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107TH CONGRESS
1ST SESSION

# S. 754

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.

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IN THE SENATE OF THE UNITED STATES

APRIL 6, 2001

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

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# 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 2001''.

**SEC. 2. FINDINGS.**

Congress finds that—

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

(2) there is a potential for drug companies owning patents on brand-name drugs to enter into private financial deals with generic drug companies in a manner that could tend to restrain trade and greatly reduce competition and increase prescription drug costs for American citizens; and

(3) enhancing competition between generic drug manufacturers and brand name manufacturers can significantly reduce prescription drug costs to American families.

**SEC. 3. PURPOSE.**

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 owning patents on branded drugs and companies who could manufacture generic or bioequivalent versions of such branded drugs; and

(2) by providing timely notice, to—

(A) enhance the effectiveness and efficiency of the enforcement of the antitrust laws of the United States; and

(B) deter pharmaceutical companies from engaging in anticompetitive actions or actions that tend to unfairly restrain trade.

**SEC. 4. DEFINITIONS.**

In this Act:

(1) AGREEMENT.—The term ''agreement'' means an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of the Federal Trade Commission Act (15 U.S.C. 45).

(2) ANTITRUST LAWS.—The term ''antitrust laws'' has the same meaning as in section 1 of the Clayton Act (15 U.S.C. 12), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(3) ANDA.—The term ''ANDA'' means an Abbreviated New Drug Application, as defined under section 505(j) of the Federal Food, Drug and Cosmetic Act.

(4) BRAND NAME DRUG COMPANY.—The term ''brand name drug company'' means a person engaged in the manufacture or marketing of a drug approved under section 505(b) of the Federal Food, Drug and Cosmetic Act.

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

(6) FDA.—The term ''FDA'' means the United States Food and Drug Administration.

(7) GENERIC DRUG.—The term ''generic drug'' is a product that the Food and Drug Administration has approved under section 505(j) of the Federal Food, Drug and Cosmetic Act.

(8) 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.

(9) 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 AFFECTING THE SALE OR MARKETING OF GENERIC DRUGS.**

A brand name drug manufacturer and a generic drug manufacturer that enter into an agreement regarding the sale or manufacture of a generic drug equivalent of a brand name drug that is manufactured by that brand name manufacturer and which agreement could have the effect of limiting—

(1) the research, development, manufacture, marketing or selling of a generic drug product that could be approved for sale by the FDA pursuant to the ANDA; or

(2) the research, development, manufacture, marketing or selling of a generic drug product that could be approved by the FDA;

both shall file with the Commission and the Attorney General the text of the agreement, an explanation of the purpose and scope of the agreement and an explanation of whether the agreement could delay, restrain, limit, or in any way interfere with the production, manufacture or sale of the generic version of the drug in question.

**SEC. 6. FILING DEADLINES.**

Any notice, agreement, or other material required to be filed under section 5 shall be filed with the Attorney General and the FTC not later than 10 business days after the date the agreements are executed.

**SEC. 7. ENFORCEMENT.**

(a) CIVIL FINE.—Any person, or any officer, director, or partner thereof, who fails to comply with any provision of this Act shall be liable for a civil penalty of not more than $20,000 for each day during which such person 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 person, or any officer, director, partner, agent, or employee thereof, fails to comply with the notification requirement under section 5 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 Commission or the Assistant Attorney General.

**SEC. 8. RULEMAKING.**

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

(1) may require that the notice described in section 5 of this Act be in such form and contain such documentary material and information relevant to the agreement as is necessary and appropriate to enable the Commission and the Assistant Attorney General to determine whether such agreement may violate the antitrust laws;

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

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

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

**SEC. 9. EFFECTIVE DATES.**

This Act shall take effect 90 days after the date of enactment of this Act.

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