II

107TH CONGRESS
1ST SESSION

S. 812

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

IN THE SENATE OF THE UNITED STATES

MAY 1, 2001

Mr. SCHUMER (for himself and Mr. MCCAIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

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,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Greater Access to Affordable Pharmaceuticals Act of 2001''.

SEC. 2. 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 Act 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. 3. ACCELERATED GENERIC DRUG COMPETITION.

(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), by striking subclause (II) and inserting the following:

''(II) the earlier of—

''(aa) the date of a final decision of a court in an action described in clause (iii) (from which no appeal can or has been taken); 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 patents that are the subject of the certification are invalid or not infringed;'';

(2) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively; and

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

''(C) FORFEITURE OF 180-DAY PERIOD.—

''(i) IN GENERAL.—The 180-day period described in subparagraph (B)(iv) shall be forfeited by the previous applicant and become available to the next applicant submitting an application containing a certification described in paragraph (2)(A)(vii)(IV) if—

''(I) the previous applicant fails to market the drug within 90 days after the date on which the approval

of the application for the drug is made effective under subparagraph (B)(iii);

''(II) the previous applicant withdraws the application;

''(III) the previous applicant amends the certification from a certification under subclause (IV) to a certification under paragraph (2)(A)(vii)(III), either voluntarily or as a result of a settlement or defeat in patent litigation;

''(IV) the previous applicant fails to get tentative approval of the 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 tentative approval of the application imposed after the date on which the application was filed; or

''(bb) other extraordinary or unusual circumstances, as determined by the Secretary;

"(V) in a case in which, after the date on which the previous application was submitted under this subsection, new patent information is submitted for the drug under subsection (c)(2) for a patent for which certification is required under paragraph (2)(A)(vii)(IV), the previous applicant fails to challenge the patent that is the subject of the information within 60 days after the date on which the patent information is submitted; or

"(VI) the previous applicant is determined by the Secretary, after a fair and sufficient hearing and in consultation with the Federal Trade Commission, to have engaged in anticompetitive or collusive conduct, or any other conduct intended to unfairly monopolize the commercial manufacturing of the drug of the application.

"(ii) AVAILABILITY.—The 180-day period described in subparagraph (B)(iv) shall be available only to—

''(I) the previous applicant submitting an application for a drug under this subsection containing a certification described in paragraph (2)(A)(vii)(IV) with respect to any patent; or

''(II) under clause (i), the next applicant submitting an application for a drug under this subsection containing such a certification with respect to any patent;

even if an application has been submitted for the drug under this subsection containing such a certification with respect to a different patent.

''(iii) APPLICABILITY.—The 180-day period described in subparagraph (B)(iv) shall apply only if—

''(I) the application contains a certification described in paragraph (2)(A)(vii)(IV); and

''(II) an action is brought for infringement of a patent that is the subject of the certification or the applicant brings an action (not later

than 50 days after the date on which the notice provided under paragraph (2)(B)(ii) was received), against the holder of the approved application for the listed drug.''.

(b) EFFECTIVE DATE.—The amendment made by this section 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)) 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.

SEC. 4. BIOEQUIVALENCE TESTING METHODS.

Section 505(j)(8)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)(B)) is amended—

(1) in clause (i), by striking ''or'' at the end;

(2) in clause (ii), by striking the period at the end and inserting ''; or''; and

(3) by adding at the end the following:

''(iii)(I) clauses (i) and (ii) are not applicable, as determined by the Secretary;

''(II) the effects of the drug and the listed drug do not show a significant difference based on tests (other than tests that assess rate and extent of absorption), including—

''(aa) a bioequivalence study with a pharmacodynamic endpoint;

''(bb) a bioequivalence study with a clinical endpoint;

''(cc) in vitro methods; or

''(dd) any other methodology that demonstrates that no significant differences in therapeutic effects of active ingredients are expected; and

''(III) limited confirmatory studies to supplement the bioequivalence testing are considered necessary by the Secretary.''.

SEC. 5. CITIZEN PETITIONS.

Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by section 3(a)) is amended by inserting after subparagraph (C) the following:

''(D) CITIZEN PETITIONS.—

''(i) IN GENERAL.—Notwithstanding any other provision of law, any petition submitted under section 10.30 of title 21, Code of Federal Regulations (or any successor regulation), shall include a statement that to the best knowledge and belief of the petitioner, the petition—

"(I) includes all information and views on which the petitioner relies;

"(II) is well grounded in fact and is warranted by law (including regulations);

"(III) is not submitted for any improper purpose, such as to harass or cause unnecessary delay;

"(IV) does not contain a materially false, misleading, or fraudulent statement that the petitioner has knowingly and willingly included; and

"(V) includes all representative data and information known to the petitioner that is favorable or unfavorable to the petition.

"(ii) APPLICABILITY OF CRIMINAL PROVISION.—Section 1001 of title 18, United States Code, shall apply to a person that submits a petition under section 10.30 of title 21, Code of Federal Regulations (or any successor regulation).

"(iii) INVESTIGATIONS.—

"(I) IN GENERAL.—The Federal Trade Commission shall investigate,

on receipt of a complaint or upon its own initiative, any petition submitted under section 10.30 of title 21, Code of Federal Regulations (or any successor regulation), that may have been submitted for an improper purpose, such as to delay competition or agency action.

''(II) REFERRAL.—If the Commission finds that a petitioner has engaged in conduct that may be illegal, the Commission shall refer the petition to the Antitrust Division of the Department of Justice for further action.

''(iv) NOTICE OF RECEIPT OF CONSIDERATION.—

''(I) IN GENERAL.—A person that submits a petition under section 10.30 of title 21, Code of Federal Regulations (or any successor regulation), shall provide a written notice to the Federal Trade Commission if the person receives any consideration for submitting the petition.

''(II) A notice under subclause (I) shall include—

''(aa) the name of the person or entity that provided the consideration;

''(bb) the dollar value of the consideration, if provided in cash, or a description of such consideration;

''(cc) the date on which the consideration was provided; and

''(dd) any other information that the Commission requires to be disclosed.''.

SEC. 6. PATENT CERTIFICATION.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by section 3(a)(2)) is amended—

(1) in subparagraph (B), by striking clause (iii) and inserting the following:

''(iii) CERTIFICATION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

''(I) IN GENERAL.—Except as provided in subclauses (II) and (III),

if the applicant made a certification described in paragraph (2)(A)(vii)(IV), the approval shall be made effective on the expiration of 45 days after the date on which the notice provided under paragraph (2)(B)(ii) was received.

''(II) ACTION FOR PATENT INFRINGEMENT.—If an action is brought for infringement of a patent that is the subject of the certification before the expiration of the 45-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received, the approval shall be made effective on the expiration of the 45-day period unless the court grants a preliminary injunction 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.

''(III) PATENT INVALID OR NOT INFRINGED.—If the court decides that

the patent is invalid or was not infringed, the approval shall be made effective on the date of the court decision.

''(IV) PATENT INFRINGED.—If the court decides that the patent was 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.

''(V) PROCEDURE.—In an action described in subclause (II)—

''(aa) each of the parties shall reasonably cooperate in expediting the action;

''(bb) until the expiration of 45 days after the date the notice provided under paragraph (2)(B)(i) was received, no civil action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent, except as provided in subparagraph (H); and

''(cc) any such civil action shall be brought in the judicial district in which the defendant has its principal place of business or a regular and established place of business.''; and

(2) by adding at the end the following:

''(G) CIVIL ACTION FOR DECLARATORY JUDGMENT.—A person that files an abbreviated application for a new drug under this paragraph may bring a civil action against the holder of an approved application for a listed drug for a declaratory judgment to determine whether the patent that claims the listed drug or a method of using the drug is invalid or will not be infringed.

''(H) CIVIL ACTION TO DETERMINE LEGAL STATUS.—Notwithstanding any other provision of law, if information on a patent for a listed drug has been published under subsection (c)(2) for at least 1 year after the date on which an abbreviated application for approval of a new drug was filed under this subsection in relation to the listed drug, the person that filed the abbreviated application or the holder of the ap-

proved application for the listed drug may immediately bring a civil action to determine the legal status of the patent for the listed drug.''.

(b) NEW DRUG APPLICATIONS.—Section 505(c)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)) is amended by striking subparagraph (C) and inserting the following:

''(C) CERTIFICATION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

''(i) IN GENERAL.—Except as provided in clauses (ii) and (iii), if the applicant made a certification described in subsection (b)(2)(A)(iv), the approval shall be made effective on the expiration of 45 days after the date on which the notice provided under subsection (b)(3)(B) was received.

''(ii) ACTION BROUGHT BEFORE EXPIRATION OF 45 DAYS.—If an action is brought for infringement of a patent that is the subject of the certification before the expiration of the 45-day period beginning on the date the notice provided under subsection (b)(3)(B) was received, the approval shall be made effective on the expiration of the 45-day period unless the

court grants a preliminary injunction 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.

''(iii) PATENT INVALID OR NOT INFRINGED.—If the court decides that the patent is invalid or not infringed, the approval shall be made effective on the date of the court decision.

''(iv) PATENT INFRINGED.—If the court decides that the patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code.

''(v) PROCEDURE.—In an action described in clause (ii)—

''(I) each of the parties shall reasonably cooperate in expediting the action;

''(II) until the expiration of 45 days after the date the notice provided under subsection (b)(3)(B) was received, no civil action may be brought

under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent, except as provided in subsection (j)(5)(H); and

''(III) any such civil action shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall not apply to an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) before the date of enactment of this Act.

SEC. 7. PATENT INFORMATION.

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

(1) in subsection (b), by striking ''(b)(1) Any person'' and all that follows through paragraph (1) and inserting the following:

''(b) APPLICATIONS.—

''(1) IN GENERAL.—

''(A) FILING.—Any person may file with the Secretary an application with respect to any drug subject to subsection (a).

''(B) CONTENTS.—A person that files an application shall submit to the Secretary as a part of the application with respect to a drug—

''(i) full reports of investigations that have been made to show whether or not such drug is safe for use and whether the drug is effective in use;

''(ii) a full list of the articles used as components of the drug;

''(iii) a full statement of the composition of the drug;

''(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug;

''(v) such samples of the drug and of the articles used as components of the drug as the Secretary may require; and

''(vi) specimens of the labeling proposed to be used for the drug.

''(C) PATENT INFORMATION.—

"(i) IN GENERAL.—The applicant shall file with the application the patent number and expiration date of any patent that claims a drug or method of using a drug and 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 for which the applicant submitted the application.

"(ii) AMENDMENT OF APPLICATION.—If an application is filed with respect to a drug and a patent as described in clause (i) is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by clause (i).

"(iii) PUBLICATION OF INFORMATION.—On approval of the application, the Secretary shall publish information submitted under clauses (i) and (ii).

"(D) GUIDANCE.—The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and

develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by subparagraph (B)(i).''; and

(2) in paragraph (2)(A)—

(A) by striking ''which claims'' the first place it appears and all that follows through ''subsection and''; and

(B) by striking ''subsection (c)—'' and inserting ''and 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 for which the investigations were conducted—'';

(3) in the first sentence of subsection (c)(2)—

(A) by inserting ''such patent information'' after ''shall file''; and

(B) by striking ''Secretary,'' and all that follows and inserting ''Secretary.'';

(4) in subsection (j)(2)(vii), by striking ''which claims the listed drug'' and all that follows through ''under this subsection and'' and inserting ''for the listed drug referred to in clause (i)''; and

(5) by adding at the end the following:

''(o) PATENT INFORMATION.—

''(1) APPLICABILITY.—This subsection applies to a holder of an approved application under subsection (c) that files a patent—

''(A) that claims, with regard to a drug of the application, a drug or method of using a drug; and

''(B) for 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, after the date of approval of the application.

''(2) CERTIFICATION.—A holder of a patent described in paragraph (1) shall—

''(A) inform the Secretary of the filing of the patent; and

''(B) certify that the information is a complete and accurate listing of all such patents.

''(3) SECRETARY.—The Secretary shall list the information provided under paragraph (2) in accordance with subsection (j)(7).''.

SEC. 8. 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 Act—

(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.

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