

108TH CONGRESS
1ST SESSION

S. 946

To enhance competition for prescription drugs by increasing the ability of the Department of Justice and Federal Trade Commission to enforce existing antitrust laws regarding brand name drugs and generic drugs.

IN THE SENATE OF THE UNITED STATES

APRIL 29, 2003

Mr. LEAHY (for himself, Mr. GRASSLEY, Mr. DURBIN, Mr. FEINGOLD, Mr. KOHL, and Mr. SCHUMER) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To enhance competition for prescription drugs by increasing the ability of the Department of Justice and Federal Trade Commission to enforce existing antitrust laws regarding brand name drugs and generic drugs.

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 “Drug Competition Act
5 of 2003”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

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

4 (2) there is a potential for companies with pat-
5 ent rights regarding brand name drugs and compa-
6 nies which could manufacture generic versions of
7 such drugs to enter into financial deals that could
8 tend to restrain trade and greatly reduce competi-
9 tion and increase prescription drug expenditures for
10 American citizens; and

11 (3) enhancing competition among these compa-
12 nies can significantly reduce prescription drug ex-
13 penditures for Americans.

14 **SEC. 3. PURPOSES.**

15 The purposes of this Act are—

16 (1) to provide timely notice to the Department
17 of Justice and the Federal Trade Commission re-
18 garding agreements between companies with patent
19 rights regarding brand name drugs and companies
20 which could manufacture generic versions of such
21 drugs; and

22 (2) by providing timely notice, to enhance the
23 effectiveness and efficiency of the enforcement of the
24 antitrust and competition laws of the United States.

1 **SEC. 4. DEFINITIONS.**

2 In this Act:

3 (1) ANDA.—The term “ANDA” means an Ab-
4 breviated New Drug Application, as defined under
5 section 201(aa) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 321(aa)).

7 (2) ASSISTANT ATTORNEY GENERAL.—The
8 term “Assistant Attorney General” means the As-
9 sistant Attorney General in charge of the Antitrust
10 Division of the Department of Justice.

11 (3) BRAND NAME DRUG.—The term “brand
12 name drug” means a drug approved under section
13 505(c) of the Federal Food, Drug, and Cosmetic Act
14 (21 U.S.C. 355(c)).

15 (4) BRAND NAME DRUG COMPANY.—The term
16 “brand name drug company” means the party that
17 received Food and Drug Administration approval to
18 market a brand name drug pursuant to an NDA,
19 where that drug is the subject of an ANDA, or a
20 party owning or controlling enforcement of any pat-
21 ent listed in the Approved Drug Products With
22 Therapeutic Equivalence Evaluations of the Food
23 and Drug Administration for that drug, under sec-
24 tion 505(b) of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 355(b)).

1 (5) COMMISSION.—The term “Commission”
2 means the Federal Trade Commission.

3 (6) GENERIC DRUG.—The term “generic drug”
4 means a product that the Food and Drug Adminis-
5 tration has approved under section 505(j) of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 355(j)).

8 (7) GENERIC DRUG APPLICANT.—The term
9 “generic drug applicant” means a person who has
10 filed or received approval for an ANDA under sec-
11 tion 505(j) of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 355(j)).

13 (8) NDA.—The term “NDA” means a New
14 Drug Application, as defined under section 505(b) et
15 seq. of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 355(b) et seq.)

17 **SEC. 5. NOTIFICATION OF AGREEMENTS.**

18 (a) IN GENERAL.—

19 (1) REQUIREMENT.—A generic drug applicant
20 that has submitted an ANDA containing a certifi-
21 cation under section 505(j)(2)(vii)(IV) of the Fed-
22 eral Food, Drug, and Cosmetic Act (21 U.S.C.
23 355(j)(2)(vii)(IV)) and a brand name drug company
24 that enter into an agreement described in paragraph
25 (2), prior to the generic drug that is the subject of

1 the application entering the market, shall each file
2 the agreement as required by subsection (b).

3 (2) DEFINITION.—An agreement described in
4 this paragraph is an agreement regarding—

5 (A) the manufacture, marketing or sale of
6 the brand name drug that is the subject of the
7 generic drug applicant’s ANDA;

8 (B) the manufacture, marketing or sale of
9 the generic drug that is the subject of the ge-
10 neric drug applicant’s ANDA; or

11 (C) the 180-day period referred to in sec-
12 tion 505(j)(5)(B)(iv) of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C.
14 355(j)(5)(B)(iv)) as it applies to such ANDA or
15 to any other ANDA based on the same brand
16 name drug.

17 (b) FILING.—

18 (1) AGREEMENT.—The generic drug applicant
19 and the brand name drug company entering into an
20 agreement described in subsection (a)(2) shall file
21 with the Assistant Attorney General and the Com-
22 mission the text of any such agreement, except that
23 the generic drug applicant and the brand-name drug
24 company shall not be required to file an agreement
25 that solely concerns—

1 (A) purchase orders for raw material sup-
2 plies;

3 (B) equipment and facility contracts;

4 (C) employment or consulting contracts; or

5 (D) packaging and labeling contracts.

6 (2) OTHER AGREEMENTS.—The generic drug
7 applicant and the brand name drug company enter-
8 ing into an agreement described in subsection (a)(2)
9 shall file with the Assistant Attorney General and
10 the Commission the text of any other agreements
11 not described in subsection (a)(2) between the ge-
12 neric drug applicant and the brand name drug com-
13 pany which are contingent upon, provide a contin-
14 gent condition for, or are otherwise related to an
15 agreement which must be filed under this Act.

16 (3) DESCRIPTION.—In the event that any
17 agreement required to be filed by paragraph (1) or
18 (2) has not been reduced to text, both the generic
19 drug applicant and the brand name drug company
20 shall file written descriptions of the non-textual
21 agreement or agreements that must be filed suffi-
22 cient to reveal all of the terms of the agreement or
23 agreements.

1 **SEC. 6. FILING DEADLINES.**

2 Any filing required under section 5 shall be filed with
3 the Assistant Attorney General and the Commission not
4 later than 10 business days after the date the agreements
5 are executed.

6 **SEC. 7. DISCLOSURE EXEMPTION.**

7 Any information or documentary material filed with
8 the Assistant Attorney General or the Commission pursu-
9 ant to this Act shall be exempt from disclosure under sec-
10 tion 552 of title 5, and no such information or documen-
11 tary material may be made public, except as may be rel-
12 evant to any administrative or judicial action or pro-
13 ceeding. Nothing in this section is intended to prevent dis-
14 closure to either body of Congress or to any duly author-
15 ized committee or subcommittee of the Congress.

16 **SEC. 8. ENFORCEMENT.**

17 (a) CIVIL PENALTY.—Any brand name drug com-
18 pany or generic drug applicant which fails to comply with
19 any provision of this Act shall be liable for a civil penalty
20 of not more than \$11,000, for each day during which such
21 entity is in violation of this Act. Such penalty may be re-
22 covered in a civil action brought by the United States, or
23 brought by the Commission in accordance with the proce-
24 dures established in section 16(a)(1) of the Federal Trade
25 Commission Act (15 U.S.C. 56(a)).

1 (b) COMPLIANCE AND EQUITABLE RELIEF.—If any
2 brand name drug company or generic drug applicant fails
3 to comply with any provision of this Act, the United States
4 district court may order compliance, and may grant such
5 other equitable relief as the court in its discretion deter-
6 mines necessary or appropriate, upon application of the
7 Assistant Attorney General or the Commission.

8 **SEC. 9. RULEMAKING.**

9 The Commission, with the concurrence of the Assist-
10 ant Attorney General and by rule in accordance with sec-
11 tion 553 of title 5 United States Code, consistent with
12 the purposes of this Act—

13 (1) may define the terms used in this Act;

14 (2) may exempt classes of persons or agree-
15 ments from the requirements of this Act; and

16 (3) may prescribe such other rules as may be
17 necessary and appropriate to carry out the purposes
18 of this Act.

19 **SEC. 10. SAVINGS CLAUSE.**

20 Any action taken by the Assistant Attorney General
21 or the Commission, or any failure of the Assistant Attor-
22 ney General or the Commission to take action, under this
23 Act shall not bar any proceeding or any action with re-
24 spect to any agreement between a brand name drug com-
25 pany and a generic drug applicant at any time under any

1 other provision of law, nor shall any filing under this Act
2 constitute or create a presumption of any violation of any
3 antitrust or competition laws.

4 **SEC. 11. EFFECTIVE DATE.**

5 This Act shall—

6 (1) take effect 30 days after the date of enact-
7 ment of this Act; and

8 (2) shall apply to agreements described in sec-
9 tion 5 that are entered into 30 days after the date
10 of enactment of this Act.

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