107TH CONGRESS
2D SESSION

S. 812

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

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

TITLE I—GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS

SEC. 101. SHORT TITLE.

This title may be cited as the ''Greater Access to Affordable Pharmaceuticals Act of 2002''.

SEC. 102. FINDINGS; PURPOSES.

(a) FINDINGS.—Congress finds that—

(1) prescription drug costs are increasing at an alarming rate and are a major worry of American families and senior citizens;

(2) enhancing competition between generic drug manufacturers and brand-name manufacturers can significantly reduce prescription drug costs for American families;

(3) the pharmaceutical market has become increasingly competitive during the last decade because of the increasing availability and accessibility of generic pharmaceuticals, but competition must be further stimulated and strengthened;

(4) the Federal Trade Commission has discovered that there are increasing opportunities for drug companies owning patents on brand-name drugs and generic drug companies to enter into private financial deals in a manner that could restrain trade and

greatly reduce competition and increase prescription drug costs for consumers;

(5) generic pharmaceuticals are approved by the Food and Drug Administration on the basis of scientific testing and other information establishing that pharmaceuticals are therapeutically equivalent to brand-name pharmaceuticals, ensuring consumers a safe, efficacious, and cost-effective alternative to brand-name innovator pharmaceuticals;

(6) the Congressional Budget Office estimates that—

(A) the use of generic pharmaceuticals for brand-name pharmaceuticals could save purchasers of pharmaceuticals between $8,000,000,000 and $10,000,000,000 each year; and

(B) generic pharmaceuticals cost between 25 percent and 60 percent less than brand-name pharmaceuticals, resulting in an estimated average savings of $15 to $30 on each prescription;

(7) generic pharmaceuticals are widely accepted by consumers and the medical profession, as the market share held by generic pharmaceuticals compared to brand-name pharmaceuticals has more than

doubled during the last decade, from approximately 19 percent to 43 percent, according to the Congressional Budget Office;

(8) expanding access to generic pharmaceuticals can help consumers, especially senior citizens and the uninsured, have access to more affordable prescription drugs;

(9) Congress should ensure that measures are taken to effectuate the amendments made by the Drug Price Competition and Patent Term Restoration Act of 1984 (98 Stat. 1585) (referred to in this section as the ''Hatch-Waxman Act'') to make generic drugs more accessible, and thus reduce health care costs; and

(10) it would be in the public interest if patents on drugs for which applications are approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) were extended only through the patent extension procedure provided under the Hatch-Waxman Act rather than through the attachment of riders to bills in Congress.

(b) PURPOSES.—The purposes of this title are—

(1) to increase competition, thereby helping all Americans, especially seniors and the uninsured, to have access to more affordable medication; and

(2) to ensure fair marketplace practices and deter pharmaceutical companies (including generic companies) from engaging in anticompetitive action or actions that tend to unfairly restrain trade.

SEC. 103. 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 re-

quired 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.''.

SEC. 104. LIMITATION OF 30-MONTH STAY TO CERTAIN PATENTS.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—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)—

(A) in clause (iii)—

(i) by striking ''(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii),'' and inserting the following:

''(iii) SUBCLAUSE (IV) CERTIFICATION WITH RESPECT TO CERTAIN PATENTS.—If the applicant made a certification described in paragraph (2)(A)(vii)(IV) with respect to a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was filed with the Secretary under subsection (c)(2)(A),''; and

(ii) by adding at the end the following: ''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 informa-

tion was filed with the Secretary under subsection (c)(2)(B).'';

(B) by redesignating clause (iv) as clause (v); and

(C) by inserting after clause (iii) the following:

''(iv) SUBCLAUSE (IV) CERTIFICATION WITH RESPECT TO OTHER PATENTS.—

''(I) IN GENERAL.—If the applicant made a certification described in paragraph (2)(A)(vii)(IV) with respect to a patent not described in clause (iii) for which patent information was published by the Secretary under subsection (c)(2)(D), 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) was 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, was filed on or before the date that is 45

days after the date on which the notice was received, 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.

''(II) COOPERATION.—Each of the parties shall reasonably cooperate in expediting a civil action under subclause (I).

''(III) EXPEDITED NOTIFICATION.—If the notice under paragraph (2)(B) contains an address for the receipt of expedited notification of a civil action under subclause (I), 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.''; and

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

''(C) FAILURE TO BRING INFRINGEMENT ACTION.—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.—Section 505(c)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) (as amended by section 9(a)(3)(A)(iii)) is amended—

(1) in paragraph (3)—

(A) in subparagraph (C)—

(i) by striking ''(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A),'' and inserting the following:

''(C) CLAUSE (iv) CERTIFICATION WITH RESPECT TO CERTAIN PATENTS.—If the applicant made a certification described in subsection (b)(2)(A)(iv) with respect to a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent

information was filed with the Secretary under paragraph (2)(A),''; and

(ii) by adding at the end the following: ''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 filed with the Secretary under paragraph (2)(B).''; and

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

''(D) CLAUSE (iv) CERTIFICATION WITH RESPECT TO OTHER PATENTS.—

''(i) IN GENERAL.—If the applicant made a certification described in subsection (b)(2)(A)(iv) with respect to a patent not described in subparagraph (C) for which patent information was published by the Secretary under paragraph (2)(D), 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) was received, unless a civil action for infringement of the patent, accom-

panied by a motion for preliminary injunction to enjoin the applicant from engaging in the commercial manufacture or sale of the drug, was filed on or before the date that is 45 days after the date on which the notice was received, 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.

"(ii) COOPERATION.—Each of the parties shall reasonably cooperate in expediting a civil action under clause (i).

"(iii) EXPEDITED NOTIFICATION.—If the notice under subsection (b)(3) contains an address for the receipt of expedited notification of a civil action under clause (i), 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."; and

(2) by inserting after paragraph (3) the following:

"(4) FAILURE TO BRING INFRINGEMENT ACTION.—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.—

(1) IN GENERAL.—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.

(2) TRANSITION PROVISION.—In the case of applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) filed before the date of enactment of this Act—

(A) a patent (other than a patent that claims a process for manufacturing a listed drug) for which information was submitted to

the Secretary of Health and Human Services under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (as in effect on the day before the date of enactment of this Act) shall be subject to subsections (c)(3)(C) and (j)(5)(B)(iii) of section 505 of the Federal Food, Drug, and Cosmetic Act (as amended by this section); and

(B) any other patent (including a patent for which information was submitted to the Secretary under section 505(c)(2) of that Act (as in effect on the day before the date of enactment of this Act)) shall be subject to subsections (c)(3)(D) and (j)(5)(B)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act (as amended by this section).

SEC. 105. 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)) (as amended by section 4(a)) is amended—

(1) in subparagraph (B)(v), by striking subclause (II) and inserting the following:

''(II) the earlier of—

''(aa) 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

''(bb) 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 (C) the following:

''(D) FORFEITURE OF 180-DAY PERIOD.—

''(i) 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) or (iv) 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 application 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 (15 U.S.C. 1).

"(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.

"(ii) FORFEITURE OF 180-DAY PERIOD.—

"(I) IN GENERAL.—Except as provided in subclause (II), if a forfeiture event occurs with respect to a first application—

"(aa) the 180-day period under subparagraph (B)(v) shall be forfeited by the first applicant; and

"(bb) any subsequent application shall become effective as provided under clause (i), (ii), (iii), or (iv) of subparagraph (B), and clause (v) 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 subclause (I) was the first among a number of subsequent applications to be filed—

"(aa) that first subsequent application shall be treated as

the first application under this subparagraph (including subclause (I)) and as the previous application under subparagraph (B)(v); and

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

''(iii) AVAILABILITY.—The 180-day period under subparagraph (B)(v) 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)(v) 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.''.

(b) APPLICABILITY.—The amendment made by subsection (a) shall be effective 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)(D)(i)(III)(ff) of that Act occurs in the case of an applicant, the applicant shall forfeit the 180-day period under section 505(j)(5)(B)(v) of that Act without regard to when the applicant made a certification under section 505(j)(2)(A)(vii)(IV) of that Act.

SEC. 106. FAIR TREATMENT FOR INNOVATORS.

(a) BASIS FOR APPLICATION.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b)(3)(B), by striking the second sentence and inserting ''The notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that, as of the date of the notice, the patent is not valid or is not infringed, and shall include, as appropriate for the relevant patent,

a description of the applicant's proposed drug substance, drug formulation, drug composition, or method of use. All information disclosed under this subparagraph shall be treated as confidential and may be used only for purposes relating to patent adjudication. Nothing in this subparagraph precludes the applicant from amending the factual or legal basis on which the applicant relies in patent litigation.''; and

(2) in subsection (j)(2)(B)(ii), by striking the second sentence and inserting ''The notice shall include a detailed statement of the factual and legal basis of the opinion of the applicant that, as of the date of the notice, the patent is not valid or is not infringed, and shall include, as appropriate for the relevant patent, a description of the applicant's proposed drug substance, drug formulation, drug composition, or method of use. All information disclosed under this subparagraph shall be treated as confidential and may be used only for purposes relating to patent adjudication. Nothing in this subparagraph precludes the applicant from amending the factual or legal basis on which the applicant relies in patent litigation.''.

(b) INJUNCTIVE RELIEF.—Section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)) (as amended by section 4(a)(1)) is amended—

(1) in clause (iii), by adding at the end the following: ''A court shall not regard the extent of the ability of an applicant to pay monetary damages as a whole or partial basis on which to deny a preliminary or permanent injunction under this clause.''; and

(2) in clause (iv), by adding at the end the following:

''(IV) INJUNCTIVE RELIEF.—A court shall not regard the extent of the ability of an applicant to pay monetary damages as a whole or partial basis on which to deny a preliminary or permanent injunction under this clause.''.

SEC. 107. 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. 108. REPORT.

(a) IN GENERAL.—Not later than the date that is 5 years after the date of enactment of this Act, the Federal Trade Commission shall submit to Congress a report describing the extent to which implementation of the amendments made by this title—

(1) has enabled products to come to market in a fair and expeditious manner, consistent with the rights of patent owners under intellectual property law; and

(2) has promoted lower prices of drugs and greater access to drugs through price competition.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000.

SEC. 109. CONFORMING AND TECHNICAL AMENDMENTS.

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

(1) in subsection (a), by striking ''(a) No person'' and inserting ''(a) IN GENERAL.—No person'';

(2) in subsection (b)—

(A) by striking ''(b)(1) Any person'' and inserting the following:

''(b) APPLICATIONS.—

''(1) REQUIREMENTS.—

''(A) IN GENERAL.—Any person'';

(B) in paragraph (1)—

(i) in the second sentence—

(I) by redesignating subparagraphs (A) through (F) as clauses (i) through (vi), respectively, and adjusting the margins appropriately;

(II) by striking ''Such persons'' and inserting the following:

''(B) INFORMATION TO BE SUBMITTED WITH APPLICATION.—A person that submits an application under subparagraph (A)''; and

(III) by striking ''application'' and inserting ''application—'';

(ii) by striking the third through fifth sentences; and

(iii) in the sixth sentence—

(I) by striking ''The Secretary'' and inserting the following:

''(C) GUIDANCE.—The Secretary''; and

(II) by striking ''clause (A)'' and inserting ''subparagraph (B)(i)''; and

(C) in paragraph (2)—

(i) by striking ''clause (A) of such paragraph'' and inserting ''paragraph (1)(B)(i)'';

(ii) in subparagraphs (A) and (B), by striking ''paragraph (1) or''; and

(iii) in subparagraph (B)—

(I) by striking ''paragraph (1)(A)'' and inserting ''paragraph (1)(B)(i)''; and

(II) by striking ''patent'' each place it appears and inserting ''claim''; and

(3) in subsection (c)—

(A) in paragraph (3)—

(i) in subparagraph (A)—

(I) by striking ''(A) If the applicant'' and inserting the following:

"(A) CLAUSE (i) OR (ii) CERTIFICATION.—If the applicant"; and

(II) by striking "may" and inserting "shall";

(ii) in subparagraph (B)—

(I) by striking "(B) If the applicant" and inserting the following:

"(B) CLAUSE (iii) CERTIFICATION.—If the applicant"; and

(II) by striking "may" and inserting "shall";

(iii) by redesignating subparagraph (D) as subparagraph (E); and

(iv) in subparagraph (E) (as redesignated by clause (iii)), by striking "clause (A) of subsection (b)(1)" each place it appears and inserting "subsection (b)(1)(B)(i)"; and

(B) by redesignating paragraph (4) as paragraph (5); and

(4) in subsection (j)—

(A) in paragraph (2)(A)—

(i) in clause (vi), by striking "clauses (B) through ((F)" and inserting "sub-

clauses (ii) through (vi) of subsection (b)(1)'';

(ii) in clause (vii), by striking ''(b) or''; and

(iii) in clause (viii)—

(I) by striking ''(b) or''; and

(II) by striking ''patent'' each place it appears and inserting ''claim''; and

(B) in paragraph (5)—

(i) in subparagraph (B)—

(I) in clause (i)—

(aa) by striking ''(i) If the applicant'' and inserting the following:

''(i) SUBCLAUSE (I) OR (II) CERTIFICATION.—If the applicant''; and

(bb) by striking ''may'' and inserting ''shall'';

(II) in clause (ii)—

(aa) by striking ''(ii) If the applicant'' and inserting the following:

''(i) SUBCLAUSE (III) CERTIFICATION.—If the applicant''; and

(bb) by striking ''may'' and inserting ''shall'';

(III) in clause (iii), by striking ''(2)(B)(i)'' each place it appears and inserting ''(2)(B)''; and

(IV) in clause (v) (as redesignated by section 4(a)(1)(B)), by striking ''continuing'' and inserting ''containing''; and

(ii) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively.

(b) SECTION 505A.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i)—

(A) by striking ''(c)(3)(D)(ii)'' each place it appears and inserting ''(c)(3)(E)(ii)''; and

(B) by striking ''(j)(5)(D)(ii)'' each place it appears and inserting ''(j)(5)(F)(ii)'';

(2) in subsections (b)(1)(A)(ii) and (c)(1)(A)(ii)—

(A) by striking ''(c)(3)(D)'' each place it appears and inserting ''(c)(3)(E)''; and

(B) by striking ''(j)(5)(D)'' each place it appears and inserting ''(j)(5)(F)'';

(3) in subsections (e) and (l)—

(A) by striking ''505(c)(3)(D)'' each place it appears and inserting ''505(c)(3)(E)''; and

(B) by striking ''505(j)(5)(D)'' each place it appears and inserting ''505(j)(5)(F)''; and

(4) in subsection (k), by striking ''505(j)(5)(B)(iv)'' and inserting ''505(j)(5)(B)(v)''.

(c) SECTION 527.—Section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)) is amended in the second sentence by striking ''505(c)(2)'' and inserting ''505(c)(1)(B)''.

TITLE II—IMPORTATION OF PRESCRIPTION DRUGS

SEC. 201. IMPORTATION OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following:

''SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer' means a pharmacist or wholesaler.

''(2) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(3) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

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

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

''(C) an infused drug (including a peritoneal dialysis solution);

''(D) an intravenously injected drug; or

''(E) a drug that is inhaled during surgery.

''(4) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

''(5) WHOLESALER.—

''(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or dis-

tributor of prescription drugs in the United States under section 503(e)(2)(A).

''(B) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 801(d)(1).

''(b) REGULATIONS.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

''(c) LIMITATION.—The regulations under subsection (b) shall—

''(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of this Act;

''(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and

''(3) contain any additional provisions determined by the Secretary to be appropriate as a safe-

guard to protect the public health or as a means to facilitate the importation of prescription drugs.

''(d) INFORMATION AND RECORDS.—

''(1) IN GENERAL.—The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

''(A) The name and quantity of the active ingredient of the prescription drug.

''(B) A description of the dosage form of the prescription drug.

''(C) The date on which the prescription drug is shipped.

''(D) The quantity of the prescription drug that is shipped.

''(E) The point of origin and destination of the prescription drug.

''(F) The price paid by the importer for the prescription drug.

''(G) Documentation from the foreign seller specifying—

''(i) the original source of the prescription drug; and

"(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

"(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

"(I) The name, address, telephone number, and professional license number (if any) of the importer.

"(J)(i) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

"(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

"(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

''(III)(aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

''(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

''(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

''(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug—

''(i) is approved for marketing in the United States; and

"(ii) meets all labeling requirements under this Act.

"(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

"(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

"(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

"(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

"(e) TESTING.—The regulations under subsection (b) shall require—

"(1) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory;

''(2) if the tests are conducted by the importer—

''(A) that information needed to—

''(i) authenticate the prescription drug being tested; and

''(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act;

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

''(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing or otherwise complying with this Act; and

''(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

''(f) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Sec-

retary the name and place of business of the establishment.

''(g) SUSPENSION OF IMPORTATION.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of the prescription drugs or by the importer that is counterfeit or in violation of any requirement under this section or poses an additional risk to the public health, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

''(h) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

''(i) PROHIBITION OF DISCRIMINATION.—

''(1) IN GENERAL.—It shall be unlawful for a manufacturer of a prescription drug to discriminate against, or cause any other person to discriminate against, a pharmacist or wholesaler that purchases or offers to purchase a prescription drug from the manufacturer or from any person that distributes a

prescription drug manufactured by the drug manufacturer.

''(2) DISCRIMINATION.—For the purposes of paragraph (1), a manufacturer of a prescription drug shall be considered to discriminate against a pharmacist or wholesaler if the manufacturer enters into a contract for sale of a prescription drug, places a limit on supply, or employs any other measure, that has the effect of—

''(A) providing pharmacists or wholesalers access to prescription drugs on terms or conditions that are less favorable than the terms or conditions provided to a foreign purchaser (other than a charitable or humanitarian organization) of the prescription drug; or

''(B) restricting the access of pharmacists or wholesalers to a prescription drug that is permitted to be imported into the United States under this section.

''(j) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian or-

ganization (including the United Nations and affiliates) or to a government of a foreign country.

''(k) WAIVER AUTHORITY FOR IMPORTATION BY INDIVIDUALS.—

''(1) DECLARATIONS.—Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

''(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

''(B) exercise discretion to permit individuals to make such importations in circumstances in which—

''(i) the importation is clearly for personal use; and

''(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

''(2) WAIVER AUTHORITY.—

''(A) IN GENERAL.—The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under

such conditions as the Secretary determines to be appropriate.

''(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

''(3) DRUGS IMPORTED FROM CANADA.—In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

''(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

''(B) is accompanied by a copy of a valid prescription;

''(C) is imported from Canada, from a seller registered with the Secretary;

''(D) is a prescription drug approved by the Secretary under chapter V;

"(E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510; and

"(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

"(l) STUDIES; REPORTS.—

"(1) BY THE INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCES.—

"(A) STUDY.—

"(i) IN GENERAL.—The Secretary shall request that the Institute of Medicine of the National Academy of Sciences conduct a study of—

"(I) importations of prescription drugs made under the regulations under subsection (b); and

"(II) information and documentation submitted under subsection (d).

"(ii) REQUIREMENTS.—In conducting the study, the Institute of Medicine shall—

"(I) evaluate the compliance of importers with the regulations under subsection (b);

"(II) compare the number of shipments under the regulations under subsection (b) during the study period that are determined to be counterfeit, misbranded, or adulterated, and compare that number with the number of shipments made during the study period within the United States that are determined to be counterfeit, misbranded, or adulterated; and

"(III) consult with the Secretary, the United States Trade Representative, and the Commissioner of Patents and Trademarks to evaluate the effect of importations under the regulations under subsection (b) on trade and patent rights under Federal law.

"(B) REPORT.—Not later than 2 years after the effective date of the regulations under subsection (b), the Institute of Medicine shall submit to Congress a report describing the findings of the study under subparagraph (A).

"(2) BY THE COMPTROLLER GENERAL.—

''(A) STUDY.—The Comptroller General of the United States shall conduct a study to determine the effect of this section on the price of prescription drugs sold to consumers at retail.

''(B) REPORT.—Not later than 18 months after the effective date of the regulations under subsection (b), the Comptroller General of the United States shall submit to Congress a report describing the findings of the study under subparagraph (A).

''(m) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.

''(n) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.

''(o) CONDITIONS.—This section shall become effective only if the Secretary of Health and Human Services certifies to the Congress that the implementation of this section will—

''(A) pose no additional risk to the public's health and safety, and

''(B) result in a significant reduction in the cost of covered products to the American consumer.''.

(b) CONFORMING AMENDMENTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301(aa) (21 U.S.C. 331(aa)), by striking ''covered product in violation of section 804'' and inserting ''prescription drug in violation of section 804''; and

(2) in section 303(a)(6) (21 U.S.C. 333(a)(6), by striking ''covered product pursuant to section 804(a)'' and inserting ''prescription drug under section 804(b)''.

SEC. 202. CLARIFICATION OF STATE AUTHORITY RELATING TO MEDICAID DRUG REBATE AGREEMENTS.

Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended by adding at the end the following:

''(l) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as prohibiting a State from—

''(1) directly entering into rebate agreements (on the State's own initiative or under a section 1115 waiver approved by the Secretary before, on, or after the date of enactment of this subsection) that are similar to a rebate agreement described in subsection (b) with a manufacturer for purposes of ensuring the affordability of outpatient prescription drugs in order to provide access to such drugs by

residents of a State who are not otherwise eligible for medical assistance under this title; or

''(2) making prior authorization (that satisfies the requirements of subsection (d) and that does not violate any requirements of this title that are designed to ensure access to medically necessary prescribed drugs for individuals enrolled in the State program under this title) a condition of not participating in such a similar rebate agreement.''.

SEC. 203. TEMPORARY STATE FISCAL RELIEF.

(a) TEMPORARY INCREASE OF MEDICAID FMAP.—

(1) PERMITTING MAINTENANCE OF FISCAL YEAR 2001 FMAP FOR LAST 2 CALENDAR QUARTERS OF FISCAL YEAR 2002.—Notwithstanding any other provision of law, but subject to paragraph (5), if the FMAP determined without regard to this subsection for a State for fiscal year 2002 is less than the FMAP as so determined for fiscal year 2001, the FMAP for the State for fiscal year 2001 shall be substituted for the State's FMAP for the third and fourth calendar quarters of fiscal year 2002, before the application of this subsection.

(2) PERMITTING MAINTENANCE OF FISCAL YEAR 2002 FMAP FOR FISCAL YEAR 2003.—Notwithstanding any other provision of law, but subject to

paragraph (5), if the FMAP determined without regard to this subsection for a State for fiscal year 2003 is less than the FMAP as so determined for fiscal year 2002, the FMAP for the State for fiscal year 2002 shall be substituted for the State's FMAP for each calendar quarter of fiscal year 2003, before the application of this subsection.

(3) GENERAL 1.35 PERCENTAGE POINTS INCREASE FOR LAST 2 CALENDAR QUARTERS OF FISCAL YEAR 2002 AND FISCAL YEAR 2003.—Notwithstanding any other provision of law, but subject to paragraphs (5) and (6), for each State for the third and fourth calendar quarters of fiscal year 2002 and each calendar quarter of fiscal year 2003, the FMAP (taking into account the application of paragraphs (1) and (2)) shall be increased by 1.35 percentage points.

(4) INCREASE IN CAP ON MEDICAID PAYMENTS TO TERRITORIES.—Notwithstanding any other provision of law, but subject to paragraph (6), with respect to the third and fourth calendar quarters of fiscal year 2002 and each calendar quarter of fiscal year 2003, the amounts otherwise determined for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa under

subsections (f) and (g) of section 1108 of the Social Security Act (42 U.S.C. 1308) shall each be increased by an amount equal to 2.7 percent of such amounts.

(5) SCOPE OF APPLICATION.—The increases in the FMAP for a State under this subsection shall apply only for purposes of title XIX of the Social Security Act and shall not apply with respect to—

(A) disproportionate share hospital payments described in section 1923 of such Act (42 U.S.C. 1396r–4); or

(B) payments under title IV or XXI of such Act (42 U.S.C. 601 et seq. and 1397aa et seq.).

(6) STATE ELIGIBILITY.—

(A) IN GENERAL.—Subject to subparagraph (B), a State is eligible for an increase in its FMAP under paragraph (3) or an increase in a cap amount under paragraph (4) only if the eligibility under its State plan under title XIX of the Social Security Act (including any waiver under such title or under section 1115 of such Act (42 U.S.C. 1315)) is no more restrictive than the eligibility under such plan (or waiver) as in effect on January 1, 2002.

(B) STATE REINSTATEMENT OF ELIGIBILITY PERMITTED.—A State that has restricted eligibility under its State plan under title XIX of the Social Security Act (including any waiver under such title or under section 1115 of such Act (42 U.S.C. 1315)) after January 1, 2002, but prior to the date of enactment of this Act is eligible for an increase in its FMAP under paragraph (3) or an increase in a cap amount under paragraph (4) in the first calendar quarter (and subsequent calendar quarters) in which the State has reinstated eligibility that is no more restrictive than the eligibility under such plan (or waiver) as in effect on January 1, 2002.

(C) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) or (B) shall be construed as affecting a State's flexibility with respect to benefits offered under the State medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (including any waiver under such title or under section 1115 of such Act (42 U.S.C. 1315)).

(7) DEFINITIONS.—In this subsection:

(A) FMAP.—The term ''FMAP'' means the Federal medical assistance percentage, as defined in section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)).

(B) STATE.—The term ''State'' has the meaning given such term for purposes of title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

(8) REPEAL.—Effective as of October 1, 2003, this subsection is repealed.

(b) ADDITIONAL TEMPORARY STATE FISCAL RELIEF.—

(1) IN GENERAL.—Title XX of the Social Security Act (42 U.S.C. 1397–1397f) is amended by adding at the end the following:

''SEC. 2008. ADDITIONAL TEMPORARY GRANTS FOR STATE FISCAL RELIEF.

''(a) IN GENERAL.—For the purpose of providing State fiscal relief allotments to States under this section, there are hereby appropriated, out of any funds in the Treasury not otherwise appropriated, $3,000,000,000. Such funds shall be available for obligation by the State through June 30, 2004, and for expenditure by the State through September 30, 2004. This section constitutes budget authority in advance of appropriations Acts and

represents the obligation of the Federal Government to provide for the payment to States of amounts provided under this section.

"(b) ALLOTMENT.—Funds appropriated under subsection (a) shall be allotted by the Secretary among the States in accordance with the following table:

"State	Allotment (in dollars)
Alabama	$33,918,100
Alaska	$8,488,200
Amer. Samoa	$88,600
Arizona	$47,601,600
Arkansas	$27,941,800
California	$314,653,900
Colorado	$27,906,200
Connecticut	$41,551,200
Delaware	$8,306,000
District of Columbia	$12,374,400
Florida	$128,271,100
Georgia	$69,106,600
Guam	$135,900
Hawaii	$9,914,700
Idaho	$10,293,600
Illinois	$102,577,900
Indiana	$50,659,800
Iowa	$27,799,700
Kansas	$21,414,300
Kentucky	$44,508,400
Louisiana	$50,974,000
Maine	$17,841,100
Maryland	$44,228,800
Massachusetts	$100,770,700
Michigan	$91,196,800
Minnesota	$57,515,400
Mississippi	$35,978,500
Missouri	$62,189,600
Montana	$8,242,000
Nebraska	$16,671,600
Nevada	$10,979,700
New Hampshire	$10,549,400
New Jersey	$87,577,300
New Mexico	$21,807,600
New York	$461,401,900
North Carolina	$79,538,300
North Dakota	$5,716,900
N. Mariana Islands	$50,000
Ohio	$116,367,800
Oklahoma	$30,941,800
Oregon	$34,327,200
Pennsylvania	$159,089,700
Puerto Rico	$3,991,900
Rhode Island	$16,594,100
South Carolina	$38,238,000
South Dakota	$6,293,700
Tennessee	$81,120,000
Texas	$159,779,800
Utah	$12,551,700
Vermont	$8,003,800
Virgin Islands	$128,800
Virginia	$44,288,300
Washington	$66,662,200
West Virginia	$19,884,400
Wisconsin	$47,218,900
Wyoming	$3,776,400
Total	**$3,000,000,000**

''(c) USE OF FUNDS.—Funds appropriated under this section may be used by a State for services directed at the goals set forth in section 2001, subject to the requirements of this title.

''(d) PAYMENT TO STATES.—Not later than 30 days after amounts are appropriated under subsection (a), in addition to any payment made under section 2002 or 2007, the Secretary shall make a lump sum payment to a State of the total amount of the allotment for the State as specified in subsection (b).

''(e) DEFINITION.—For purposes of this section, the term 'State' means the 50 States, the District of Columbia, and the territories contained in the list under subsection (b).''.

(2) REPEAL.—Effective as of January 1, 2005, section 2008 of the Social Security Act, as added by paragraph (1), is repealed.

(c) EMERGENCY DESIGNATION.—The entire amount necessary to carry out this section is designated by Congress as an emergency requirement pursuant to section

252(e) of the Balanced Budget and Emergency Deficit Control Act of 1985 (2 U.S.C. 902(e)).

Passed the Senate July 31, 2002.

Attest:

Secretary.

107TH CONGRESS
2D SESSION

S. 812

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.