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106TH CONGRESS
2D SESSION

H. R. 5235

To ensure the timely availability of generic drugs through enhancement of drug approval and antitrust laws enforced by the Food and Drug Administration and the Federal Trade Commission regarding brand name drugs and generic drugs.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 20, 2000

Mr. WAXMAN (for himself, Mr. STARK, Mr. BROWN of Ohio, Mr. BERRY, Mr. COBURN, and Mr. DEUTSCH) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To ensure the timely availability of generic drugs through enhancement of drug approval and antitrust laws enforced by the Food and Drug Administration and the Federal Trade Commission 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 ''Prescription Drug Competition Act of 2000''.

SEC. 2. FINDINGS.

Congress finds that—

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

(2) there is a potential for drug companies owning patents on brand-name drugs to enter to 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 Food and Drug Administration 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) ensure the prompt availability of safe and effective generic drugs;

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

(C) 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'' means a product that is the subject of an ANDA.

(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) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 5. NOTIFICATION OF AGREEMENTS AFFECTING THE SALE OR MARKETING OF GENERIC DRUGS.

A brand name drug company and a generic drug applicant that enter into an agreement regarding the sale or manufacture of a generic drug that the Secretary has determined is the therapeutic equivalent of a brand name drug that is manufactured or marketed by that brand name drug company, or for which the generic drug applicant seeks such a determination of therapeutic equivalence, and which agreement could have the effect of lim-

iting the research, development, manufacture, marketing, or selling of a generic drug that has been or could be approved for sale by the FDA pursuant to an ANDA, shall file with the Commission and the Secretary 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 Commission and the Secretary not later than 10 business days after the date the agreement is 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, in consultation with the Secretary, and 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 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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