

109TH CONGRESS
1ST SESSION

H. R. 1626

To amend part D of title XVIII of the Social Security Act to authorize the Secretary of Health and Human Services to negotiate for lower prices for Medicare prescription drugs and to eliminate the gap in coverage of Medicare prescription drug benefits, to authorize the Secretary of Health and Human Services to promulgate regulations for the reimportation of prescription drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 13, 2005

Mr. WU introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend part D of title XVIII of the Social Security Act to authorize the Secretary of Health and Human Services to negotiate for lower prices for Medicare prescription drugs and to eliminate the gap in coverage of Medicare prescription drug benefits, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Medicare Prescription
3 Drug Improvement Act”.

4 **TITLE I—IMPROVEMENT OF**
5 **MEDICARE PRESCRIPTION**
6 **DRUG BENEFITS**

7 **SEC. 101. PERMITTING THE NEGOTIATION OF FAIR PRICES**
8 **FOR MEDICARE PRESCRIPTION DRUGS ON**
9 **BEHALF OF MEDICARE BENEFICIARIES.**

10 Section 1860D–11 of the Social Security Act (42
11 U.S.C. 1395w–111) is amended by striking subsection (i)
12 (relating to noninterference) and inserting the following:

13 “(i) **AUTHORITY TO NEGOTIATE PRICES WITH MAN-**
14 **UFACTURERS.**—In order to ensure that beneficiaries en-
15 rolled under prescription drug plans, MA–PD plans, and
16 qualified retiree prescription drug plans pay the lowest
17 possible price, the Secretary shall have authority similar
18 to that of the Secretary of Veterans Affairs, Secretary of
19 Defense, and the heads of other Federal agencies and de-
20 partments that purchase prescription drugs in bulk to ne-
21 gotiate contracts with manufacturers of covered part D
22 drugs, consistent with the requirements and in further-
23 ance of the goals of providing quality care and containing
24 costs under this part.”.

1 **SEC. 102. ELIMINATION OF GAP IN COVERAGE OF PRE-**
2 **SCRIPTION DRUG BENEFITS.**

3 (a) **IN GENERAL.**—Paragraph (3) of section 1860D–
4 2(b) of the Social Security Act (42 U.S.C. 1395w–102(b))
5 is repealed.

6 (b) **CONFORMING AMENDMENTS.**—(1) Section
7 1860D–2 of such Act (42 U.S.C. 1395w–102) is amend-
8 ed—

9 (A) in subsection (a)(2)(A)(i)(I), by strik-
10 ing “, or an increase in the initial coverage
11 limit with respect to covered part D drugs”;

12 (B) in subsection (b)(2)(A), by striking
13 “and up to the initial coverage limit under
14 paragraph (3)”;

15 (C) in subsection (b)(4)(C)(i)—

16 (i) by striking the comma after “para-
17 graph (1)” and inserting “and”; and

18 (ii) by striking “, and for amounts for
19 which benefits are not provided because of
20 the application of the initial coverage limit
21 described in paragraph (3)”;

22 (D) in subsection (c)(1), by striking sub-
23 paragraph (C); and

24 (E) in subsection (d)(1)(A), by striking “or
25 an initial coverage limit (described in subsection
26 (b)(3))”.

1 (2) Section 1860D–4(a)(4)(B) of such Act (42
2 U.S.C. 1395w–104(a)(4)(B)) is amended to read as
3 follows:

4 “(B) when prescription drug benefits are
5 provided under this part, a notice of the bene-
6 fits in relation to the annual out-of-pocket
7 threshold for the current year.”.

8 (3)(A) Section 1860D–14(a) of such Act (42
9 U.S.C. 1395w–114(a)) is amended—

10 (i) in paragraph (1), by striking subpara-
11 graph (C) and redesignating subparagraphs (D)
12 and (E) as subparagraphs (C) and (D), respec-
13 tively;

14 (ii) in paragraph (2), by striking subpara-
15 graph (C) and redesignating subparagraphs (D)
16 and (E) as subparagraphs (C) and (D), respec-
17 tively; and

18 (iii) in paragraph (4)(A) in the matter pre-
19 ceding clause (i), by striking “paragraph
20 (1)(D)(ii)” and inserting “paragraph
21 (1)(C)(ii)”.

22 (B) Section 1860D–14(e)(1) of such Act (42
23 U.S.C. 1395w–114(e)(1)) is amended in the second
24 sentence by striking “subsections (a)(1)(D) and

1 (a)(2)(E)” and inserting “subsections (a)(1)(C) and
2 (a)(2)(D)”.

3 (C) Section 1860D–15(e)(1)(B) of such Act (42
4 U.S.C. 1395w–115(e)(1)(B)) is amended by striking
5 “paragraphs (1)(D) and (2)(E)” and inserting
6 “paragraphs (1)(C) and (2)(D)”.

7 (4)(A) Section 1860D–41(a)(6) of such Act (42
8 U.S.C. 1395w–151(a)(6)) is amended by striking
9 paragraph (6) and redesignating paragraphs (7)
10 through (18) as paragraphs (6) through (17), re-
11 spectively.

12 (B) Section 1860D–1(a)(1)(A) of such Act (42
13 U.S.C. 1395w–101(a)(1)(A)) is amended by striking
14 “1860D–41(a)(14)” and inserting “1860D–
15 41(a)(13)”.

16 (c) EFFECTIVE DATE.—The amendments made by
17 this section shall take effect as if included in the enact-
18 ment of the Medicare Prescription Drug, Improvement,
19 and Modernization Act of 2003 (Public law 108–173).

20 **TITLE II—IMPORTATION OF**
21 **PRESCRIPTION DRUGS**

22 **SEC. 201. SHORT TITLE.**

23 This title may be cited as the “Pharmaceutical Mar-
24 ket Access Act of 2005”.

1 **SEC. 202. IMPORTATION OF PRESCRIPTION DRUGS.**

2 (a) NULLIFICATION OF CERTAIN AMENDMENTS
3 MADE BY PUBLIC LAW 108–173.—The Federal Food,
4 Drug, and Cosmetic Act is amended—

5 (1) in section 804 (21 U.S.C. 384), by amend-
6 ing the section to read as if section 1121(a) of Pub-
7 lic Law 108–173 had not been enacted;

8 (2) in section 301 (21 U.S.C. 331), by amend-
9 ing the section to read as if section 1121(b)(1) of
10 Public Law 108–173 had not been enacted; and

11 (3) in section 303 (21 U.S.C. 333), by amend-
12 ing the section to read as if section 1121(b)(2) of
13 Public Law 108–173 had not been enacted.

14 (b) IMPORTATION OF PRESCRIPTION DRUGS.—Sec-
15 tion 804 of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 384), as amended by subsection (a)(1) of this
17 section, is amended—

18 (1) in subsection (a)—

19 (A) by striking “The Secretary” and in-
20 serting “Not later than 180 days after the date
21 of the enactment of the Pharmaceutical Market
22 Access Act of 2003, the Secretary”; and

23 (B) by striking “pharmacists and whole-
24 salers” and inserting “pharmacists, wholesalers,
25 and qualifying individuals”;

26 (2) in subsection (b)—

1 (A) by amending paragraph (1) to read as
2 follows:

3 “(1) require that each covered product imported
4 pursuant to such subsection complies with sections
5 501, 502, and 505, and other applicable require-
6 ments of this Act; and”;

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

10 (C) by striking paragraph (3);

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

14 (4) in subsection (d)—

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

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

19 (C) in paragraph (6)—

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

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

1 (iii) in subparagraph (E), by striking
2 “labeling”;

3 (D) in paragraph (7)—

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

7 (ii) by amending subparagraph (B) to
8 read as follows:

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

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

15 (5) by amending subsection (e) to read as fol-
16 lows:

17 “(e) TESTING.—

18 “(1) IN GENERAL.—Subject to paragraph (2),
19 regulations under subsection (a) shall require that
20 testing referred to in paragraphs (5) through (7) of
21 subsection (d) be conducted by the importer of the
22 covered product, unless the covered product is a pre-
23 scription drug subject to the requirements of section
24 505C for counterfeit-resistant technologies.

1 “(2) EXCEPTION.—The testing requirements of
2 paragraphs (5) through (7) of subsection (d) shall
3 not apply to an importer unless the importer is a
4 wholesaler.”;

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

9 (7) in subsection (g)—

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

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

15 (8) in subsection (i)(1)—

16 (A) by amending subparagraph (A) to read
17 as follows:

18 “(A) IN GENERAL.—The Secretary shall
19 conduct, or contract with an entity to conduct,
20 a study on the imports permitted pursuant to
21 subsection (a), including consideration of the
22 information received under subsection (d). In
23 conducting such study, the Secretary or entity
24 shall evaluate the compliance of importers with
25 regulations under subsection (a), and the inci-

1 dence of shipments pursuant to such sub-
2 section, if any, that have been determined to be
3 misbranded or adulterated, and determine how
4 such compliance contrasts with the incidence of
5 shipments of prescription drugs transported
6 within the United States that have been deter-
7 mined to be misbranded or adulterated.”; and

8 (B) in subparagraph (B), by striking “Not
9 later than 2 years after the effective date of
10 final regulations under subsection (a),” and in-
11 serting “Not later than 18 months after the
12 date of the enactment of the Pharmaceutical
13 Market Access Act of 2003,”;

14 (9) in subsection (k)(2)—

15 (A) by redesignating subparagraphs (D)
16 and (E) as subparagraphs (E) and (F), respec-
17 tively; and

18 (B) by inserting after subparagraph (C)
19 the following:

20 “(D) The term ‘qualifying individual’
21 means an individual who is not a pharmacist or
22 a wholesaler.”; and

23 (10) by striking subsections (l) and (m).

1 **SEC. 203. USE OF COUNTERFEIT-RESISTANT TECH-**
2 **NOLOGIES TO PREVENT COUNTERFEITING.**

3 (a) MISBRANDING.—Section 502 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 352; deeming
5 drugs and devices to be misbranded) is amended by adding
6 at the end the following:

7 “(x) If it is a drug subject to section 503(b), unless
8 the packaging of such drug complies with the require-
9 ments of section 505C for counterfeit-resistant tech-
10 nologies.”.

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

14 **“SEC. 505C. COUNTERFEIT-RESISTANT TECHNOLOGIES.**

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

19 “(1) overt optically variable counterfeit-resist-
20 ant technologies that are described in subsection (b)
21 and comply with the standards of subsection (c); or

22 “(2) technologies that have an equivalent func-
23 tion of security, as determined by the Secretary.

24 “(b) ELIGIBLE TECHNOLOGIES.—Technologies de-
25 scribed in this subsection—

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

5 “(2) shall be similar to that used by the Bureau
6 of Engraving and Printing to secure United States
7 currency;

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

10 “(4) should incorporate additional layers of
11 non-visible covert security features up to and includ-
12 ing forensic capability.

13 “(c) STANDARDS FOR PACKAGING.—

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

22 “(2) LABELING OF SHIPPING CONTAINER.—
23 Shipments of drugs described in subsection (a) shall
24 include a label on the shipping container that incor-
25 porates the technologies described in subsection (b),

1 so that officials inspecting the packages will be able
2 to determine the authenticity of the shipment. Chain
3 of custody procedures shall apply to such labels and
4 shall include procedures applicable to contractual
5 agreements for the use and distribution of the labels,
6 methods to audit the use of the labels, and database
7 access for the relevant governmental agencies for
8 audit or verification of the use and distribution of
9 the labels.”.

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