Calendar No. 431

107TH CONGRESS
2D SESSION

S. 754

[Report No. 107–167]

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 6, 2001

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

JUNE 20, 2002

Reported by Mr. LEAHY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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 en-

gaged 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.~~

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 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 in-

crease 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; or

(C) employment or consulting 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 contin-

gent 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. Equitable relief under this subsection may include an order by the district court which renders unenforceable, by the brand name drug company or generic drug applicant failing to file, any agreement that was not filed as required by this Act for the period of time during which the agreement was not filed by the company or applicant as required by this Act.

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.

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