106TH CONGRESS
2D SESSION

S. 3051

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

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 14, 2000

Mr. SCHUMER (for himself, Mr. MCCAIN, and Mr. JOHNSON) 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'' or the ''GAAP Act of 2000''.

SEC. 2. NEW DRUG APPLICATIONS.

(a) LIMITATIONS ON THE USE OF PATENTS TO PREVENT APPROVAL OF ABBREVIATED NEW DRUG APPLICA-

TIONS.—Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)) is amended—

(1) in subparagraph (A)—

(A) in the matter preceding clause (i), by striking ''the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection'' and inserting ''an active ingredient of the drug for which such investigations were conducted, alone or in combination with another active ingredient or which claims the first approved use for such drug for which the applicant is seeking approval under this subsection''; and

(B) in clause (iv), by striking ''; and'' and inserting a period;

(2) in the matter preceding subparagraph (A), by striking ''shall also include—'' and all that follows through ''a certification'' and inserting ''shall also include a certification'';

(3) by striking subparagraph (B); and

(4) by redesignating clauses (i) through (iv) as subparagraphs (A) through (D), respectively, and aligning the margins of the subparagraphs with the

margins of subparagraph (A) of section 505(c)(1) of that Act (21 U.S.C. 355(c)(1)).

(b) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)) is amended—

(1) in clause (vi), by striking the semicolon and inserting ''; and''; and

(2) in clause (vii)—

(A) in the matter preceding subclause (I), by striking ''the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection'' and inserting ''an active ingredient of the listed drug referred to in clause (i), alone or in combination with another active ingredient or which claims the first approved use for such drug for which the applicant is seeking approval under this subsection'';

(B) in subclause (IV), by striking ''; and'' and inserting a period; and

(C) by striking clause (viii).

(c) EFFECTIVE DATE.—The amendments made by this section shall only be effective with respect to a listed drug for which no certification pursuant to section

505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, Cosmetic Act was made prior to the date of enactment of this Act.

SEC. 3. CITIZEN PETITION REVIEW.

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

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

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

''(C) Notwithstanding any other provision of law, the submission of a citizen's petition filed pursuant to section 10.30 of title 21, Code of Federal Regulations, with respect to an application submitted under paragraph (2)(A), shall not cause the Secretary to delay review and approval of such application, unless such petition demonstrates through substantial scientific proof that approval of such application would pose a threat to public health and safety.''.

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 and inserting ''; or''; and

(3) by adding at the end the following:

''(iii) 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 comparative pharmacodynamic studies, limited confirmation studies, or in vitro methods, that demonstrate that no significant differences in therapeutic effects of active or inactive ingredients are expected.''.

SEC. 5. 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 date of a final decision of a court in an action described in clause (ii) from which no appeal can or has been taken, or the date of a settlement order or consent decree signed by a Federal judge, that enters a final judgement, and includes a finding that the relevant patents that are the subject of the certification involved are invalid or not infringed, whichever is earlier,'';

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

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

''(C) The one-hundred and eighty day period described in subparagraph (B)(iv) shall become available to the next applicant submitting an application containing a certification described in paragraph (2)(A)(vii)(IV) if the previous applicant fails to commence commercial marketing of its drug product once its application is made effective, withdraws its application, or amends the certification from a certification under subclause (IV) to a certification under subclause (III) of such paragraph, either voluntarily or as a result of a settlement or defeat in patent litigation.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall only be effective with respect to an application filed under section 505(j) of the Federal Food, Drug, Cosmetic Act for a listed drug for which no certification pursuant to 505(j)(2)(A)(vii)(IV) of such Act was made prior to the date of enactment of this Act.

SEC. 6. SENSE OF CONGRESS.

It is the sense of Congress that measures should be taken to effectuate the purpose of the Drug Price Competition and Patent Term Restoration Act of 1984 (re-

ferred to in this section as the ''Hatch-Waxman Act'') to make generic drugs more available and accessible, and thereby reduce health care costs, including measures that require manufacturers of a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 255(c)) desiring to extend a patent of such drug to utilize the patent extension procedure provided under the Hatch-Waxman Act.

SEC. 7. CONFORMING AMENDMENTS.

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

(1) in subsection (b)(3), in subparagraphs (A) and (C), by striking ''paragraph (2)(A)(iv)'' and inserting ''paragraph (2)'';

(2) in subsection (c)(3)—

(A) in subparagraph (A), by striking ''clause (i) or (ii) of subsection (b)(2)(A)'' and inserting ''subparagraph (A) or (B) of subsection (b)(2)'';

(B) in subparagraph (B), by striking ''clause (iii) of subsection (b)(2)(A)'' and all that follows through the period and inserting ''subparagraph (C) of subsection (b)(2), the ap-

proval may be made effective on the date certified under subparagraph (C).'';

(C) in subparagraph (C), by striking ''clause (iv) of subsection (b)(2)(A)'' and inserting ''subparagraph (D) of subsection (b)(2)''; and

(D) in subparagraph (D)(ii), by striking ''clause (iv) of subsection (b)(2)(A)'' and inserting ''subparagraph (D) of subsection (b)(2)''; and

(3) in subsection (j), in paragraph (2)(A), in the matter following clause (vii)(IV), by striking ''clauses (i) through (viii)'' and inserting ''clauses (i) through (vii)''.

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

(1) in subsection (a)(2)—

(A) in clause (i) of subparagraph (A), by striking ''(b)(2)(A)(ii)'' and inserting ''(b)(2)'';

(B) in clause (ii) of subparagraph (A), by striking ''(b)(2)(A)(iii)'' and inserting ''(b)(2)''; and

(C) in subparagraph (B), by striking ''subsection (b)(2)(A)(iv)'' and inserting ''subsection (b)(2)''; and

(2) in subsection (c)(2)—

(A) in clause (i) of subparagraph (A), by striking ''(b)(2)(A)(ii)'' and inserting ''(b)(2)'';

(B) in clause (ii) of subparagraph (A), by striking ''(b)(2)(A)(iii)'' and inserting ''(b)(2)''; and

(C) in subparagraph (B), by striking ''subsection (b)(2)(A)(iv)'' and inserting ''subsection (b)(2)''.

(c) DEFINITION.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(kk) For purposes of the references to court decisions in clauses (i) and (iii) of section 505(c)(3)(C) and clauses (iii)(I), (iii)(III) of section 505(j)(5)(B), the term 'the court' means the court that enters final judgment from which no appeal (not including a writ of certiorari) can or has been taken.''.

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