

106TH CONGRESS
2D SESSION

H. R. 5247

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

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 21, 2000

Mr. BALDACCİ (for himself and Mr. COBURN) introduced the following bill;
which was referred to the Committee on Commerce

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Greater Access to Af-
5 fordable Pharmaceuticals Act” or the “GAAP Act of
6 2000”.

7 **SEC. 2. NEW DRUG APPLICATIONS.**

8 (a) LIMITATIONS ON THE USE OF PATENTS TO PRE-
9 VENT APPROVAL OF ABBREVIATED NEW DRUG APPLICA-

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

3 (1) in subparagraph (A)—

4 (A) in the matter preceding clause (i), by
5 striking “the drug for which such investigations
6 were conducted or which claims a use for such
7 drug for which the applicant is seeking approval
8 under this subsection” and inserting “an active
9 ingredient of the drug for which such investiga-
10 tions were conducted, alone or in combination
11 with another active ingredient or which claims
12 the first approved use for such drug for which
13 the applicant is seeking approval under this
14 subsection”; and

15 (B) in clause (iv), by striking “; and” and
16 inserting a period;

17 (2) in the matter preceding subparagraph (A),
18 by striking “shall also include—” and all that fol-
19 lows through “a certification” and inserting “shall
20 also include a certification”;

21 (3) by striking subparagraph (B); and

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

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

3 (b) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-
4 tion 505(j)(2)(A) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 355(j)(2)(A)) is amended—

6 (1) in clause (vi), by striking the semicolon and
7 inserting “; and”; and

8 (2) in clause (vii)—

9 (A) in the matter preceding subclause (I),
10 by striking “the listed drug referred to in clause
11 (i) or which claims a use for such listed drug
12 for which the applicant is seeking approval
13 under this subsection” and inserting “an active
14 ingredient of the listed drug referred to in
15 clause (i), alone or in combination with another
16 active ingredient or which claims the first ap-
17 proved use for such drug for which the appli-
18 cant is seeking approval under this subsection”;

19 (B) in subclause (IV), by striking “; and”
20 and inserting a period; and

21 (C) by striking clause (viii).

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

1 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, Cosmetic
2 Act was made prior to the date of enactment of this Act.

3 **SEC. 3. CITIZEN PETITION REVIEW.**

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

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

8 (2) by inserting after subparagraph (B) the fol-
9 lowing:

10 “(C) Notwithstanding any other provision of law, the
11 submission of a citizen’s petition filed pursuant to section
12 10.30 of title 21, Code of Federal Regulations, with re-
13 spect to an application submitted under paragraph (2)(A),
14 shall not cause the Secretary to delay review and approval
15 of such application, unless such petition demonstrates
16 through substantial scientific proof that approval of such
17 application would pose a threat to public health and safe-
18 ty.”.

19 **SEC. 4. BIOEQUIVALENCE TESTING METHODS.**

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

22 (1) in clause (i), by striking “or” at the end;

23 (2) in clause (ii), by striking the period and in-
24 serting “; or”; and

25 (3) by adding at the end the following:

1 “(iii) the effects of the drug and the listed
2 drug do not show a significant difference based
3 on tests (other than tests that assess rate and
4 extent of absorption), including comparative
5 pharmacodynamic studies, limited confirmation
6 studies, or in vitro methods, that demonstrate
7 that no significant differences in therapeutic ef-
8 fects of active or inactive ingredients are ex-
9 pected.”.

10 **SEC. 5. ACCELERATED GENERIC DRUG COMPETITION.**

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

14 (1) in subparagraph (B)(iv), by striking sub-
15 clause (II) and inserting the following:

16 “(II) the date of a final decision of a court
17 in an action described in clause (ii) from which
18 no appeal can or has been taken, or the date of
19 a settlement order or consent decree signed by
20 a Federal judge, that enters a final judgement,
21 and includes a finding that the relevant patents
22 that are the subject of the certification involved
23 are invalid or not infringed, whichever is ear-
24 lier.”;

1 (2) by redesignating subparagraphs (C) and
2 (D) as subparagraphs (D) and (E), respectively; and
3 (3) by inserting after subparagraph (B), the
4 following:

5 “(C) The one-hundred and eighty day period de-
6 scribed in subparagraph (B)(iv) shall become available to
7 the next applicant submitting an application containing a
8 certification described in paragraph (2)(A)(vii)(IV) if the
9 previous applicant fails to commence commercial mar-
10 keting of its drug product once its application is made ef-
11 fective, withdraws its application, or amends the certifi-
12 cation from a certification under subclause (IV) to a cer-
13 tification under subclause (III) of such paragraph, either
14 voluntarily or as a result of a settlement or defeat in pat-
15 ent litigation.”.

16 (b) **EFFECTIVE DATE.**—The amendments made by
17 this section shall only be effective with respect to an appli-
18 cation filed under section 505(j) of the Federal Food,
19 Drug, Cosmetic Act for a listed drug for which no certifi-
20 cation pursuant to 505(j)(2)(A)(vii)(IV) of such Act was
21 made prior to the date of enactment of this Act.

22 **SEC. 6. SENSE OF CONGRESS.**

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

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

9 **SEC. 7. CONFORMING AMENDMENTS.**

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

13 (1) in subsection (b)(3), in subparagraphs (A)
14 and (C), by striking “paragraph (2)(A)(iv)” and in-
15 sserting “paragraph (2)”;

16 (2) in subsection (c)(3)—

17 (A) in subparagraph (A), by striking
18 “clause (i) or (ii) of subsection (b)(2)(A)” and
19 inserting “subparagraph (A) or (B) of sub-
20 section (b)(2)”;

21 (B) in subparagraph (B), by striking
22 “clause (iii) of subsection (b)(2)(A)” and all
23 that follows through the period and inserting
24 “subparagraph (C) of subsection (b)(2), the ap-

1 proval may be made effective on the date cer-
2 tified under subparagraph (C).”;

3 (C) in subparagraph (C), by striking
4 “clause (iv) of subsection (b)(2)(A)” and insert-
5 ing “subparagraph (D) of subsection (b)(2)”;
6 and

7 (D) in subparagraph (D)(ii), by striking
8 “clause (iv) of subsection (b)(2)(A)” and insert-
9 ing “subparagraph (D) of subsection (b)(2)”;
10 and

11 (3) in subsection (j), in paragraph (2)(A), in
12 the matter following clause (vii)(IV), by striking
13 “clauses (i) through (viii)” and inserting “clauses (i)
14 through (vii)”.

15 (b) PEDIATRIC STUDIES OF DRUGS.—Section 505A
16 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 355a) is amended—

18 (1) in subsection (a)(2)—

19 (A) in clause (i) of subparagraph (A), by
20 striking “(b)(2)(A)(ii)” and inserting “(b)(2)”;

21 (B) in clause (ii) of subparagraph (A), by
22 striking “(b)(2)(A)(iii)” and inserting “(b)(2)”;

23 and

1 (C) in subparagraph (B), by striking “sub-
2 section (b)(2)(A)(iv)” and inserting “subsection
3 (b)(2)”; and
4 (2) in subsection (c)(2)—

5 (A) in clause (i) of subparagraph (A), by
6 striking “(b)(2)(A)(ii)” and inserting “(b)(2)”;

7 (B) in clause (ii) of subparagraph (A), by
8 striking “(b)(2)(A)(iii)” and inserting “(b)(2)”;
9 and

10 (C) in subparagraph (B), by striking “sub-
11 section (b)(2)(A)(iv)” and inserting “subsection
12 (b)(2)”.

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

16 “(kk) For purposes of the references to court deci-
17 sions in clauses (i) and (iii) of section 505(c)(3)(C) and
18 clauses (iii)(I), (iii)(III) of section 505(j)(5)(B), the term
19 ‘the court’ means the court that enters final judgment
20 from which no appeal (not including a writ of certiorari)
21 can or has been taken.”.

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