4 pharmaceutical narcotics) only if the drugs and the
5 facilities in which the drugs are manufactured are
6 approved by the Food and Drug Administration; and

7 (4) to require that imported prescription drugs
8 be packaged and shipped using counterfeit-resistant
9 technologies approved by the Bureau of Engraving
10 and Printing, similar to the technologies used to se-
11 cure United States currency.

12 **SEC. 4. IMPORTATION OF PRESCRIPTION DRUGS.**

13 Section 804 of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 384) is amended—

15 (1) in subsection (a)—

16 (A) by striking “The Secretary” and in-
17 serting “Not later than 180 days after the date
18 of enactment of the Pharmaceutical Market Ac-
19 cess Act of 2003, the Secretary”; and

20 (B) by striking “pharmacists and whole-
21 salers” and inserting “pharmacists, wholesalers,
22 and qualifying individuals”;

23 (2) in subsection (b)—

24 (A) by striking paragraph (1) and insert-
25 ing the following:

1 “(1) require that each covered product imported
 2 under that subsection complies with sections 501,
 3 502, and 505 and other applicable requirements of
 4 this Act; and”;

5 (B) in paragraph (2), by striking “, includ-
 6 ing subsection (d); and” and inserting a period;
 7 and

8 (C) by striking paragraph (3);

9 (3) in subsection (c), by inserting “by phar-
 10 macists and wholesalers (but not qualifying individ-
 11 uals)” after “importation of covered products”;

12 (4) in subsection (d)—

13 (A) by striking paragraphs (3) and (10);

14 (B) in paragraph (5), by striking “, includ-
 15 ing the professional license number of the im-
 16 porter, if any”;

17 (C) in paragraph (6)—

18 (i) in subparagraph (C), by inserting
 19 “(if required under subsection (e))” before
 20 the period;

21 (ii) in subparagraph (D), by inserting
 22 “(if required under subsection (e))” before
 23 the period; and

24 (iii) in subparagraph (E), by striking
 25 “labeling”;

1 (D) in paragraph (7)—

2 (i) in subparagraph (A), by inserting
3 “(if required under subsection (e))” before
4 the period; and

5 (ii) by striking subparagraph (B) and
6 inserting the following:

7 “(B) Certification from the importer or
8 manufacturer of the product that the product
9 meets all requirements of this Act.”; and

10 (E) by redesignating paragraphs (4)
11 through (9) as paragraphs (3) through (8), re-
12 spectively;

13 (5) by striking subsection (e) and inserting the
14 following:

15 “(e) TESTING.—

16 “(1) IN GENERAL.—Subject to paragraph (2),
17 regulations under subsection (a) shall require that
18 testing referred to in paragraphs (5) through (7) of
19 subsection (d) be conducted by the importer of the
20 covered product, unless the covered product is a pre-
21 scription drug subject to the requirements of section
22 505B for counterfeit-resistant technologies.

23 “(2) EXCEPTION.—The testing requirements of
24 paragraphs (5) through (7) of subsection (d) shall

1 not apply to an importer unless the importer is a
2 wholesaler.”;

3 (6) in subsection (f), by striking “or designated
4 by the Secretary, subject to such limitations as the
5 Secretary determines to be appropriate to protect
6 the public health”;

7 (7) in subsection (g)—

8 (A) by striking “counterfeit or”; and

9 (B) by striking “and the Secretary deter-
10 mines that the public is adequately protected
11 from counterfeit and violative covered products
12 being imported pursuant to subsection (a)”;

13 (8) in subsection (i)(1)—

14 (A) by striking subparagraph (A) and in-
15 serting the following:

16 “(A) STUDY.—

17 “(i) IN GENERAL.—The Secretary
18 shall conduct, or contract with an entity to
19 conduct, a study on the imports permitted
20 under subsection (a), including consider-
21 ation of the information received under
22 subsection (d).

23 “(ii) EVALUATION.— In conducting
24 the study, the Secretary or entity shall—

1 “(I) evaluate the compliance of
 2 importers with regulations under sub-
 3 section (a), and the incidence of ship-
 4 ments under that subsection, if any,
 5 that have been determined to be mis-
 6 branded or adulterated; and

7 “(II) determine how that compli-
 8 ance contrasts with the incidence of
 9 shipments of prescription drugs trans-
 10 ported within the United States that
 11 have been determined to be mis-
 12 branded or adulterated.”; and

13 (B) in subparagraph (B), by striking “Not
 14 later than 2 years after the effective date of
 15 final regulations under subsection (a),” and in-
 16 serting “Not later than 18 months after the
 17 date of enactment of the Pharmaceutical Mar-
 18 ket Access Act of 2003,”;

19 (9) in subsection (k)(2)—

20 (A) by redesignating subparagraphs (D)
 21 and (E) as subparagraphs (E) and (F), respec-
 22 tively; and

23 (B) by inserting after subparagraph (C)
 24 the following:

1 “(D) QUALIFYING INDIVIDUAL.—The term
 2 ‘qualifying individual’ means an individual who
 3 is not a pharmacist or a wholesaler. ”; and
 4 (10) by striking subsections (l) and (m).

5 **SEC. 5. USE OF COUNTERFEIT-RESISTANT TECHNOLOGIES**
 6 **TO PREVENT COUNTERFEITING.**

7 (a) MISBRANDING.—Section 502 of the Federal
 8 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amend-
 9 ed by adding at the end the following:

10 “(w) If it is a drug subject to section 503(b), unless
 11 the packaging of the drug complies with the requirements
 12 of section 505B for counterfeit-resistant technologies.”.

13 (b) REQUIREMENTS.—Title V of the Federal Food,
 14 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
 15 ed by inserting after section 505A the following:

16 **“SEC. 505B. COUNTERFEIT-RESISTANT TECHNOLOGIES.**

17 “(a) INCORPORATION OF COUNTERFEIT-RESISTANT
 18 TECHNOLOGIES INTO PRESCRIPTION DRUG PACK-
 19 AGING.—The Secretary shall require that the packaging
 20 of any drug subject to section 503(b) incorporate—

21 “(1) overt optically variable counterfeit-resist-
 22 ant technologies that are described in subsection (b)
 23 and comply with the standards of subsection (c); or
 24 “(2) technologies that have an equivalent func-
 25 tion of security, as determined by the Secretary.

1 “(b) ELIGIBLE TECHNOLOGIES.—Technologies de-
2 scribed in this subsection—

3 “(1) shall be visible to the naked eye, providing
4 for visual identification of product authenticity with-
5 out the need for readers, microscopes, lighting de-
6 vices, or scanners;

7 “(2) shall be similar to the technologies used by
8 the Bureau of Engraving and Printing to secure
9 United States currency;

10 “(3) shall be manufactured and distributed in a
11 highly secure, tightly controlled environment; and

12 “(4) should incorporate additional layers of
13 nonvisible covert security features up to and includ-
14 ing forensic capability.

15 “(c) STANDARDS FOR PACKAGING.—

16 “(1) MULTIPLE ELEMENTS.—For the purpose
17 of making it more difficult to counterfeit the pack-
18 aging of drugs subject to section 503(b), a manufac-
19 turer of the drugs shall incorporate the technologies
20 described in subsection (b) into multiple elements of
21 the physical packaging of the drugs, including blister
22 packs, shrink wrap, package labels, package seals,
23 bottles, and boxes.

24 “(2) LABELING OF SHIPPING CONTAINER.—

1 “(A) IN GENERAL.—A shipment of a drug
2 described in subsection (a) shall include a label
3 on the shipping container that incorporates the
4 technologies described in subsection (b), so that
5 officials inspecting the packages will be able to
6 determine the authenticity of the shipment.

7 “(B) CHAIN-OF-CUSTODY PROCEDURES.—

8 “(i) IN GENERAL.—A manufacturer of
9 a drug described in subsection (a) shall en-
10 sure that chain-of-custody procedures
11 apply to a label required under subpara-
12 graph (A).

13 “(ii) REQUIRED PROCEDURES.—
14 Chain-of-custody procedures required
15 under clause (i) shall include—

16 “(I) procedures applicable to con-
17 tractual agreements for the use and
18 distribution of the labels;

19 “(II) methods to audit the use of
20 the labels; and

21 “(III) database access for the rel-
22 evant governmental agencies for audit
23 or verification of the use and distribu-
24 tion of the labels.”.

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