

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 328

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 25, 2005

Mr. GUTKNECHT (for himself, Mr. EMANUEL, Mrs. EMERSON, Mr. SANDERS, Ms. DELAURO, Mrs. NORTHUP, Mr. BURTON of Indiana, Ms. GINNY BROWN-WAITE of Florida, Mr. JONES of North Carolina, Mr. BROWN of Ohio, Mr. ISTOOK, Mr. KINGSTON, Mr. RAMSTAD, Mr. KING of Iowa, and Mr. LANGEVIN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, 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 the Federal Food, Drug, and Cosmetic Act with respect to the importation 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 2005”.

1 **SEC. 2. FINDINGS.**

2 Congress finds as follows:

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 world's largest  
7 market for pharmaceuticals yet consumers still pay  
8 the world's highest prices.

9 (3) An unaffordable drug is neither safe nor ef-  
10 fective. Allowing and structuring the importation of  
11 prescription drugs ensures access to affordable  
12 drugs, thus providing a level of safety to American  
13 consumers they do not currently enjoy.

14 (4) According to the Congressional Budget Of-  
15 fice, American seniors alone will spend  
16 \$1,800,000,000,000 on pharmaceuticals over the  
17 next 10 years.

18 (5) Allowing open pharmaceutical markets  
19 could save American consumers at least  
20 \$635,000,000,000 of their own money.

21 **SEC. 3. PURPOSES.**

22 The purposes of this Act are as follows:

23 (1) To give all Americans immediate relief from  
24 the outrageously high cost of pharmaceuticals.

25 (2) To reverse the perverse economics of the  
26 American pharmaceutical market.

1           (3) To allow the importation of prescription  
2 drugs only if the drugs and facilities where such  
3 drugs are manufactured are approved by the Food  
4 and Drug Administration, and to exclude pharma-  
5 ceutical narcotics.

6           (4) To require that imported prescription drugs  
7 be packaged and shipped using counterfeit-resistant  
8 technologies.

9 **SEC. 4. AMENDMENTS TO SECTION 804 OF THE FEDERAL**  
10 **FOOD, DRUG, AND COSMETIC.**

11           (a) DEFINITIONS.—Section 804(a) of the Federal  
12 Food, Drug, and Cosmetic Act (21 U.S.C. 384(a)) is  
13 amended to read as follows:

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

15                   “(1) IMPORTER.—The term ‘importer’ means a  
16 pharmacy, group of pharmacies, pharmacist, or  
17 wholesaler.

18                   “(2) PERMITTED COUNTRY.—The term ‘per-  
19 mitted country’ means a country, union, or economic  
20 area that is listed in subparagraph (A) of section  
21 802(b)(1) (as of December 31, 2003), except that  
22 the Secretary—

23                           “(A) may add a country, union, or eco-  
24 nomic area to such list for purposes of this sec-  
25 tion if the Secretary determines that the coun-

1 try, union, or economic area has a pharma-  
2 ceutical infrastructure that is substantially  
3 equivalent or superior to the pharmaceutical in-  
4 frastructure of the United States, taking into  
5 consideration pharmacist qualifications, phar-  
6 macy storage procedures, the drug distribution  
7 system, the drug dispensing system, and market  
8 regulation; and

9 “(B) may remove a country, union, or eco-  
10 nomic area from such list for purposes of this  
11 section if the Secretary determines that the  
12 country, union, or economic area does not have  
13 such a pharmaceutical infrastructure.

14 “(3) PHARMACIST.—The term ‘pharmacist’  
15 means a person licensed by the relevant govern-  
16 mental authority to practice pharmacy, including the  
17 dispensing and selling of prescription drugs.

18 “(4) PHARMACY.—The term ‘pharmacy’ means  
19 a person that is licensed by the relevant govern-  
20 mental authority to engage in the business of selling  
21 prescription drugs that employs 1 or more phar-  
22 macists.

23 “(5) PRESCRIPTION DRUG.—The term ‘pre-  
24 scription drug’ means a drug subject to section  
25 503(b), other than—

1           “(A) a controlled substance (as defined in  
2 section 102 of the Controlled Substances Act  
3 (21 U.S.C. 802));

4           “(B) a biological product (as defined in  
5 section 351 of the Public Health Service Act  
6 (42 U.S.C. 262));

7           “(C) an infused drug (including a peri-  
8 toneal dialysis solution);

9           “(D) an intravenously injected drug;

10          “(E) a drug that is inhaled during surgery;

11          or

12          “(F) a drug which is a parenteral drug,  
13 the importation of which pursuant to subsection  
14 (b) is determined by the Secretary to pose a  
15 threat to the public health, in which case sec-  
16 tion 801(d)(1) shall continue to apply.

17          “(6) QUALIFYING DRUG.—The term ‘qualifying  
18 drug’ means a prescription drug that—

19           “(A) is approved pursuant to an applica-  
20 tion submitted under section 505(b)(1); and

21           “(B) is not—

22               “(i) a drug manufactured through 1  
23 or more biotechnology processes;

24               “(ii) a drug that is required to be re-  
25 frigerated; or

1 “(iii) a photoreactive drug.

2 “(7) QUALIFYING INTERNET PHARMACY.—The  
3 term ‘qualifying Internet pharmacy’ means a reg-  
4 istered exporter that dispenses qualifying drugs to  
5 individuals over an Internet website.

6 “(8) QUALIFYING LABORATORY.—The term  
7 ‘qualifying laboratory’ means a laboratory in the  
8 United States that has been approved by the Sec-  
9 retary for the purposes of this section.

10 “(9) REGISTERED EXPORTER.—The term ‘reg-  
11 istered exporter’ means a person that is in the busi-  
12 ness of exporting a drug to persons in the United  
13 States (or that seeks to be in such business), for  
14 which a registration under this section has been ap-  
15 proved and is in effect.

16 “(10) WHOLESALER.—

17 “(A) IN GENERAL.—The term ‘wholesaler’  
18 means a person licensed as a wholesaler or dis-  
19 tributor of prescription drugs in the United  
20 States under section 503(e)(2)(A).

21 “(B) EXCLUSION.—The term ‘wholesaler’  
22 does not include a person authorized to import  
23 drugs under section 801(d)(1).”.

1 (b) REGULATIONS.—Section 804(b) of the Federal  
2 Food, Drug, and Cosmetic Act (21 U.S.C. 384(b)) is  
3 amended to read as follows:

4 “(b) REGULATIONS.—Not later than 180 days after  
5 the date of enactment of the Pharmaceutical Market Ac-  
6 cess Act of 2005, the Secretary, after consultation with  
7 the United States Trade Representative and the Commis-  
8 sioner of Customs, shall promulgate regulations permit-  
9 ting pharmacists, pharmacies, and wholesalers to import  
10 qualifying drugs from permitted countries into the United  
11 States.”.

12 (c) LIMITATION.—Section 804(c) of the Federal  
13 Food, Drug, and Cosmetic Act (21 U.S.C. 384(c)) is  
14 amended by striking “prescription drug” each place it ap-  
15 pears and inserting “qualifying drug”.

16 (d) INFORMATION AND RECORDS.—Section  
17 804(d)(1) of the Federal Food, Drug, and Cosmetic Act  
18 (21 U.S.C. 384(d)(1)) is amended—

19 (1) by striking subparagraph (G) and redesignig-  
20 nating subparagraphs (H) through (N) as subpara-  
21 graphs (G) through (M), respectively;

22 (2) in subparagraph (H) (as so redesignated),  
23 by striking “telephone number, and professional li-  
24 cense number (if any)” and inserting “and telephone  
25 number”; and

1           (3) in subparagraph (L) (as so redesignated),  
2           by striking “(J) and (L)” and inserting “(I) and  
3           (K)”.

4           (e) TESTING.—Section 804(e) of the Federal Food,  
5 Drug, and Cosmetic Act (21 U.S.C. 384(e)) is amended  
6 to read as follows:

7           “(e) TESTING.—The regulations under subsection (b)  
8 shall require that the testing described under subpara-  
9 graphs (I) and (K) of subsection (d)(1) be conducted by  
10 the importer of the qualifying drug, unless the qualifying  
11 drug is subject to the requirements under section 505C  
12 for counterfeit-resistant technologies.”.

13           (f) REGISTRATION OF EXPORTERS; INSPECTIONS.—  
14 Section 804(f) of the Federal Food, Drug, and Cosmetic  
15 Act (21 U.S.C. 384(f)) is amended to read as follows:

16           “(f) REGISTRATION OF EXPORTERS; INSPECTIONS.—

17           “(1) IN GENERAL.—Any person that seeks to  
18 be a registered exporter (referred to in this sub-  
19 section as the ‘registrant’) shall submit to the Sec-  
20 retary a registration that includes the following:

21           “(A) The name of the registrant and iden-  
22 tification of all places of business of the reg-  
23 istrant that relate to qualifying drugs, including  
24 each warehouse or other facility owned or con-  
25 trolled by, or operated for, the registrant;

1 “(B) An agreement by the registrant to—  
2 “(i) make its places of business that  
3 relate to qualifying drugs (including ware-  
4 houses and other facilities owned or con-  
5 trolled by, or operated for, the exporter)  
6 and records available to the Secretary for  
7 on-site inspections, without prior notice,  
8 for the purpose of determining whether the  
9 registrant is in compliance with this Act’s  
10 requirements;  
11 “(ii) export only qualifying drugs;  
12 “(iii) export only to persons author-  
13 ized to import the drugs;  
14 “(iv) notify the Secretary of a recall  
15 or withdrawal of a qualifying drug distrib-  
16 uted in a permitted country to or from  
17 which the registrant has exported or im-  
18 ported, or intends to export or import, to  
19 the United States;  
20 “(v) monitor compliance with registra-  
21 tion conditions and report any noncompli-  
22 ance promptly;  
23 “(vi) submit a compliance plan show-  
24 ing how the registrant will correct viola-  
25 tions, if any; and

1           “(vii) promptly notify the Secretary of  
2           changes in the registration information of  
3           the registrant.

4           “(2) NOTICE OF APPROVAL OR DISAPPROVAL.—

5           “(A) IN GENERAL.—Not later than 90  
6           days after receiving a completed registration  
7           from a registrant, the Secretary shall—

8           “(i) notify such registrant of receipt  
9           of the registration;

10          “(ii) assign such registrant a registra-  
11          tion number; and

12          “(ii) approve or disapprove the appli-  
13          cation.

14          “(B) DISAPPROVAL OF APPLICATION.—

15          “(i) IN GENERAL.—The Secretary  
16          shall disapprove a registration, and notify  
17          the registrant of such disapproval, if the  
18          Secretary has reason to believe that such  
19          registrant is not in compliance with a reg-  
20          istration condition.

21          “(ii) SUBSEQUENT APPROVAL.—The  
22          Secretary may subsequently approve a reg-  
23          istration that was denied under clause (i)  
24          if the Secretary finds that the registrant is

1 in compliance with all registration condi-  
2 tions.

3 “(3) LIST.—The Secretary shall—

4 “(A) maintain an up-to-date list of reg-  
5 istered exporters (including qualifying Internet  
6 pharmacies that sell qualifying drugs to individ-  
7 uals);

8 “(B) make such list available to the public  
9 on the Internet site of the Food and Drug Ad-  
10 ministration and via a toll-free telephone num-  
11 ber; and

12 “(C) update such list promptly after the  
13 approval of a registration under this subsection.

14 “(4) EDUCATION OF CONSUMERS.—The Sec-  
15 retary shall carry out activities, by use of the Inter-  
16 net website and toll-free telephone number under  
17 paragraph (3), that educate consumers with regard  
18 to the availability of qualifying drugs for import for  
19 personal use under this section, including informa-  
20 tion on how to verify whether an exporter is reg-  
21 istered.

22 “(5) INSPECTION OF IMPORTERS AND REG-  
23 ISTERED EXPORTERS.—The Secretary shall inspect  
24 the warehouses, other facilities, and records of im-  
25 porters and registered exporters as often as the Sec-

1       retary determines necessary to ensure that such im-  
2       porters and registered exporters are in compliance  
3       with this section.”.

4       (g) SUSPENSION OF IMPORTATION.—Section 804(g)  
5       of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
6       384(g)) is amended by—

7               (1) striking “and the Secretary determines that  
8       the public is adequately protected from counterfeit  
9       and violative prescription drugs being imported  
10       under subsection (b)”;

11              (2) by adding after the period at the end the  
12       following: “The Secretary shall reinstate the impor-  
13       tation by a specific importer upon a determination  
14       by the Secretary that the violation has been cor-  
15       rected and that the importer has demonstrated that  
16       further violations will not occur. This subsection  
17       shall not apply to a prescription drug imported by  
18       an individual, or to a prescription drug shipped to  
19       an individual by a qualifying Internet pharmacy.”.

20       (h) WAIVER AUTHORITY FOR INDIVIDUALS.—Section  
21       804(j) of the Federal Food, Drug, and Cosmetic Act (21  
22       U.S.C. 384(j)) is amended to read as follows:

23              “(j) IMPORTATION BY INDIVIDUALS.—

24                      “(1) IN GENERAL.—Not later than 180 days  
25       after the enactment of the Pharmaceutical Market

1 Access Act of 2005, the Secretary shall by regula-  
2 tion permit an individual to import a drug from a  
3 permitted country to the United States if the drug  
4 is—

5 “(A) a qualifying drug;

6 “(B) imported from a licensed pharmacy  
7 or qualifying Internet pharmacy;

8 “(C) for personal use by an individual, or  
9 family member of the individual, not for resale;

10 “(D) in a quantity that does not exceed a  
11 90-day supply during any 90-day period; and

12 “(E) accompanied by a copy of a prescrip-  
13 tion for the drug, which—

14 “(i) is valid under applicable Federal  
15 and State laws; and

16 “(ii) was issued by a practitioner who  
17 is authorized to administer prescription  
18 drugs.

19 “(2) DRUGS DISPENSED OUTSIDE THE UNITED  
20 STATES.—An individual may import a drug from a  
21 country that is not a permitted country if—

22 “(A) the drug was dispensed to the indi-  
23 vidual while the individual was in such country,  
24 and the drug was dispensed in accordance with  
25 the laws and regulations of such country;

1           “(B) the individual is entering the United  
2 States and the drug accompanies the individual  
3 at the time of entry;

4           “(C) the drug is approved for commercial  
5 distribution in the country in which the drug  
6 was obtained;

7           “(D) the drug does not appear to be adul-  
8 terated; and

9           “(E) the quantity of the drug does not ex-  
10 ceed a 14-day supply.”.

11           (i) REPEAL OF CERTAIN PROVISIONS.—Section 804  
12 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13 384) is amended by striking subsections (l) and (m).

14 **SEC. 5. REGISTRATION FEES.**

15           Subchapter C of chapter VII of the Federal Food,  
16 Drug, and Cosmetic Act (21 U.S.C. 397f et seq.) is  
17 amended by adding at the end the following:

18           **“PART 5—FEES RELATING TO PRESCRIPTION**

19                                   **DRUG IMPORTATION**

20           **“SEC. 740A. FEES RELATING TO PRESCRIPTION DRUG IM-**  
21                                   **PORTATION.**

22           “(a) REGISTRATION FEE.—The Secretary shall es-  
23 tablish a registration fee program under which a reg-  
24 istered exporter under section 804 shall be required to pay

1 an annual fee to the Secretary in accordance with this sub-  
2 section.

3 “(b) COLLECTION.—

4 “(1) COLLECTION ON INITIAL REGISTRATION.—

5 A fee under this section shall be payable for the fis-  
6 cal year in which the registered exporter first sub-  
7 mits a registration under section 804 (or reregisters  
8 under that section if that person has withdrawn its  
9 registration and subsequently reregisters) in a  
10 amount of \$10,000, due on the date the exporter  
11 first submits a registration to the Secretary under  
12 section 804.

13 “(2) COLLECTION IN SUBSEQUENT YEARS.—

14 After the fee is paid for the first fiscal year, the fee  
15 described under this subsection shall be payable on  
16 or before October 1 of each year.

17 “(3) ONE FEE PER FACILITY.—The fee shall be  
18 paid only once for each registered exporter for a fis-  
19 cal year in which the fee is payable.

20 “(c) FEE AMOUNT.—

21 “(1) IN GENERAL.—Subject to subsection  
22 (b)(1), the amount of the fee shall be determined  
23 each year by the Secretary and shall be based on the  
24 anticipated costs to the Secretary of enforcing the

1 amendments made by the Pharmaceutical Market  
2 Access Act of 2005 in the subsequent fiscal year.

3 “(2) LIMITATION.—

4 “(A) IN GENERAL.—The aggregate total of  
5 fees collected under this section shall not exceed  
6 1 percent of the total price of drugs exported  
7 annually to the United States by registered ex-  
8 porters under this section.

9 “(B) REASONABLE ESTIMATE.—Subject to  
10 the limitation described in subparagraph (A), a  
11 fee under this subsection for an exporter shall  
12 be an amount that is a reasonable estimate by  
13 the Secretary of the annual share of the ex-  
14 porter of the volume of drugs exported by ex-  
15 porters under this section.

16 “(d) USE OF FEES.—The fees collected under this  
17 section shall be used for the sole purpose of administering  
18 this section with respect to registered exporters, including  
19 the costs associated with—

20 “(1) inspecting the facilities of registered ex-  
21 porters, and of other entities in the chain of custody  
22 of a qualifying drug;

23 “(2) developing, implementing, and maintaining  
24 a system to determine registered exporters’ compli-  
25 ance with the registration conditions under the

1       Pharmaceutical Market Access Act of 2005, includ-  
2       ing when shipments of qualifying drugs are offered  
3       for import into the United States; and

4             “(3) inspecting such shipments, as necessary,  
5       when offered for import into the United States to  
6       determine if any such shipment should be refused  
7       admission.

8       “(e) ANNUAL FEE SETTING.—The Secretary shall  
9       establish, 60 days before the beginning of each fiscal year  
10      beginning after September 30, 2005, for that fiscal year,  
11      registration fees.

12      “(f) EFFECT OF FAILURE TO PAY FEES.—

13             “(1) DUE DATE.—A fee payable under this sec-  
14      tion shall be paid by the date that is 30 days after  
15      the date on which the fee is due.

16             “(2) FAILURE TO PAY.—If a registered exporter  
17      subject to a fee under this section fails to pay the  
18      fee, the Secretary shall not permit the registered ex-  
19      porter to engage in exportation to the United States  
20      or offering for exportation prescription drugs under  
21      this Act until all such fees owed by that person are  
22      paid.

23      “(g) REPORTS.—

1           “(1) FEE ESTABLISHMENT.—Not later than 60  
2 days before the beginning of each fiscal year, the  
3 Secretary shall—

4                   “(A) publish registration fees under this  
5 section for that fiscal year;

6                   “(B) hold a meeting at which the public  
7 may comment on the recommendations; and

8                   “(C) provide for a period of 30 days for  
9 the public to provide written comments on the  
10 recommendations.

11           “(2) PERFORMANCE AND FISCAL REPORT.—Be-  
12 ginning with fiscal year 2005, not later than 60 days  
13 after the end of each fiscal year during which fees  
14 are collected under this section, the Secretary shall  
15 submit to the Committee on Health, Education,  
16 Labor, and Pensions of the Senate and the Com-  
17 mittee on Energy and Commerce of the House of  
18 Representatives a report that describes—

19                   “(A) implementation of the registration fee  
20 authority during the fiscal year; and

21                   “(B) the use by the Secretary of the fees  
22 collected during the fiscal year for which the re-  
23 port is made.”.

1 **SEC. 6. COUNTERFEIT-RESISTANT TECHNOLOGY.**

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

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

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

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

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

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

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

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

25 “(1) shall be visible to the naked eye, providing  
26 for visual identification of product authenticity with-

1 out the need for readers, microscopes, lighting de-  
2 vices, or scanners;

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

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

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

11 “(c) STANDARDS FOR PACKAGING.—

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

20 “(2) LABELING OF SHIPPING CONTAINER.—  
21 Shipments of drugs described in subsection (a) shall  
22 include a label on the shipping container that incor-  
23 porates the technologies described in subsection (b),  
24 so that officials inspecting the packages will be able  
25 to determine the authenticity of the shipment. Chain

1 of custody procedures shall apply to such labels and  
2 shall include procedures applicable to contractual  
3 agreements for the use and distribution of the labels,  
4 methods to audit the use of the labels, and database  
5 access for the relevant governmental agencies for  
6 audit or verification of the use and distribution of  
7 the labels.

8 “(d) **EFFECTIVE DATE.**—This section shall take ef-  
9 fect 180 days after the date of enactment of the Pharma-  
10 ceutical Market Access Act of 2005.”.

11 **SEC. 7. PROHIBITED ACTS.**

12 Section 301 of the Federal Food, Drug, and Cosmetic  
13 Act (21 U.S.C. 331) is amended by inserting after sub-  
14 section (k) the following:

15 “(l) The failure to register in accordance with section  
16 804(f) or to import or offer to import a prescription drug  
17 in violation of a suspension order under section 804(g).”.

18 **SEC. 8. PATENTS.**

19 Section 271 of title 35, United States Code, is  
20 amended—

21 (1) by redesignating subsections (h) and (i) as  
22 subsections (i) and (j), respectively; and

23 (2) by inserting after subsection (g) the fol-  
24 lowing:

1       “(h) It shall not be an act of infringement to use,  
2 offer to sell, or sell within the United States or to import  
3 into the United States any patented invention under sec-  
4 tion 804 (21 U.S.C. 384) of the Federal Food, Drug, and  
5 Cosmetic Act that was first sold abroad by or under au-  
6 thority of the owner or licensee of such patent.”.

7 **SEC. 9. OTHER ENFORCEMENT ACTIONS.**

8       (a) IN GENERAL.—Section 804 of the Federal Food,  
9 Drug, and Cosmetic Act (as amended in section 4) is  
10 amended by adding at the end the following:

11       “(1) UNFAIR OR DISCRIMINATORY ACTS AND PRAC-  
12 TICES.—

13               “(1) IN GENERAL.—It is unlawful for a manu-  
14 facturer, directly or indirectly (including by being a  
15 party to a licensing or other agreement) to—

16                       “(A) discriminate by charging a higher  
17 price for a prescription drug sold to a person in  
18 a permitted country that exports a prescription  
19 drug to the United States under this section  
20 than the price that is charged to another person  
21 that is in the same country and that does not  
22 export a prescription drug into the United  
23 States under this section;

24                       “(B) discriminate by charging a higher  
25 price for a prescription drug sold to a person

1 that distributes, sells, or uses a prescription  
2 drug imported into the United States under  
3 this section than the price that is charged to  
4 another person in the United States that does  
5 not import a prescription drug under this sec-  
6 tion, or that does not distribute, sell, or use  
7 such a drug;

8 “(C) discriminate by denying supplies of a  
9 prescription drug to a person in a permitted  
10 country that exports a prescription drug to the  
11 United States under this section or distributes,  
12 sells, or uses a prescription drug imported into  
13 the United States under this section;

14 “(D) discriminate by publicly, privately, or  
15 otherwise refusing to do business with a person  
16 in a permitted country that exports a prescrip-  
17 tion drug to the United States under this sec-  
18 tion or distributes, sells, or uses a prescription  
19 drug imported into the United States under  
20 this section;

21 “(E) discriminate by specifically restricting  
22 or delaying the supply of a prescription drug to  
23 a person in a permitted country that exports a  
24 prescription drug to the United States under  
25 this section or distributes, sells, or uses a pre-

1            prescription drug imported into the United States  
2            under this section;

3            “(F) cause there to be a difference (includ-  
4            ing a difference in active ingredient, route of  
5            administration, dosage form, strength, formula-  
6            tion, manufacturing establishment, manufac-  
7            turing process, or person that manufactures the  
8            drug) between a prescription drug for distribu-  
9            tion in the United States and the drug for dis-  
10           distribution in a permitted country for the purpose  
11           of restricting importation of the drug into the  
12           United States under this section;

13           “(G) refuse to allow an inspection author-  
14           ized under this section of an establishment that  
15           manufactures a prescription drug that may be  
16           imported or offered for import under this sec-  
17           tion;

18           “(H) fail to conform to the methods used  
19           in, or the facilities used for, the manufacturing,  
20           processing, packing, or holding of a prescription  
21           drug that may be imported or offered for im-  
22           port under this section to good manufacturing  
23           practice under this Act;

24           “(I) become a party to a licensing or other  
25           agreement related to a prescription drug that

1 fails to provide for compliance with all require-  
2 ments of this section with respect to such pre-  
3 scription drug or that has the effect of prohib-  
4 iting importation of the drug under this section;  
5 or

6 “(J) engage in any other action that the  
7 Federal Trade Commission determines to dis-  
8 criminate against a person that engages in, or  
9 to impede, delay, or block the process for, the  
10 importation of a prescription drug under this  
11 section.

12 “(2) AFFIRMATIVE DEFENSE.—It shall be an  
13 affirmative defense to a charge that a person has  
14 discriminated under subparagraph (A), (B), (C),  
15 (D), or (E) of paragraph (1) that the higher price  
16 charged for a prescription drug sold to a person, the  
17 denial of supplies of a prescription drug to a person,  
18 the refusal to do business with a person, or the spe-  
19 cific restriction or delay of supplies to a person is  
20 not based, in whole or in part, on—

21 “(A) the person exporting or importing a  
22 prescription drug into the United States under  
23 this section; or

1           “(B) the person distributing, selling, or  
2           using a prescription drug imported into the  
3           United States under this section.

4           “(3) PRESUMPTION AND AFFIRMATIVE DE-  
5           FENSE.—

6           “(A) PRESUMPTION.—A difference (includ-  
7           ing a difference in active ingredient, route of  
8           administration, dosage form, strength, formula-  
9           tion, manufacturing establishment, manufac-  
10          turing process, or person that manufactures the  
11          drug) created after January 1, 2005, between a  
12          prescription drug for distribution in the United  
13          States and the drug for distribution in a per-  
14          mitted country shall be presumed under para-  
15          graph (1)(H) to be for the purpose of restrict-  
16          ing importation of the drug into the United  
17          States under this section.

18          “(B) AFFIRMATIVE DEFENSE.—It shall be  
19          an affirmative defense to the presumption  
20          under subparagraph (A) that—

21                  “(i) the difference was required by the  
22                  country in which the drug is distributed; or

23                  “(ii) the Secretary has determined  
24                  that the difference was necessary to im-

1           prove the safety or effectiveness of the  
2           drug.

3           “(4) EFFECT OF SUBSECTION.—

4           “(A) SALES IN OTHER COUNTRIES.—This  
5           subsection applies only to the sale or distribu-  
6           tion of a prescription drug in a country if the  
7           manufacturer of the drug chooses to sell or dis-  
8           tribute the drug in the country. Nothing in this  
9           subsection shall be construed to compel the  
10          manufacturer of a drug to distribute or sell the  
11          drug in a country.

12          “(B) DISCOUNTS TO INSURERS, HEALTH  
13          PLANS, PHARMACY BENEFIT MANAGERS, AND  
14          COVERED ENTITIES.—Nothing in this sub-  
15          section shall be construed to—

16                 “(i) prevent or restrict a manufac-  
17                 turer of a prescription drug from providing  
18                 discounts to an insurer, health plan, phar-  
19                 macy benefit manager in the United  
20                 States, or covered entity in the drug dis-  
21                 count program under section 340B in re-  
22                 turn for inclusion of the drug on a for-  
23                 mulary;

1           “(ii) require that such discounts be  
2           made available to other purchasers of the  
3           prescription drug; or

4           “(iii) prevent or restrict any other  
5           measures taken by an insurer, health plan,  
6           or pharmacy benefit manager to encourage  
7           consumption of such prescription drug.

8           “(C) CHARITABLE CONTRIBUTIONS.—  
9           Nothing in this subsection shall be construed  
10          to—

11           “(i) prevent a manufacturer from do-  
12           nating a prescription drug, or supplying a  
13           prescription drug at nominal cost, to a  
14           charitable or humanitarian organization,  
15           including the United Nations and affili-  
16           ates, or to a government of a foreign coun-  
17           try; or

18           “(ii) apply to such donations or sup-  
19           plying of a prescription drug.

20          “(5) ENFORCEMENT.—

21           “(A) UNFAIR OR DECEPTIVE ACT OR PRAC-  
22           TICE.—A violation of this subsection shall be  
23           treated as a violation of a rule defining an un-  
24           fair or deceptive act or practice prescribed

1 under section 18(a)(1)(B) of the Federal Trade  
2 Commission Act.

3 “(B) ACTIONS BY THE COMMISSION.—The  
4 Federal Trade Commission—

5 “(i) shall enforce this subsection in  
6 the same manner, by the same means, and  
7 with the same jurisdiction, powers, and du-  
8 ties as though all applicable terms and pro-  
9 visions of the Federal Trade Commission  
10 Act were incorporated into and made a  
11 part of this section; and

12 “(ii) may seek monetary relief three-  
13 fold the damages sustained.

14 “(6) ACTIONS BY STATES.—

15 “(A) IN GENERAL.—

16 “(i) CIVIL ACTIONS.—The attorney  
17 general of a State may bring a civil action  
18 on behalf of the residents of the State, and  
19 persons doing business in the State, in a  
20 district court of the United States of ap-  
21 propriate jurisdiction for a violation of  
22 paragraph (1) to—

23 “(I) enjoin that practice;

24 “(II) enforce compliance with  
25 this subsection;

1           “(III) obtain damages, restitu-  
2           tion, or other compensation on behalf  
3           of residents of the State and persons  
4           doing business in the State, including  
5           threefold the damages; or

6           “(IV) obtain such other relief as  
7           the court may consider to be appro-  
8           priate.

9           “(ii) NOTICE.—

10           “(I) IN GENERAL.—Before filing  
11           an action under clause (i), the attor-  
12           ney general of the State involved shall  
13           provide to the Federal Trade Commis-  
14           sion—

15           “(aa) written notice of that  
16           action; and

17           “(bb) a copy of the com-  
18           plaint for that action.

19           “(II) EXEMPTION.—Subclause  
20           (I) shall not apply with respect to the  
21           filing of an action by an attorney gen-  
22           eral of a State under this paragraph,  
23           if the attorney general determines  
24           that it is not feasible to provide the  
25           notice described in that subclause be-

1 fore filing of the action. In such case,  
2 the attorney general of a State shall  
3 provide notice and a copy of the com-  
4 plaint to the Federal Trade Commis-  
5 sion at the same time as the attorney  
6 general files the action.

7 “(B) INTERVENTION.—

8 “(i) IN GENERAL.—On receiving no-  
9 tice under subparagraph (A)(ii), the Com-  
10 mission shall have the right to intervene in  
11 the action that is the subject of the notice.

12 “(ii) EFFECT OF INTERVENTION.—If  
13 the Commission intervenes in an action  
14 under subparagraph (A), it shall have the  
15 right—

16 “(I) to be heard with respect to  
17 any matter that arises in that action;  
18 and

19 “(II) to file a petition for appeal.

20 “(C) CONSTRUCTION.—For purposes of  
21 bringing any civil action under subparagraph  
22 (A), nothing in this subsection shall be con-  
23 strued to prevent an attorney general of a State  
24 from exercising the powers conferred on the at-  
25 torney general by the laws of that State to—

1 “(i) conduct investigations;

2 “(ii) administer oaths or affirmations;

3 or

4 “(iii) compel the attendance of wit-  
5 nesses or the production of documentary  
6 and other evidence.

7 “(D) ACTIONS BY THE COMMISSION.—

8 “(i) IN GENERAL.—In any case in  
9 which an action is instituted by or on be-  
10 half of the Commission for a violation of  
11 paragraph (1), a State may not, during the  
12 pendency of that action, institute an action  
13 under subparagraph (A) for the same vio-  
14 lation against any defendant named in the  
15 complaint in that action.

16 “(ii) INTERVENTION.—An attorney  
17 general of a State may intervene, on behalf  
18 of the residents of that State, in an action  
19 instituted by the Commission.

20 “(iii) EFFECT OF INTERVENTION.—If  
21 an attorney general of a State intervenes  
22 in an action instituted by the Commission,  
23 such attorney general shall have the  
24 right—

1                   “(I) to be heard with respect to  
2                   any matter that arises in that action;  
3                   and

4                   “(II) to file a petition for appeal.

5                   “(E) VENUE.—Any action brought under  
6                   subparagraph (A) may be brought in the dis-  
7                   trict court of the United States that meets ap-  
8                   plicable requirements relating to venue under  
9                   section 1391 of title 28, United States Code.

10                  “(F) SERVICE OF PROCESS.—In an action  
11                  brought under subparagraph (A), process may  
12                  be served in any district in which the defend-  
13                  ant—

14                         “(i) is an inhabitant; or

15                         “(ii) may be found.

16                  “(G) LIMITATION OF ACTIONS.—Any ac-  
17                  tion under this paragraph to enforce a cause of  
18                  action under this subsection by the Federal  
19                  Trade Commission or the attorney general of a  
20                  State shall be forever barred unless commenced  
21                  within 5 years after the Federal Trade Commis-  
22                  sion, or the attorney general, as the case may  
23                  be, knew or should have known that the cause  
24                  of action accrued. No cause of action barred  
25                  under existing law on the effective date of the

1           Pharmaceutical Market Access Act of 2005  
2           shall be revived by such Act.

3           “(H) MEASUREMENT OF DAMAGES.—In  
4           any action under this paragraph to enforce a  
5           cause of action under this subsection in which  
6           there has been a determination that a defend-  
7           ant has violated a provision of this subsection,  
8           damages may be proved and assessed in the ag-  
9           gregate by statistical or sampling methods, by  
10          the computation of illegal overcharges or by  
11          such other reasonable system of estimating ag-  
12          gregate damages as the court in its discretion  
13          may permit without the necessity of separately  
14          proving the individual claim of, or amount of  
15          damage to, persons on whose behalf the suit  
16          was brought.

17          “(I) EXCLUSION ON DUPLICATIVE RE-  
18          LIEF.—The district court shall exclude from the  
19          amount of monetary relief awarded in an action  
20          under this paragraph brought by the attorney  
21          general of a State any amount of monetary re-  
22          lief which duplicates amounts which have been  
23          awarded for the same injury.

24          “(7) EFFECT ON ANTITRUST LAWS.—Nothing  
25          in this subsection shall be construed to modify, im-

1 pair, or supersede the operation of the antitrust  
2 laws. For the purpose of this subsection, the term  
3 ‘antitrust laws’ has the meaning given it in the first  
4 section of the Clayton Act, except that it includes  
5 section 5 of the Federal Trade Commission Act to  
6 the extent that such section 5 applies to unfair  
7 methods of competition.

8 “(8) MANUFACTURER.—In this subsection, the  
9 term ‘manufacturer’ means any entity, including any  
10 affiliate or licensee of that entity, that is engaged  
11 in—

12 “(A) the production, preparation, propaga-  
13 tion, compounding, conversion, or processing of  
14 a prescription drug, either directly or indirectly  
15 by extraction from substances of natural origin,  
16 or independently by means of chemical syn-  
17 thesis, or by a combination of extraction and  
18 chemical synthesis; or

19 “(B) the packaging, repackaging, labeling,  
20 relabeling, or distribution of a prescription  
21 drug.”.

22 (b) REGULATIONS.—The Federal Trade Commission  
23 shall promulgate regulations to carry out the enforcement  
24 program under section 804(l) of the Federal Food, Drug,  
25 and Cosmetic Act (as added by subsection (a)).

1 (c) SUSPENSION AND TERMINATION OF EXPORT-  
2 ERS.—Section 804(g) of the Federal Food, Drug, and  
3 Cosmetic Act (as amended by section 4(g)) (21 U.S.C.  
4 384(g)) is amended by—

5 (1) striking “SUSPENSION OF IMPORTATION.—

6 The Secretary” and inserting

7 “SUSPENSION OF IMPORTATION.—

8 “(1) IN GENERAL.—The Secretary”; and

9 (2) adding at the end the following:

10 “(2) SUSPENSION AND TERMINATION OF EX-  
11 PORTERS.—

12 “(A) SUSPENSION.—With respect to the  
13 effectiveness of a registration submitted under  
14 subsection (f) by a registered exporter:

15 “(i) Subject to clause (ii), if the Sec-  
16 retary determines, after notice and oppor-  
17 tunity for a hearing, that the registered ex-  
18 porter has failed to maintain substantial  
19 compliance with all registration conditions,  
20 the Secretary may suspend the registra-  
21 tion.

22 “(ii) If the Secretary determines that,  
23 under color of the registration, the reg-  
24 istered exporter has exported a drug that  
25 is not a qualifying drug, or a drug that

1 does not meet the criteria under this sec-  
2 tion, or has exported a qualifying drug to  
3 an individual in violation of this section,  
4 the Secretary shall immediately suspend  
5 the registration. A suspension under the  
6 preceding sentence is not subject to the  
7 provision by the Secretary of prior notice,  
8 and the Secretary shall provide to the reg-  
9 istered exporter involved an opportunity  
10 for a hearing not later than 10 days after  
11 the date on which the registration is sus-  
12 pended.

13 “(iii) The Secretary may reinstate the  
14 registration, whether suspended under  
15 clause (i) or (ii), if the Secretary deter-  
16 mines that the registered exporter has  
17 demonstrated that further violations of  
18 registration conditions will not occur.

19 “(B) TERMINATION.—The Secretary, after  
20 notice and opportunity for a hearing, may ter-  
21minate the registration under subsection (f) of  
22 a registered exporter if the Secretary deter-  
23 mines that the registered exporter has engaged  
24 in a pattern or practice of violating 1 or more  
25 registration conditions, or if on 1 or more occa-

1           sions the Secretary has under subparagraph  
2           (A)(ii) suspended the registration of the reg-  
3           istered exporter. The Secretary may make the  
4           termination permanent, or for a fixed period of  
5           not less than 1 year. During the period in  
6           which the registration of a registered exporter  
7           is terminated, any registration submitted under  
8           subsection (f) by such exporter or a person who  
9           is a partner in the export enterprise or a prin-  
10          cipal officer in such enterprise, and any reg-  
11          istration prepared with the assistance of such  
12          exporter or such a person, has no legal effect  
13          under this section.”.

14 **SEC. 10. AUTHORIZATION OF APPROPRIATIONS.**

15          There are authorized to be appropriated such sums  
16 as may be necessary to carry out this Act (and the amend-  
17 ments made by this Act).

○