

108TH CONGRESS  
2D SESSION

# H. R. 4512

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.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 3, 2004

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

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## 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, as  
11 added by section 101(a) of the Medicare Prescription  
12 Drug, Improvement, and Modernization Act of 2003 (Pub-  
13 lic Law 108–173), is amended by striking subsection (i)  
14 (relating to noninterference) and by inserting the fol-  
15 lowing:

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

1 ance of the goals of providing quality care and containing  
2 costs under this part.”.

3 **SEC. 102. ELIMINATION OF GAP IN COVERAGE OF PRE-**  
4 **SCRIPTION DRUG BENEFITS.**

5 (a) IN GENERAL.—Section 1860D–2(b) of the Social  
6 Security Act (42 U.S.C. 1395w–102(b)), as added by sec-  
7 tion 101(a) of the Medicare Prescription Drug, Improve-  
8 ment, and Modernization Act of 2003 (Public Law 108–  
9 173), is amended by striking paragraph (3) and inserting  
10 the following:

11 “(3) Repealed.”.

12 (b) CONFORMING AMENDMENTS.—

13 (1) Section 1860D–2 of the Social Security Act  
14 (42 U.S.C. 1395w–102) is amended—

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

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

21 (C) in subsection (b)(4)(C)(i)—

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

24 (ii) by striking “, and for amounts for  
25 which benefits are not provided because of

1 the application of the initial coverage limit  
2 described in paragraph (3)”;

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

5 (E) in subsection (d)(1)(A), by striking “or  
6 an initial coverage limit (described in subsection  
7 (b)(3))”.

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

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

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

17 (i) in paragraph (1), by striking subpara-  
18 graph (C) and redesignating subparagraphs (D)  
19 and (E) as subparagraphs (C) and (D), respec-  
20 tively;

21 (ii) in paragraph (2), by striking subpara-  
22 graph (C) and redesignating subparagraphs (D)  
23 and (E) as subparagraphs (C) and (D), respec-  
24 tively; and

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

5 (B) Section 1860D–14(e)(1) of such Act (42  
6 U.S.C. 1395w–114(e)(1)) is amended in the second  
7 sentence by striking “subsections (a)(1)(D) and  
8 (a)(2)(E)” and inserting “subsections (a)(1)(C) and  
9 (a)(2)(D)”.

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

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

19 (B) Section 1860D–1(a)(1)(A) of such Act (42  
20 U.S.C. 1395w–101(a)(1)(A)) is amended by striking  
21 “1860D–41(a)(14)” and inserting “1860D–  
22 41(a)(13)”.

23 (c) EFFECTIVE DATE.—The amendments made by  
24 this section shall take effect as if included in the enact-

1 ment of the Medicare Prescription Drug, Improvement,  
2 and Modernization Act of 2003 (Public law 108–173).

3 **TITLE II—IMPORTATION OF**  
4 **PRESCRIPTION DRUGS**

5 **SEC. 201. SHORT TITLE.**

6 This title may be cited as the “Pharmaceutical Mar-  
7 ket Access Act of 2004”.

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

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

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

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

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

21 (b) IMPORTATION OF PRESCRIPTION DRUGS.—Sec-  
22 tion 804 of the Federal Food, Drug, and Cosmetic Act  
23 (21 U.S.C. 384), as amended by subsection (a)(1) of this  
24 section, is amended—

25 (1) in subsection (a)—

1 (A) by striking “The Secretary” and in-  
2 serting “Not later than 180 days after the date  
3 of the enactment of the Pharmaceutical Market  
4 Access Act of 2003, the Secretary”; and

5 (B) by striking “pharmacists and whole-  
6 salers” and inserting “pharmacists, wholesalers,  
7 and qualifying individuals”;

8 (2) in subsection (b)—

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

11 “(1) require that each covered product imported  
12 pursuant to such subsection complies with sections  
13 501, 502, and 505, and other applicable require-  
14 ments of this Act; and”;

15 (B) in paragraph (2), by striking “, includ-  
16 ing subsection (d); and” and inserting a period;  
17 and

18 (C) by striking paragraph (3);

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

22 (4) in subsection (d)—

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

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

4 (C) in paragraph (6)—

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

8 (ii) in subparagraph (D), by inserting  
9 “(if required under subsection (e))” before  
10 the period; and

11 (iii) in subparagraph (E), by striking  
12 “labeling”;

13 (D) in paragraph (7)—

14 (i) in subparagraph (A), by inserting  
15 “(if required under subsection (e))” before  
16 the period; and

17 (ii) by amending subparagraph (B) to  
18 read as follows:

19 “(B) Certification from the importer or  
20 manufacturer of such product that the product  
21 meets all requirements of this Act.”; and

22 (E) by redesignating paragraphs (4)  
23 through (9) as paragraphs (3) through (8), re-  
24 spectively;

1           (5) by amending subsection (e) to read as fol-  
2 lows:

3           “(e) TESTING.—

4           “(1) IN GENERAL.—Subject to paragraph (2),  
5 regulations under subsection (a) shall require that  
6 testing referred to in paragraphs (5) through (7) of  
7 subsection (d) be conducted by the importer of the  
8 covered product, unless the covered product is a pre-  
9 scription drug subject to the requirements of section  
10 505C for counterfeit-resistant technologies.

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

15           (6) in subsection (f), by striking “or designated  
16 by the Secretary, subject to such limitations as the  
17 Secretary determines to be appropriate to protect  
18 the public health”;

19           (7) in subsection (g)—

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

21                   (B) by striking “and the Secretary deter-  
22 mines that the public is adequately protected  
23 from counterfeit and violative covered products  
24 being imported pursuant to subsection (a)”;

25           (8) in subsection (i)(1)—

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

3 “(A) IN GENERAL.—The Secretary shall  
4 conduct, or contract with an entity to conduct,  
5 a study on the imports permitted pursuant to  
6 subsection (a), including consideration of the  
7 information received under subsection (d). In  
8 conducting such study, the Secretary or entity  
9 shall evaluate the compliance of importers with  
10 regulations under subsection (a), and the inci-  
11 dence of shipments pursuant to such sub-  
12 section, if any, that have been determined to be  
13 misbranded or adulterated, and determine how  
14 such compliance contrasts with the incidence of  
15 shipments of prescription drugs transported  
16 within the United States that have been deter-  
17 mined to be misbranded or adulterated.”; and

18 (B) in subparagraph (B), by striking “Not  
19 later than 2 years after the effective date of  
20 final regulations under subsection (a),” and in-  
21 sserting “Not later than 18 months after the  
22 date of the enactment of the Pharmaceutical  
23 Market Access Act of 2003,”;

24 (9) in subsection (k)(2)—

1 (A) by redesignating subparagraphs (D)  
2 and (E) as subparagraphs (E) and (F), respec-  
3 tively; and

4 (B) by inserting after subparagraph (C)  
5 the following:

6 “(D) The term ‘qualifying individual’  
7 means an individual who is not a pharmacist or  
8 a wholesaler.”; and

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

10 **SEC. 203. USE OF COUNTERFEIT-RESISTANT TECH-**  
11 **NOLOGIES TO PREVENT COUNTERFEITING.**

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

16 “(w) If it is a drug subject to section 503(b), unless  
17 the packaging of such drug complies with the require-  
18 ments of section 505C for counterfeit-resistant tech-  
19 nologies.”.

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

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

24 “(a) INCORPORATION OF COUNTERFEIT-RESISTANT  
25 TECHNOLOGIES INTO PRESCRIPTION DRUG PACK-

1 AGING.—The Secretary shall require that the packaging  
2 of any drug subject to section 503(b) incorporate—

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

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

8 “(b) ELIGIBLE TECHNOLOGIES.—Technologies de-  
9 scribed in this subsection—

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

14 “(2) shall be similar to that used by the Bureau  
15 of Engraving and Printing to secure United States  
16 currency;

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

19 “(4) should incorporate additional layers of  
20 non-visible covert security features up to and includ-  
21 ing forensic capability.

22 “(c) STANDARDS FOR PACKAGING.—

23 “(1) MULTIPLE ELEMENTS.—For the purpose  
24 of making it more difficult to counterfeit the pack-  
25 aging of drugs subject to section 503(b), manufac-

1       turers of the drugs shall incorporate the technologies  
2       described in subsection (b) into multiple elements of  
3       the physical packaging of the drugs, including blister  
4       packs, shrink wrap, package labels, package seals,  
5       bottles, and boxes.

6               “(2) LABELING OF SHIPPING CONTAINER.—  
7       Shipments of drugs described in subsection (a) shall  
8       include a label on the shipping container that incor-  
9       porates the technologies described in subsection (b),  
10       so that officials inspecting the packages will be able  
11       to determine the authenticity of the shipment. Chain  
12       of custody procedures shall apply to such labels and  
13       shall include procedures applicable to contractual  
14       agreements for the use and distribution of the labels,  
15       methods to audit the use of the labels, and database  
16       access for the relevant governmental agencies for  
17       audit or verification of the use and distribution of  
18       the labels.”.

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