

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.

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

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 2001”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

1 (1) prescription drug costs are increasing at an
2 alarming rate and are a major worry of senior citi-
3 zens and American families;

4 (2) there is a potential for drug companies own-
5 ing patents on brand-name drugs to enter into pri-
6 vate financial deals with generic drug companies in
7 a manner that could tend to restrain trade and
8 greatly reduce competition and increase prescription
9 drug costs for American citizens; and

10 (3) enhancing competition between generic drug
11 manufacturers and brand name manufacturers can
12 significantly reduce prescription drug costs to Amer-
13 ican families.

14 **SEC. 3. PURPOSE.**

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 owning pat-
19 ents on branded drugs and companies who could
20 manufacture generic or bioequivalent versions of
21 such branded drugs; and

22 (2) by providing timely notice, to—

23 (A) enhance the effectiveness and effi-
24 ciency of the enforcement of the antitrust laws
25 of the United States; and

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

4 **SEC. 4. DEFINITIONS.**

5 In this Act:

6 (1) **AGREEMENT.**—The term “agreement”
7 means an agreement under section 1 of the Sherman
8 Act (15 U.S.C. 1) or section 5 of the Federal Trade
9 Commission Act (15 U.S.C. 45).

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

16 (3) **ANDA.**—The term “ANDA” means an Ab-
17 breviated New Drug Application, as defined under
18 section 505(j) of the Federal Food, Drug and Cos-
19 metic Act.

20 (4) **BRAND NAME DRUG COMPANY.**—The term
21 “brand name drug company” means a person en-
22 gaged in the manufacture or marketing of a drug
23 approved under section 505(b) of the Federal Food,
24 Drug and Cosmetic Act.

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

3 (6) FDA.—The term “FDA” means the United
4 States Food and Drug Administration.

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

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

14 (9) NDA.—The term “NDA” means a New
15 Drug Application, as defined under section 505(b) et
16 seq. of the Federal Food, Drug and Cosmetic Act
17 (21 U.S.C. 355(b) et seq.)

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

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

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

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

8 both shall file with the Commission and the Attorney Gen-
9 eral the text of the agreement, an explanation of the pur-
10 pose and scope of the agreement and an explanation of
11 whether the agreement could delay, restrain, limit, or in
12 any way interfere with the production, manufacture or
13 sale of the generic version of the drug in question.

14 **SEC. 6. FILING DEADLINES.**

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

19 **SEC. 7. ENFORCEMENT.**

20 (a) CIVIL FINE.—Any person, or any officer, direc-
21 tor, or partner thereof, who fails to comply with any provi-
22 sion of this Act shall be liable for a civil penalty of not
23 more than \$20,000 for each day during which such person
24 is in violation of this Act. Such penalty may be recovered
25 in a civil action brought by the United States, or brought

1 by the Commission in accordance with the procedures es-
2 tablished in section 16(a)(1) of the Federal Trade Com-
3 mission Act (15 U.S.C. 56(a)).

4 (b) COMPLIANCE AND EQUITABLE RELIEF.—If any
5 person, or any officer, director, partner, agent, or em-
6 ployee thereof, fails to comply with the notification re-
7 quirement under section 5 of this Act, the United States
8 district court may order compliance, and may grant such
9 other equitable relief as the court in its discretion deter-
10 mines necessary or appropriate, upon application of the
11 Commission or the Assistant Attorney General.

12 **SEC. 8. RULEMAKING.**

13 The Commission, with the concurrence of the Assist-
14 ant Attorney General and by rule in accordance with sec-
15 tion 553 of title 5, consistent with the purposes of this
16 Act—

17 (1) may require that the notice described in sec-
18 tion 5 of this Act be in such form and contain such
19 documentary material and information relevant to
20 the agreement as is necessary and appropriate to en-
21 able the Commission and the Assistant Attorney
22 General to determine whether such agreement may
23 violate the antitrust laws;

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

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

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

6 **SEC. 9. EFFECTIVE DATES.**

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

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