

108TH CONGRESS
1ST SESSION

H. R. 2640

To provide greater access to affordable pharmaceuticals, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 26, 2003

Mr. KENNEDY of Rhode Island (for himself, Mr. FROST, and Ms. NORTON) 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 provide greater access to affordable pharmaceuticals, 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 “Prescription Afford-
5 ability and Medicine Safety Act of 2003”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

1 (1) Although prescription drugs represent one
2 of the increasingly used medical care interventions in
3 treating common acute and chronic diseases, many
4 Americans, especially the elderly and other vulner-
5 able populations, are often unable to afford their
6 medication because of excessive and persistent drug
7 price inflation.

8 (2) In 1999, the top 5 pharmaceutical compa-
9 nies allocated a higher proportion of their revenue to
10 their income than to research and development.

11 (3) In 2000, over $\frac{1}{3}$ of the most frequently pre-
12 scribed drugs for seniors rose in price at a rate that
13 was 3 times the rate of inflation.

14 (4) Prescription drug manufacturers continue
15 to make enormous profits on the backs of Ameri-
16 cans.

17 (5) Because of the limited availability of private
18 or public prescription drug coverage for the elderly,
19 prescription drugs represent the highest out-of-pock-
20 et medical care cost for 3 of 4 elderly patients, sur-
21 passed only by the cost of long-term care services.

22 (6) Ninety percent of Americans who are 60
23 years of age or older take 1 or more medications
24 daily.

1 (7) According to a recent study, around 60 per-
2 cent of doctors say that patients somewhat often
3 talk with them about specific disease or treatment
4 they heard about from prescription drug advertise-
5 ments.

6 (8) The National Institutes of Health, the Gov-
7 ernment's most important health research arm, has
8 helped develop almost all of the 50 top-selling drugs
9 from 1992 through 1997 for a cost of over
10 \$175,000,000.

11 (9) The pharmaceutical industry makes large
12 profits off the sale of drugs produced from the ben-
13 efit of research paid for by the United States and,
14 aside from royalties, none of such profits are reim-
15 bursed to United States taxpayers.

16 (10) Only 24 percent of people over age 45 al-
17 ways ask their pharmacist about drug side effects.

18 (11) Only 31 percent of people over age 45 al-
19 ways ask their pharmacists about cost-saving generic
20 equivalents for new prescriptions.

21 **SEC. 3. GENERIC DRUG APPLICATION REVIEW.**

22 For the purpose of enabling the Food and Drug Ad-
23 ministration to employ additional staff for the Office of
24 Generic Drugs to review abbreviated applications for the
25 approval of new drugs under section 505(j) of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), and
 2 for the purpose of otherwise providing for accelerated re-
 3 views of such applications, there is authorized to be appro-
 4 priated \$5,000,000 for each fiscal year, in addition to
 5 other authorizations of appropriations that are available
 6 for such purposes.

7 **SEC. 4. GENERIC DRUG EDUCATION.**

8 For the purpose of enabling the Food and Drug Ad-
 9 ministration, through the Office of Generic Drugs, to con-
 10 tinue the education program started in fiscal year 2001
 11 on the use and therapeutic equivalency of drugs approved
 12 under section 505(j) of the Federal Food, Drug, and Cos-
 13 metic Act (21 U.S.C. 355(j)), there is authorized to be
 14 appropriated \$1,000,000 for each fiscal year, in addition
 15 to other authorizations of appropriations that are available
 16 for such purpose.

17 **SEC. 5. PRESCRIPTION DRUG ASSISTANCE PROGRAM;
 18 PROFITS FROM RESEARCH.**

19 The Public Health Service Act (42 U.S.C. 201 et
 20 seq.) is amended by adding at the end the following:

21 **“TITLE XXIX—PHARMACY
 22 ASSISTANCE**

23 **“SEC. 2901. GRANTS.**

24 “(a) AUTHORIZATION.—From amounts available
 25 from the revolving fund established under section 2903,

1 the Secretary may make grants to States for the purpose
2 of providing pharmacy assistance as described in sub-
3 section (b).

4 “(b) USE OF FUNDS.—A grant may be made under
5 subsection (a) only if the State involved agrees that funds
6 received under the grant will be used—

7 “(1) to provide outreach services and education
8 regarding an existing State pharmacy benefit assist-
9 ance program; or

10 “(2) to establish or expand such a program.

11 “(c) APPLICATION.—To seek a grant under this sec-
12 tion, a State shall submit an application to the Secretary
13 at such time, in such manner, and accompanied by such
14 information as the Secretary may reasonably require.

15 “(d) STATE DEFINED.—For purposes of this section,
16 the term ‘State’ means any of the several States, the Dis-
17 trict of Columbia, the Commonwealth of Puerto Rico, the
18 Commonwealth of the Northern Mariana Islands, Amer-
19 ican Samoa, Guam, the Virgin Islands, or any other terri-
20 tory or possession of the United States.

21 **“SEC. 2902. PROFITS FROM RESEARCH.**

22 “(a) IN GENERAL.—Subject to subsection (b), the
23 Secretary shall not approve any covered application for the
24 approval of a biological product under section 351 of this
25 Act or of a drug under section 505 of the Federal Food,

1 Drug, and Cosmetic Act unless the manufacturer submit-
2 ting the application enters into an agreement with the Sec-
3 retary that—

4 “(1) requires the manufacturer to pay the Sec-
5 retary 7 percent of the gross amount received by the
6 manufacturer from sales of such biological product
7 or drug; and

8 “(2) specifies the manner in which such gross
9 amount will be determined.

10 “(b) EXCEPTION.—The Secretary may waive the ap-
11 plication of subsection (a) to a manufacturer of a biologi-
12 cal product or drug when the Secretary determines that
13 it would be in the public interest to exempt such manufac-
14 turer.

15 “(c) COVERED APPLICATION.—For purposes of this
16 section, the term ‘covered application’ means an applica-
17 tion that includes the results of research carried out—

18 “(1) by an entity of the National Institutes of
19 Health; or

20 “(2) under an agreement under section 12 of
21 the Stevenson-Wydler Technology Innovation Act of
22 1980.

23 **“SEC. 2903. REVOLVING FUND.**

24 “(a) ESTABLISHMENT.—There is hereby established
25 in the Treasury a revolving fund which shall consist of

1 the amounts deposited by the Secretary under subsection
2 (b).

3 “(b) DEPOSIT OF FUNDS.—The Secretary shall de-
4 posit in the fund established under this section all pay-
5 ments made to the Secretary under an agreement pursu-
6 ant to section 2902(a)(1).

7 “(c) USE OF AMOUNTS IN FUND.—To the extent or
8 in the amounts made available in advance in appropria-
9 tions Acts, amounts in the fund established under this sec-
10 tion shall be available to the Secretary to make grants
11 under section 2901.”.

12 **SEC. 6. LIMITATION ON DEDUCTIONS FOR ADVERTISING BY**
13 **PRESCRIPTION DRUG MANUFACTURERS.**

14 (a) IN GENERAL.—Part IX of subchapter B of chap-
15 ter 1 of subtitle A of the Internal Revenue Code of 1986
16 (relating to items not deductible) is amended by adding
17 at the end the following:

18 **“SEC. 280I. LIMITATION ON DEDUCTIONS FOR ADVER-**
19 **TISING BY PRESCRIPTION DRUG MANUFAC-**
20 **TURERS.**

21 “(a) IN GENERAL.—No deduction shall be allowed
22 under this chapter for any taxable year for any expendi-
23 ture relating to the advertising, promoting, or marketing
24 (in any medium) of any prescription drug manufactured
25 by the taxpayer to the extent the aggregate amount of

1 such expenditures exceeds 50 percent of the taxpayer's ag-
2 gregate research and development expenditures for such
3 taxable year.

4 “(b) DEFINITIONS AND SPECIAL RULES.—For pur-
5 poses of this section:

6 “(1) PRESCRIPTION DRUGS.—The term ‘pre-
7 scription drug’ means any drug subject to section
8 503(b)(1) of the Federal Food, Drug, and Cosmetic
9 Act.

10 “(2) RESEARCH AND DEVELOPMENT EXPENDI-
11 TURES.—The term ‘research and development ex-
12 penditures’ means any expenditures that may be
13 treated as expenses under section 174.

14 “(3) AGGREGATION RULES.—All members of
15 the same controlled group of corporations (within
16 the meaning of section 52(a)) and all persons under
17 common control (within the meaning of section
18 52(b)) shall be treated as 1 person.”.

19 (b) CLERICAL AMENDMENT.—The table of sections
20 for such part IX is amended by adding after the item re-
21 lating to section 280H the following:

“Sec. 280I. Limitation on deductions for advertising by pre-
scription drug manufacturers.”.

22 (c) EFFECTIVE DATE.—The amendments made by
23 this section shall apply to taxable years beginning after
24 December 31, 2002.

1 (d) TRANSFER TO THE FEDERAL HOSPITAL INSUR-
2 ANCE TRUST FUND OF RESULTING BUDGETARY SAV-
3 INGS.—There are authorized to be appropriated to the
4 Federal Hospital Insurance Trust Fund established under
5 section 1817 of the Social Security Act amounts equal to
6 the increase in Federal revenues resulting from the
7 amendment made by subsection (a). Such appropriated
8 amounts may be transferred from the general fund of the
9 Treasury on the basis of estimates of such revenues made
10 by the Secretary of the Treasury.

11 **SEC. 7. LIMITATION OF 30-MONTH STAY TO CERTAIN PAT-**
12 **ENTS.**

13 (a) ABBREVIATED NEW DRUG APPLICATIONS.—

14 (1) IN GENERAL.—Clause (iii) of section
15 505(j)(5)(B) of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 355(j)(5)(B)) is amended to
17 read as follows:

18 “(iii) If the applicant made a certification de-
19 scribed in subclause (IV) of paragraph (2)(A)(vii):

20 “(I) If such certification concerns a patent
21 (other than a patent that claims a process for
22 manufacturing the listed drug) for which patent
23 information was submitted under subsection
24 (b), the approval shall be made effective imme-
25 diately unless an action is brought for infringe-

1 ment of a patent which is the subject of the cer-
2 tification before the expiration of 45 days from
3 the date the notice provided under paragraph
4 (2)(B)(i) is received. If such an action is
5 brought before the expiration of such days, the
6 approval shall be made effective upon the expi-
7 ration of the 30-month period beginning on the
8 date of the receipt of the notice provided under
9 paragraph (2)(B)(i) or such shorter or longer
10 period as the court may order because either
11 party to the action failed to reasonably cooper-
12 ate in expediting the action, except that—

13 “(aa) if before the expiration of such
14 period the court decides that such patent is
15 invalid or not infringed, the approval shall
16 be made effective on the date of the court
17 decision;

18 “(bb) if before the expiration of such
19 period the court decides that such patent
20 has been infringed, the approval shall be
21 made effective on such date as the court
22 orders under section 271(e)(4)(A) of title
23 35, United States Code; or

24 “(cc) if before the expiration of such
25 period the court grants a preliminary in-

1 junction prohibiting the applicant from en-
2 gaging in the commercial manufacture or
3 sale of the drug until the court decides the
4 issues of patent validity and infringement
5 and if the court decides that such patent
6 is invalid or not infringed, the approval
7 shall be made effective on the date of such
8 court decision.

9 “In such an action, each of the parties shall
10 reasonably cooperate in expediting the action.
11 Until the expiration of 45 days from the date
12 the notice made under paragraph (2)(B)(i) is
13 received, no action may be brought under sec-
14 tion 2201 of title 28, United States Code, for
15 a declaratory judgment with respect to the pat-
16 ent. Any action brought under such section
17 2201 shall be brought in the judicial district
18 where the defendant has its principal place of
19 business or a regular and established place of
20 business. The 30-month period provided under
21 the second sentence of this clause shall not
22 apply to a certification under paragraph
23 (2)(A)(vii)(IV) made with respect to a patent
24 for which patent information was submitted
25 under subsection (c)(2).

1 “(II) If the certification referred to at the
2 beginning of this clause concerns a patent
3 (other than a patent that claims a process for
4 manufacturing the listed drug) for which patent
5 information was submitted under subsection
6 (c)(2), the approval shall be made effective on
7 the date that is 45 days after the date on which
8 the notice provided under paragraph (2)(B) is
9 received, unless a civil action for infringement
10 of the patent, accompanied by a motion for pre-
11 liminary injunction to enjoin the applicant from
12 engaging in the commercial manufacture or sale
13 of the drug, is filed on or before such date, in
14 which case the approval shall be made effec-
15 tive—

16 “(aa) on the date of a court action de-
17 clining to grant a preliminary injunction;
18 or

19 “(bb) if the court has granted a pre-
20 liminary injunction prohibiting the appli-
21 cant from engaging in the commercial
22 manufacture or sale of the drug—

23 “(AA) on issuance by a court of
24 a determination that the patent is in-
25 valid or is not infringed;

1 “(BB) on issuance by a court of
2 an order revoking the preliminary in-
3 junction or permitting the applicant to
4 engage in the commercial manufac-
5 ture or sale of the drug; or

6 “(CC) on the date specified in a
7 court order under section
8 271(e)(4)(A) of title 35, United
9 States Code, if the court determines
10 that the patent is infringed.

11 “Each of the parties shall reasonably cooperate
12 in expediting a civil action under this subclause.
13 If the notice under paragraph (2)(B) contains
14 an address for the receipt of expedited notifica-
15 tion of a civil action under this subclause, the
16 plaintiff shall, on the date on which the com-
17 plaint is filed, simultaneously cause a notifica-
18 tion of the civil action to be delivered to that
19 address by the next business day.”.

20 (2) FAILURE TO BRING INFRINGEMENT AC-
21 TION.—Paragraph (5) of section 505(j) of the Fed-
22 eral Food, Drug, and Cosmetic Act (21 U.S.C.
23 355(j)) is amended by adding at the end the fol-
24 lowing:

1 “(E) If, in connection with an application under this
2 subsection, the applicant provides an owner of a patent
3 notice under paragraph (2)(B) with respect to the patent,
4 and the owner of the patent fails to bring a civil action
5 against the applicant for infringement of the patent on
6 or before the date that is 45 days after the date on which
7 the notice is received, the owner of the patent shall be
8 barred from bringing a civil action for infringement of the
9 patent in connection with the development, manufacture,
10 use, offer to sell, or sale of the drug for which the applica-
11 tion was filed or approved under this subsection.”.

12 (b) OTHER APPLICATIONS.—

13 (1) IN GENERAL.—Subparagraph (C) of section
14 505(c)(3) of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 355(c)(3)) is amended to read as fol-
16 lows:

17 “(C) If the applicant made a certification de-
18 scribed in subsection (b)(2)(A)(iv):

19 “(i) If such certification concerns a patent
20 (other than a patent that claims a process for
21 manufacturing the listed drug) for which patent
22 information was submitted under subsection
23 (b), the approval shall be made effective imme-
24 diately unless an action is brought for infringe-
25 ment of a patent which is the subject of the cer-

1 tification before the expiration of 45 days from
2 the date the notice provided under subsection
3 (b)(3)(A) is received. If such an action is
4 brought before the expiration of such days, the
5 approval may be made effective upon the expi-
6 ration of the 30-month period beginning on the
7 date of the receipt of the notice provided under
8 subsection (b)(3)(A) or such shorter or longer
9 period as the court may order because either
10 party to the action failed to reasonably cooper-
11 ate in expediting the action, except that—

12 “(I) if before the expiration of such
13 period the court decides that such patent is
14 invalid or not infringed, the approval shall
15 be made effective on the date of the court
16 decision;

17 “(II) if, before the expiration of such
18 period, the court decides that such patent
19 has been infringed, the approval shall be
20 made effective on such date as the court
21 orders under section 271(e)(4)(A) of title
22 35, United States Code; or

23 “(III) if before the expiration of such
24 period the court grants a preliminary in-
25 junction prohibiting the applicant from en-

1 gaging in the commercial manufacture or
2 sale of the drug until the court decides the
3 issues of patent validity and infringement
4 and if the court decides that such patent
5 is invalid or not infringed, the approval
6 shall be made effective on the date of such
7 court decision.

8 “In such an action, each of the parties shall
9 reasonably cooperate in expediting the action.
10 Until the expiration of 45 days from the date
11 the notice made under subsection (b)(3)(A) is
12 received, no action may be brought under sec-
13 tion 2201 of title 28, United States Code, for
14 a declaratory judgment with respect to the pat-
15 ent. Any action brought under such section
16 2201 shall be brought in the judicial district
17 where the defendant has its principal place of
18 business or a regular and established place of
19 business. The 30-month period provided under
20 the second sentence of this subparagraph shall
21 not apply to a certification under subsection
22 (b)(2)(A)(iv) made with respect to a patent for
23 which patent information was submitted under
24 subsection (c)(2).

1 “(ii) If the certification referred to at the
2 beginning of this subparagraph concerns a pat-
3 ent (other than a patent that claims a process
4 for manufacturing the listed drug) for which
5 patent information was submitted under sub-
6 section (c)(2), the approval shall be made effec-
7 tive on the date that is 45 days after the date
8 on which the notice provided under subsection
9 (b)(3) is received, unless a civil action for in-
10 fringement of the patent, accompanied by a mo-
11 tion for preliminary injunction to enjoin the ap-
12 plicant from engaging in the commercial manu-
13 facture or sale of the drug, is filed on or before
14 such date, in which case the approval shall be
15 made effective—

16 “(I) on the date of a court action de-
17 clining to grant a preliminary injunction;
18 or

19 “(II) if the court has granted a pre-
20 liminary injunction prohibiting the appli-
21 cant from engaging in the commercial
22 manufacture or sale of the drug—

23 “(aa) on issuance by a court of a
24 determination that the patent is in-
25 valid or is not infringed;

1 “(bb) on issuance by a court of
2 an order revoking the preliminary in-
3 junction or permitting the applicant to
4 engage in the commercial manufac-
5 ture or sale of the drug; or

6 “(cc) on the date specified in a
7 court order under section
8 271(e)(4)(A) of title 35, United
9 States Code, if the court determines
10 that the patent is infringed.

11 “Each of the parties shall reasonably cooperate
12 in expediting a civil action under this clause. If
13 the notice under subsection (b)(3) contains an
14 address for the receipt of expedited notification
15 of a civil action under this clause, the plaintiff
16 shall, on the date on which the complaint is
17 filed, simultaneously cause a notification of the
18 civil action to be delivered to that address by
19 the next business day.”.

20 (2) FAILURE TO BRING INFRINGEMENT AC-
21 TION.—Subsection (c) of section 505 of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C.
23 355(c)(3)) is amended by adding at the end the fol-
24 lowing:

1 “(5) If, in connection with an application under sub-
2 section (b)(2), the applicant provides an owner of a patent
3 notice under subsection (b)(3) with respect to the patent,
4 and the owner of the patent fails to bring a civil action
5 against the applicant for infringement of the patent on
6 or before the date that is 45 days after the date on which
7 the notice is received, the owner of the patent shall be
8 barred from bringing a civil action for infringement of the
9 patent in connection with the development, manufacture,
10 use, offer to sell, or sale of the drug for which the applica-
11 tion was filed or approved under subsection (b)(2).”.

12 (c) EFFECTIVE DATE.—The amendments made by
13 subsections (a) and (b) shall be effective with respect to
14 any certification under subsection (b)(2)(A)(iv) or
15 (j)(2)(A)(vii)(IV) of section 505 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 355) made after the
17 date of enactment of this Act in an application filed under
18 subsection (b)(2) or (j) of that section, including with re-
19 spect to patent information that was submitted to the Sec-
20 retary before such date under subsection (c)(2) of such
21 Act.

1 **SEC. 8. EXCLUSIVITY FOR ACCELERATED GENERIC DRUG**
2 **APPLICANTS.**

3 (a) IN GENERAL.—Section 505(j)(5) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is
5 amended—

6 (1) in subparagraph (B)(iv)—

7 (A) in the text preceding subclause (I), by
8 inserting “the earlier of—” after “not earlier
9 than one hundred and eighty days after”;

10 (B) by striking “or” at the end of sub-
11 clause (I);

12 (C) by striking subclause (II) and all that
13 follows through the end; and

14 (D) by adding after subclause (I) the fol-
15 lowing:

16 “(II) the date of a final decision of a court
17 (from which no appeal has been or can be
18 taken, other than a petition to the Supreme
19 Court for a writ of certiorari) holding that the
20 patent that is the subject of the certification is
21 invalid or not infringed, or

22 “(III) the date of a settlement order or
23 consent decree signed by a Federal judge that
24 enters a final judgment and includes a finding
25 that the patent that is the subject of the certifi-
26 cation is invalid or not infringed.”; and

1 (2) by inserting after subparagraph (D) the fol-
2 lowing:

3 “(E) FORFEITURE OF 180-DAY PERIOD.—

4 “ (i) IN GENERAL.—Except as provided in
5 clause (ii), if a forfeiture event occurs with respect
6 to a first application—

7 “ (I) the 180-day period under subpara-
8 graph (B)(iv) shall be forfeited by the first ap-
9 plicant; and

10 “ (II) any subsequent application shall be-
11 come effective as provided under clause (i), (ii),
12 or (iii) of subparagraph (B), and clause (iv) of
13 subparagraph (B) shall not apply to the subse-
14 quent application.

15 “ (ii) FORFEITURE TO FIRST SUBSEQUENT AP-
16 PLICANT.—If the subsequent application that is the
17 first to be made effective under clause (i) was the
18 first among a number of subsequent applications to
19 be filed—

20 “ (I) that first subsequent application shall
21 be treated as the first application under this
22 subparagraph (including clause (i)) and as the
23 previous application under subparagraph
24 (B)(iv); and

1 “(II) any other subsequent applications
2 shall become effective as provided under clause
3 (i), (ii), or (iii) of subparagraph (B), but clause
4 (iv) of subparagraph (B) shall apply to any
5 such subsequent application.

6 “(iii) AVAILABILITY.—The 180-day period
7 under subparagraph (B)(iv) shall be available to a
8 first applicant submitting an application for a drug
9 with respect to any patent without regard to whether
10 an application has been submitted for the drug
11 under this subsection containing such a certification
12 with respect to a different patent.

13 “(iv) APPLICABILITY.—The 180-day period de-
14 scribed in subparagraph (B)(iv) shall apply to an ap-
15 plication only if a civil action is brought against the
16 applicant for infringement of a patent that is the
17 subject of the certification.

18 “(v) DEFINITIONS.—In this subparagraph:

19 “(I) APPLICATION.—The term ‘application’
20 means an application for approval of a drug
21 under this subsection containing a certification
22 under paragraph (2)(A)(vii)(IV) with respect to
23 a patent.

1 “(II) FIRST APPLICATION.—The term
2 ‘first application’ means the first application to
3 be filed for approval of the drug.

4 “(III) FORFEITURE EVENT.—The term
5 ‘forfeiture event’, with respect to an application
6 under this subsection, means the occurrence of
7 any of the following:

8 “(aa) FAILURE TO MARKET.—The ap-
9 plicant fails to market the drug by the
10 later of—

11 “(AA) the date that is 60 days
12 after the date on which the approval
13 of the application for the drug is
14 made effective under clause (iii) of
15 subparagraph (B) (unless the Sec-
16 retary extends the date because of ex-
17 traordinary or unusual cir-
18 cumstances); or

19 “(BB) if 1 or more civil actions
20 have been brought against the appli-
21 cant for infringement of a patent sub-
22 ject to a certification under paragraph
23 (2)(A)(vii)(IV) or 1 or more civil ac-
24 tions have been brought by the appli-
25 cant for a declaratory judgment that

1 such a patent is invalid or not in-
2 fringed, the date that is 60 days after
3 the date of a final decision (from
4 which no appeal has been or can be
5 taken, other than a petition to the Su-
6 preme Court for a writ of certiorari)
7 in the last of those civil actions to be
8 decided (unless the Secretary extends
9 the date because of extraordinary or
10 unusual circumstances).

11 “(bb) WITHDRAWAL OF APPLICA-
12 TION.—The applicant withdraws the appli-
13 cation.

14 “(cc) AMENDMENT OF CERTIFI-
15 CATION.—The applicant, voluntarily or as
16 a result of a settlement or defeat in patent
17 litigation, amends the certification from a
18 certification under paragraph
19 (2)(A)(vii)(IV) to a certification under
20 paragraph (2)(A)(vii)(III).

21 “(dd) FAILURE TO OBTAIN AP-
22 PROVAL.—The applicant fails to obtain
23 tentative approval of an application within
24 30 months after the date on which the ap-

1 application is filed, unless the failure is
2 caused by—

3 “(AA) a change in the require-
4 ments for approval of the application
5 imposed after the date on which the
6 application is filed; or

7 “(BB) other extraordinary cir-
8 cumstances warranting an exception,
9 as determined by the Secretary.

10 “(ee) FAILURE TO CHALLENGE PAT-
11 ENT.—In a case in which, after the date
12 on which the applicant submitted the ap-
13 plication, new patent information is sub-
14 mitted under subsection (c)(2) for the list-
15 ed drug for a patent for which certification
16 is required under paragraph (2)(A), the
17 applicant fails to submit, not later than the
18 date that is 60 days after the date on
19 which the Secretary publishes the new pat-
20 ent information under paragraph
21 (7)(A)(iii) (unless the Secretary extends
22 the date because of extraordinary or un-
23 usual circumstances)—

24 “(AA) a certification described in
25 paragraph (2)(A)(vii)(IV) with respect

1 to the patent to which the new patent
2 information relates; or

3 “(BB) a statement that any
4 method of use claim of that patent
5 does not claim a use for which the ap-
6 plicant is seeking approval under this
7 subsection in accordance with para-
8 graph (2)(A)(viii).

9 “(ff) UNLAWFUL CONDUCT.—The
10 Federal Trade Commission determines
11 that the applicant engaged in unlawful
12 conduct with respect to the application in
13 violation of section 1 of the Sherman Act.

14 “(IV) SUBSEQUENT APPLICATION.—The
15 term ‘subsequent application’ means an applica-
16 tion for approval of a drug that is filed subse-
17 quent to the filing of a first application for ap-
18 proval of that drug.”.

19 (b) APPLICABILITY.—The amendment made by sub-
20 section (a) shall apply only with respect to an application
21 filed under section 505(j) of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 355(j)) after the date of enact-
23 ment of this Act for a listed drug for which no certification
24 under section 505(j)(2)(A)(vii)(IV) of that Act was made
25 before the date of enactment of this Act, except that if

1 a forfeiture event described in section
2 505(j)(5)(E)(v)(III)(ff) of that Act (as amended by this
3 section) occurs in the case of an applicant, the applicant
4 shall forfeit the 180-day period under section
5 505(j)(5)(B)(iv) of that Act without regard to when the
6 applicant made a certification under section
7 505(j)(2)(A)(vii)(IV) of that Act.

8 **SEC. 9. BIOEQUIVALENCE.**

9 (a) IN GENERAL.—The amendments to part 320 of
10 title 21, Code of Federal Regulations, promulgated by the
11 Commissioner of Food and Drugs on July 17, 1991 (57
12 Fed. Reg. 17997 (April 28, 1992)), shall continue in effect
13 as an exercise of authorities under sections 501, 502, 505,
14 and 701 of the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 351, 352, 355, 371).

16 (b) EFFECT.—Subsection (a) does not affect the au-
17 thority of the Commissioner of Food and Drugs to amend
18 part 320 of title 21, Code of Federal Regulations.

19 (c) EFFECT OF SECTION.—This section shall not be
20 construed to alter the authority of the Secretary of Health
21 and Human Services to regulate biological products under
22 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
23 et seq.). Any such authority shall be exercised under that
24 Act as in effect on the day before the date of enactment
25 of this Act.

1 **SEC. 10. FILING OF PATENT INFORMATION WITH THE FOOD**
2 **AND DRUG ADMINISTRATION.**

3 (a) FILING AFTER APPROVAL OF AN APPLICA-
4 TION.—

5 (1) IN GENERAL.—Section 505 of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 355) (as
7 amended by section 9(a)(2)(B)(ii)) is amended in
8 subsection (c) by striking paragraph (2) and insert-
9 ing the following:

10 “(2) PATENT INFORMATION.—

11 “(A) IN GENERAL.—Not later than the
12 date that is 30 days after the date of an order
13 approving an application under subsection (b)
14 (unless the Secretary extends the date because
15 of extraordinary or unusual circumstances), the
16 holder of the application shall file with the Sec-
17 retary the patent information described in sub-
18 paragraph (C) with respect to any patent—

19 “(i)(I) that claims the drug for which
20 the application was approved; or

21 “(II) that claims an approved method
22 of using the drug; and

23 “(ii) with respect to which a claim of
24 patent infringement could reasonably be
25 asserted if a person not licensed by the

1 owner engaged in the manufacture, use, or
2 sale of the drug.

3 “(B) SUBSEQUENTLY ISSUED PATENTS.—

4 In a case in which a patent described in sub-
5 paragraph (A) is issued after the date of an
6 order approving an application under subsection
7 (b), the holder of the application shall file with
8 the Secretary the patent information described
9 in subparagraph (C) not later than the date
10 that is 30 days after the date on which the pat-
11 ent is issued (unless the Secretary extends the
12 date because of extraordinary or unusual cir-
13 cumstances).

14 “(C) PATENT INFORMATION.—The patent
15 information required to be filed under subpara-
16 graph (A) or (B) includes—

17 “(i) the patent number;

18 “(ii) the expiration date of the patent;

19 “(iii) with respect to each claim of the
20 patent—

21 “(I) whether the patent claims
22 the drug or claims a method of using
23 the drug; and

24 “(II) whether the claim covers—

25 “(aa) a drug substance;

1 “(bb) a drug formulation;

2 “(cc) a drug composition; or

3 “(dd) a method of use;

4 “(iv) if the patent claims a method of
5 use, the approved use covered by the claim;

6 “(v) the identity of the owner of the
7 patent (including the identity of any agent
8 of the patent owner); and

9 “(vi) a declaration that the applicant,
10 as of the date of the filing, has provided
11 complete and accurate patent information
12 for all patents described in subparagraph
13 (A).

14 “(D) PUBLICATION.—On filing of patent
15 information required under subparagraph (A)
16 or (B), the Secretary shall—

17 “(i) immediately publish the informa-
18 tion described in clauses (i) through (iv) of
19 subparagraph (C); and

20 “(ii) make the information described
21 in clauses (v) and (vi) of subparagraph (C)
22 available to the public on request.

23 “(E) CIVIL ACTION FOR CORRECTION OR
24 DELETION OF PATENT INFORMATION.—

1 “(i) IN GENERAL.—A person that has
2 filed an application under subsection (b)(2)
3 or (j) for a drug may bring a civil action
4 against the holder of the approved applica-
5 tion for the drug seeking an order requir-
6 ing that the holder of the application
7 amend the application—

8 “(I) to correct patent information
9 filed under subparagraph (A); or

10 “(II) to delete the patent infor-
11 mation in its entirety for the reason
12 that—

13 “(aa) the patent does not
14 claim the drug for which the ap-
15 plication was approved; or

16 “(bb) the patent does not
17 claim an approved method of
18 using the drug.

19 “(ii) LIMITATIONS.—Clause (i) does
20 not authorize—

21 “(I) a civil action to correct pat-
22 ent information filed under subpara-
23 graph (B); or

24 “(II) an award of damages in a
25 civil action under clause (i).

1 “(F) NO CLAIM FOR PATENT INFRINGE-
2 MENT.—An owner of a patent with respect to
3 which a holder of an application fails to file in-
4 formation on or before the date required under
5 subparagraph (A) or (B) shall be barred from
6 bringing a civil action for infringement of the
7 patent against a person that—

8 “(i) has filed an application under
9 subsection (b)(2) or (j); or

10 “(ii) manufactures, uses, offers to sell,
11 or sells a drug approved under an applica-
12 tion under subsection (b)(2) or (j).”.

13 (2) TRANSITION PROVISION.—

14 (A) FILING OF PATENT INFORMATION.—

15 Each holder of an application for approval of a
16 new drug under section 505(b) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C.
18 355(b)) that has been approved before the date
19 of enactment of this Act shall amend the appli-
20 cation to include the patent information re-
21 quired under the amendment made by para-
22 graph (1) not later than the date that is 30
23 days after the date of enactment of this Act
24 (unless the Secretary of Health and Human

1 Services extends the date because of extraor-
2 dinary or unusual circumstances).

3 (B) NO CLAIM FOR PATENT INFRINGE-
4 MENT.—An owner of a patent with respect to
5 which a holder of an application under sub-
6 section (b) of section 505 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 355) fails
8 to file information on or before the date re-
9 quired under subparagraph (A) shall be barred
10 from bringing a civil action for infringement of
11 the patent against a person that—

12 (i) has filed an application under sub-
13 section (b)(2) or (j) of that section; or

14 (ii) manufactures, uses, offers to sell,
15 or sells a drug approved under an applica-
16 tion under subsection (b)(2) or (j) of that
17 section.

18 (b) FILING WITH AN APPLICATION.—Section 505 of
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 355) is amended—

21 (1) in subsection (b)(2)—

22 (A) in subparagraph (A), by striking
23 “and” at the end;

24 (B) in subparagraph (B), by striking the
25 period at the end and inserting “; and”; and

1 (C) by adding at the end the following:

2 “(C) with respect to a patent that claims
3 both the drug and a method of using the drug
4 or claims more than 1 method of using the drug
5 for which the application is filed—

6 “(i) a certification under subpara-
7 graph (A)(iv) on a claim-by-claim basis;

8 and

9 “(ii) a statement under subparagraph
10 (B) regarding the method of use claim.”;

11 and

12 (2) in subsection (j)(2)(A), by inserting after
13 clause (viii) the following:

14 “With respect to a patent that claims both the drug and
15 a method of using the drug or claims more than 1 method
16 of using the drug for which the application is filed, the
17 application shall contain a certification under clause
18 (vii)(IV) on a claim-by-claim basis and a statement under
19 clause (viii) regarding the method of use claim.”.

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