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.

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 ''Drug Competition Act of 2003''.

SEC. 2. FINDINGS.

Congress finds that—

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

(2) there is a potential for companies with patent rights regarding brand name drugs and companies which could manufacture generic versions of such drugs to enter into financial deals that could tend to restrain trade and greatly reduce competition and increase prescription drug expenditures for American citizens; and

(3) enhancing competition among these companies can significantly reduce prescription drug expenditures for Americans.

SEC. 3. PURPOSES.

The purposes of this Act are—

(1) to provide timely notice to the Department of Justice and the Federal Trade Commission regarding agreements between companies with patent rights regarding brand name drugs and companies which could manufacture generic versions of such drugs; and

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

SEC. 4. DEFINITIONS.

In this Act:

(1) ANDA.—The term ''ANDA'' means an Abbreviated New Drug Application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(aa)).

(2) ASSISTANT ATTORNEY GENERAL.—The term ''Assistant Attorney General'' means the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice.

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

(4) BRAND NAME DRUG COMPANY.—The term ''brand name drug company'' means the party that received Food and Drug Administration approval to market a brand name drug pursuant to an NDA, where that drug is the subject of an ANDA, or a party owning or controlling enforcement of any patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations of the Food and Drug Administration for that drug, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

(5) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

(6) GENERIC DRUG.—The term ''generic drug'' means a product that the Food and Drug Administration has approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(7) GENERIC DRUG APPLICANT.—The term ''generic drug applicant'' means a person who has filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

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

SEC. 5. NOTIFICATION OF AGREEMENTS.

(a) IN GENERAL.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(vii)(IV)) and a brand name drug company that enter into an agreement described in paragraph (2), prior to the generic drug that is the subject of

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

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

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

(B) the manufacture, marketing or sale of the generic drug that is the subject of the generic drug applicant's ANDA; or

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

(b) FILING.—

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

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The generic drug applicant and the brand name drug company entering into an agreement described in subsection (a)(2) shall file with the Assistant Attorney General and the Commission the text of any other agreements not described in subsection (a)(2) between the generic drug applicant and the brand name drug company which are contingent upon, provide a contingent condition for, or are otherwise related to an agreement which must be filed under this Act.

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

SEC. 6. FILING DEADLINES.

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

SEC. 7. DISCLOSURE EXEMPTION.

Any information or documentary material filed with the Assistant Attorney General or the Commission pursuant to this Act shall be exempt from disclosure under section 552 of title 5, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of Congress or to any duly authorized committee or subcommittee of the Congress.

SEC. 8. ENFORCEMENT.

(a) CIVIL PENALTY.—Any brand name drug company or generic drug applicant which fails to comply with any provision of this Act shall be liable for a civil penalty of not more than $11,000, for each day during which such entity is in violation of this Act. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

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

SEC. 9. RULEMAKING.

The Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5 United States Code, consistent with the purposes of this Act—

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

(2) may exempt classes of persons or agreements from the requirements of this Act; and

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

SEC. 10. SAVINGS CLAUSE.

Any action taken by the Assistant Attorney General or the Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this Act shall not bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant at any time under any

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

SEC. 11. EFFECTIVE DATE.

This Act shall—

(1) take effect 30 days after the date of enactment of this Act; and

(2) shall apply to agreements described in section 5 that are entered into 30 days after the date of enactment of this Act.

○