

107<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 1063

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 HOUSE OF REPRESENTATIVES

MARCH 15, 2001

Mr. ANDREWS introduced the following bill; which was referred to the Committee on Energy and 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 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 in private  
6           financial deals with generic drug companies in a  
7           manner that could tend to restrain trade and greatly  
8           reduce competition and increase prescription drug  
9           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 brand name drugs and companies who could  
20          manufacture generic or bioequivalent versions of  
21          such brand name 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 (21 U.S.C. 355(j)).

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 (21 U.S.C. 355(b)).

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 (221 U.S.C. 355(j)).

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 (21 U.S.C. 355(j)).

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

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—

22           (1) regarding the sale or manufacture of a ge-  
23 neric drug equivalent of a brand name drug that is  
24 manufactured by that brand name manufacturer.  
25           and

1           (2) which agreement could have the effect of  
2           limiting the research, development, manufacture,  
3           marketing or selling of a generic drug product that  
4           could be approved for sale by the FDA pursuant to  
5           an ANDA,

6 shall both file with the Commission and the Attorney Gen-  
7 eral a notice that such an agreement has been entered  
8 into, the text of the agreement, an explanation of the pur-  
9 pose and scope of the agreement, and an explanation of  
10 whether the agreement could delay, restrain, limit, or in  
11 any way interfere with the production, manufacture, or  
12 sale of the generic version of the drug in question.

13 **SEC. 6. FILING DEADLINES.**

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

18 **SEC. 7. ENFORCEMENT.**

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

1 tablished in section 16(a)(1) of the Federal Trade Com-  
2 mission Act (15 U.S.C. 56(a)).

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

13 **SEC. 8. RULEMAKING.**

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

18 (1) may require that the notice of an agreement  
19 described in section 5 of this Act be in such form  
20 and contain such documentary material and infor-  
21 mation relevant to the agreement as is necessary  
22 and appropriate to enable the Commission and the  
23 Assistant Attorney General to determine whether  
24 such agreement may violate the antitrust laws;

25 (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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