I

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.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Prescription Affordability and Medicine Safety Act of 2003''.

**SEC. 2. FINDINGS.**

The Congress finds as follows:

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

(2) In 1999, the top 5 pharmaceutical companies allocated a higher proportion of their revenue to their income than to research and development.

(3) In 2000, over ⅓ of the most frequently prescribed drugs for seniors rose in price at a rate that was 3 times the rate of inflation.

(4) Prescription drug manufacturers continue to make enormous profits on the backs of Americans.

(5) Because of the limited availability of private or public prescription drug coverage for the elderly, prescription drugs represent the highest out-of-pocket medical care cost for 3 of 4 elderly patients, surpassed only by the cost of long-term care services.

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

(7) According to a recent study, around 60 percent of doctors say that patients somewhat often talk with them about specific disease or treatment they heard about from prescription drug advertisements.

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

(9) The pharmaceutical industry makes large profits off the sale of drugs produced from the benefit of research paid for by the United States and, aside from royalties, none of such profits are reimbursed to United States taxpayers.

(10) Only 24 percent of people over age 45 always ask their pharmacist about drug side effects.

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

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

For the purpose of enabling the Food and Drug Administration to employ additional staff for the Office of Generic Drugs to review abbreviated applications for the approval of new drugs under section 505(j) of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), and for the purpose of otherwise providing for accelerated reviews of such applications, there is authorized to be appropriated $5,000,000 for each fiscal year, in addition to other authorizations of appropriations that are available for such purposes.

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

For the purpose of enabling the Food and Drug Administration, through the Office of Generic Drugs, to continue the education program started in fiscal year 2001 on the use and therapeutic equivalency of drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), there is authorized to be appropriated $1,000,000 for each fiscal year, in addition to other authorizations of appropriations that are available for such purpose.

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

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

# "TITLE XXIX—PHARMACY ASSISTANCE

**"SEC. 2901. GRANTS.**

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

the Secretary may make grants to States for the purpose of providing pharmacy assistance as described in subsection (b).

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

''(1) to provide outreach services and education regarding an existing State pharmacy benefit assistance program; or

''(2) to establish or expand such a program.

''(c) APPLICATION.—To seek a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

''(d) STATE DEFINED.—For purposes of this section, the term 'State' means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Virgin Islands, or any other territory or possession of the United States.

**''SEC. 2902. PROFITS FROM RESEARCH.**

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

Drug, and Cosmetic Act unless the manufacturer submitting the application enters into an agreement with the Secretary that—

''(1) requires the manufacturer to pay the Secretary 7 percent of the gross amount received by the manufacturer from sales of such biological product or drug; and

''(2) specifies the manner in which such gross amount will be determined.

''(b) EXCEPTION.—The Secretary may waive the application of subsection (a) to a manufacturer of a biological product or drug when the Secretary determines that it would be in the public interest to exempt such manufacturer.

''(c) COVERED APPLICATION.—For purposes of this section, the term 'covered application' means an application that includes the results of research carried out—

''(1) by an entity of the National Institutes of Health; or

''(2) under an agreement under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980.

**''SEC. 2903. REVOLVING FUND.**

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

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

''(b) DEPOSIT OF FUNDS.—The Secretary shall deposit in the fund established under this section all payments made to the Secretary under an agreement pursuant to section 2902(a)(1).

''(c) USE OF AMOUNTS IN FUND.—To the extent or in the amounts made available in advance in appropriations Acts, amounts in the fund established under this section shall be available to the Secretary to make grants under section 2901.''.

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

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

**''SEC. 280I. LIMITATION ON DEDUCTIONS FOR ADVERTISING BY PRESCRIPTION DRUG MANUFACTURERS.**

''(a) IN GENERAL.—No deduction shall be allowed under this chapter for any taxable year for any expenditure relating to the advertising, promoting, or marketing (in any medium) of any prescription drug manufactured by the taxpayer to the extent the aggregate amount of

such expenditures exceeds 50 percent of the taxpayer's aggregate research and development expenditures for such taxable year.

''(b) DEFINITIONS AND SPECIAL RULES.—For purposes of this section:

''(1) PRESCRIPTION DRUGS.—The term 'prescription drug' means any drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act.

''(2) RESEARCH AND DEVELOPMENT EXPENDITURES.—The term 'research and development expenditures' means any expenditures that may be treated as expenses under section 174.

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

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

''Sec. 280I. Limitation on deductions for advertising by prescription drug manufacturers.''.

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

(d) TRANSFER TO THE FEDERAL HOSPITAL INSURANCE TRUST FUND OF RESULTING BUDGETARY SAVINGS.—There are authorized to be appropriated to the Federal Hospital Insurance Trust Fund established under section 1817 of the Social Security Act amounts equal to the increase in Federal revenues resulting from the amendment made by subsection (a). Such appropriated amounts may be transferred from the general fund of the Treasury on the basis of estimates of such revenues made by the Secretary of the Treasury.

**SEC. 7. LIMITATION OF 30-MONTH STAY TO CERTAIN PATENTS.**

(a) ABBREVIATED NEW DRUG APPLICATIONS.—

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

''(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii):

''(I) If such certification concerns a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was submitted under subsection (b), the approval shall be made effective immediately unless an action is brought for infringe-

ment of a patent which is the subject of the certification before the expiration of 45 days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the 30-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

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

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

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

junction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

''In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of 45 days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business. The 30-month period provided under the second sentence of this clause shall not apply to a certification under paragraph (2)(A)(vii)(IV) made with respect to a patent for which patent information was submitted under subsection (c)(2).

''(II) If the certification referred to at the beginning of this clause concerns a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was submitted under subsection (c)(2), the approval shall be made effective on the date that is 45 days after the date on which the notice provided under paragraph (2)(B) is received, unless a civil action for infringement of the patent, accompanied by a motion for preliminary injunction to enjoin the applicant from engaging in the commercial manufacture or sale of the drug, is filed on or before such date, in which case the approval shall be made effective—

''(aa) on the date of a court action declining to grant a preliminary injunction; or

''(bb) if the court has granted a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug—

''(AA) on issuance by a court of a determination that the patent is invalid or is not infringed;

''(BB) on issuance by a court of an order revoking the preliminary injunction or permitting the applicant to engage in the commercial manufacture or sale of the drug; or

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

''Each of the parties shall reasonably cooperate in expediting a civil action under this subclause. If the notice under paragraph (2)(B) contains an address for the receipt of expedited notification of a civil action under this subclause, the plaintiff shall, on the date on which the complaint is filed, simultaneously cause a notification of the civil action to be delivered to that address by the next business day.''.

(2) FAILURE TO BRING INFRINGEMENT ACTION.—Paragraph (5) of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended by adding at the end the following:

''(E) If, in connection with an application under this subsection, the applicant provides an owner of a patent notice under paragraph (2)(B) with respect to the patent, and the owner of the patent fails to bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice is received, the owner of the patent shall be barred from bringing a civil action for infringement of the patent in connection with the development, manufacture, use, offer to sell, or sale of the drug for which the application was filed or approved under this subsection.''.

(b) OTHER APPLICATIONS.—

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

''(C) If the applicant made a certification described in subsection (b)(2)(A)(iv):

''(i) If such certification concerns a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was submitted under subsection (b), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the cer-

tification before the expiration of 45 days from the date the notice provided under subsection (b)(3)(A) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the 30-month period beginning on the date of the receipt of the notice provided under subsection (b)(3)(A) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

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

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

''(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from en-

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

''In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of 45 days from the date the notice made under subsection (b)(3)(A) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business. The 30-month period provided under the second sentence of this subparagraph shall not apply to a certification under subsection (b)(2)(A)(iv) made with respect to a patent for which patent information was submitted under subsection (c)(2).

''(ii) If the certification referred to at the beginning of this subparagraph concerns a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was submitted under subsection (c)(2), the approval shall be made effective on the date that is 45 days after the date on which the notice provided under subsection (b)(3) is received, unless a civil action for infringement of the patent, accompanied by a motion for preliminary injunction to enjoin the applicant from engaging in the commercial manufacture or sale of the drug, is filed on or before such date, in which case the approval shall be made effective—

''(I) on the date of a court action declining to grant a preliminary injunction; or

''(II) if the court has granted a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug—

''(aa) on issuance by a court of a determination that the patent is invalid or is not infringed;

''(bb) on issuance by a court of an order revoking the preliminary injunction or permitting the applicant to engage in the commercial manufacture or sale of the drug; or

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

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

(2) FAILURE TO BRING INFRINGEMENT ACTION.—Subsection (c) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)) is amended by adding at the end the following:

"(5) If, in connection with an application under subsection (b)(2), the applicant provides an owner of a patent notice under subsection (b)(3) with respect to the patent, and the owner of the patent fails to bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice is received, the owner of the patent shall be barred from bringing a civil action for infringement of the patent in connection with the development, manufacture, use, offer to sell, or sale of the drug for which the application was filed or approved under subsection (b)(2).".

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

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

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

(1) in subparagraph (B)(iv)—

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

(B) by striking ''or'' at the end of subclause (I);

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

(D) by adding after subclause (I) the following:

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

''(III) the date of a settlement order or consent decree signed by a Federal judge that enters a final judgment and includes a finding that the patent that is the subject of the certification is invalid or not infringed.''; and

(2) by inserting after subparagraph (D) the following:

''(E) FORFEITURE OF 180-DAY PERIOD.—

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

''(I) the 180-day period under subparagraph (B)(iv) shall be forfeited by the first applicant; and

''(II) any subsequent application shall become effective as provided under clause (i), (ii), or (iii) of subparagraph (B), and clause (iv) of subparagraph (B) shall not apply to the subsequent application.

''(ii) FORFEITURE TO FIRST SUBSEQUENT APPLICANT.—If the subsequent application that is the first to be made effective under clause (i) was the first among a number of subsequent applications to be filed—

''(I) that first subsequent application shall be treated as the first application under this subparagraph (including clause (i)) and as the previous application under subparagraph (B)(iv); and

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

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

''(iv) APPLICABILITY.—The 180-day period described in subparagraph (B)(iv) shall apply to an application only if a civil action is brought against the applicant for infringement of a patent that is the subject of the certification.

''(v) DEFINITIONS.—In this subparagraph:

''(I) APPLICATION.—The term 'application' means an application for approval of a drug under this subsection containing a certification under paragraph (2)(A)(vii)(IV) with respect to a patent.

"(II) FIRST APPLICATION.—The term 'first application' means the first application to be filed for approval of the drug.

"(III) FORFEITURE EVENT.—The term 'forfeiture event', with respect to an application under this subsection, means the occurrence of any of the following:

"(aa) FAILURE TO MARKET.—The applicant fails to market the drug by the later of—

"(AA) the date that is 60 days after the date on which the approval of the application for the drug is made effective under clause (iii) of subparagraph (B) (unless the Secretary extends the date because of extraordinary or unusual circumstances); or

"(BB) if 1 or more civil actions have been brought against the applicant for infringement of a patent subject to a certification under paragraph (2)(A)(vii)(IV) or 1 or more civil actions have been brought by the applicant for a declaratory judgment that

such a patent is invalid or not infringed, the date that is 60 days after the date of a final decision (from which no appeal has been or can be taken, other than a petition to the Supreme Court for a writ of certiorari) in the last of those civil actions to be decided (unless the Secretary extends the date because of extraordinary or unusual circumstances).

''(bb) WITHDRAWAL OF APPLICATION.—The applicant withdraws the application.

''(cc) AMENDMENT OF CERTIFICATION.—The applicant, voluntarily or as a result of a settlement or defeat in patent litigation, amends the certification from a certification under paragraph (2)(A)(vii)(IV) to a certification under paragraph (2)(A)(vii)(III).

''(dd) FAILURE TO OBTAIN APPROVAL.—The applicant fails to obtain tentative approval of an application within 30 months after the date on which the ap-

plication is filed, unless the failure is caused by—

"(AA) a change in the requirements for approval of the application imposed after the date on which the application is filed; or

"(BB) other extraordinary circumstances warranting an exception, as determined by the Secretary.

"(ee) FAILURE TO CHALLENGE PATENT.—In a case in which, after the date on which the applicant submitted the application, new patent information is submitted under subsection (c)(2) for the listed drug for a patent for which certification is required under paragraph (2)(A), the applicant fails to submit, not later than the date that is 60 days after the date on which the Secretary publishes the new patent information under paragraph (7)(A)(iii) (unless the Secretary extends the date because of extraordinary or unusual circumstances)—

"(AA) a certification described in paragraph (2)(A)(vii)(IV) with respect

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

''(BB) a statement that any method of use claim of that patent does not claim a use for which the applicant is seeking approval under this subsection in accordance with paragraph (2)(A)(viii).

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

''(IV) SUBSEQUENT APPLICATION.—The term 'subsequent application' means an application for approval of a drug that is filed subsequent to the filing of a first application for approval of that drug.''.

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

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

**SEC. 9. BIOEQUIVALENCE.**

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

(b) EFFECT.—Subsection (a) does not affect the authority of the Commissioner of Food and Drugs to amend part 320 of title 21, Code of Federal Regulations.

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

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

(a) FILING AFTER APPROVAL OF AN APPLICATION.—

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

''(2) PATENT INFORMATION.—

''(A) IN GENERAL.—Not later than the date that is 30 days after the date of an order approving an application under subsection (b) (unless the Secretary extends the date because of extraordinary or unusual circumstances), the holder of the application shall file with the Secretary the patent information described in subparagraph (C) with respect to any patent—

''(i)(I) that claims the drug for which the application was approved; or

''(II) that claims an approved method of using the drug; and

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

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

"(B) SUBSEQUENTLY ISSUED PATENTS.—In a case in which a patent described in subparagraph (A) is issued after the date of an order approving an application under subsection (b), the holder of the application shall file with the Secretary the patent information described in subparagraph (C) not later than the date that is 30 days after the date on which the patent is issued (unless the Secretary extends the date because of extraordinary or unusual circumstances).

"(C) PATENT INFORMATION.—The patent information required to be filed under subparagraph (A) or (B) includes—

"(i) the patent number;

"(ii) the expiration date of the patent;

"(iii) with respect to each claim of the patent—

"(I) whether the patent claims the drug or claims a method of using the drug; and

"(II) whether the claim covers—

"(aa) a drug substance;

"(bb) a drug formulation;

"(cc) a drug composition; or

"(dd) a method of use;

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

"(v) the identity of the owner of the patent (including the identity of any agent of the patent owner); and

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

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

"(i) immediately publish the information described in clauses (i) through (iv) of subparagraph (C); and

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

"(E) CIVIL ACTION FOR CORRECTION OR DELETION OF PATENT INFORMATION.—

"(i) IN GENERAL.—A person that has filed an application under subsection (b)(2) or (j) for a drug may bring a civil action against the holder of the approved application for the drug seeking an order requiring that the holder of the application amend the application—

"(I) to correct patent information filed under subparagraph (A); or

"(II) to delete the patent information in its entirety for the reason that—

"(aa) the patent does not claim the drug for which the application was approved; or

"(bb) the patent does not claim an approved method of using the drug.

"(ii) LIMITATIONS.—Clause (i) does not authorize—

"(I) a civil action to correct patent information filed under subparagraph (B); or

"(II) an award of damages in a civil action under clause (i).

''(F) NO CLAIM FOR PATENT INFRINGEMENT.—An owner of a patent with respect to which a holder of an application fails to file information on or before the date required under subparagraph (A) or (B) shall be barred from bringing a civil action for infringement of the patent against a person that—

''(i) has filed an application under subsection (b)(2) or (j); or

''(ii) manufactures, uses, offers to sell, or sells a drug approved under an application under subsection (b)(2) or (j).''.

(2) TRANSITION PROVISION.—

(A) FILING OF PATENT INFORMATION.—Each holder of an application for approval of a new drug under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) that has been approved before the date of enactment of this Act shall amend the application to include the patent information required under the amendment made by paragraph (1) not later than the date that is 30 days after the date of enactment of this Act (unless the Secretary of Health and Human

Services extends the date because of extraordinary or unusual circumstances).

(B) NO CLAIM FOR PATENT INFRINGEMENT.—An owner of a patent with respect to which a holder of an application under subsection (b) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) fails to file information on or before the date required under subparagraph (A) shall be barred from bringing a civil action for infringement of the patent against a person that—

(i) has filed an application under subsection (b)(2) or (j) of that section; or

(ii) manufactures, uses, offers to sell, or sells a drug approved under an application under subsection (b)(2) or (j) of that section.

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

(1) in subsection (b)(2)—

(A) in subparagraph (A), by striking ''and'' at the end;

(B) in subparagraph (B), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

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

''(i) a certification under subparagraph (A)(iv) on a claim-by-claim basis; and

''(ii) a statement under subparagraph (B) regarding the method of use claim.''; and

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

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

○