

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 3995

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 9, 2012

Mr. RUSH (for himself and Mr. WAXMAN) 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 prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and for other purposes.

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 “Protecting Consumer  
5 Access to Generic Drugs Act of 2012”.

1 **SEC. 2. UNFAIR AND DECEPTIVE ACTS AND PRACTICES RE-**  
2 **LATED TO NEW DRUG APPLICATIONS.**

3 (a) CONDUCT PROHIBITED.—It shall be unlawful for  
4 any person to directly or indirectly be a party to any  
5 agreement resolving or settling a patent infringement  
6 claim in which—

7 (1) an ANDA filer receives anything of value;

8 and

9 (2) the ANDA filer agrees not to research, de-  
10 velop, manufacture, market, or sell, for any period  
11 of time, the drug that is to be manufactured under  
12 the ANDA involved and is the subject of the patent  
13 infringement claim.

14 (b) EXCEPTIONS.—Notwithstanding subsection  
15 (a)(1), subsection (a) does not prohibit a resolution or set-  
16 tlement of a patent infringement claim in which the value  
17 received by the ANDA filer includes no more than—

18 (1) the right to market the drug that is to be  
19 manufactured under the ANDA involved and is the  
20 subject of the patent infringement claim, before the  
21 expiration of—

22 (A) the patent that is the basis for the pat-  
23 ent infringement claim; or

24 (B) any other statutory exclusivity that  
25 would prevent the marketing of such drug; and

1           (2) the waiver of a patent infringement claim  
2           for damages based on prior marketing of such drug.

3           (c) ENFORCEMENT.—A violation of subsection (a)  
4 shall be treated as an unfair and deceptive act or practice  
5 and an unfair method of competition in or affecting inter-  
6 state commerce prohibited under section 5 of the Federal  
7 Trade Commission Act (15 U.S.C. 45). The Federal Trade  
8 Commission shall enforce this Act in the same manner,  
9 by the same means, and with the same jurisdiction as  
10 though all applicable terms and provisions of the Federal  
11 Trade Commission Act were incorporated into and made  
12 a part of this Act.

13           (d) DEFINITIONS.—In this section:

14           (1) AGREEMENT.—The term “agreement”  
15 means anything that would constitute an agreement  
16 for purposes of section 5 of the Federal Trade Com-  
17 mission Act (15 U.S.C. 45).

18           (2) AGREEMENT RESOLVING OR SETTling.—  
19 The term “agreement resolving or settling”, in ref-  
20 erence to a patent infringement claim, includes any  
21 agreement that is contingent upon, provides a con-  
22 tingent condition for, or is otherwise related to the  
23 resolution or settlement of the claim.

24           (3) ANDA.—The term “ANDA” means an ab-  
25 breviated new drug application for the approval of a

1 new drug under section 505(j) of the Federal Food,  
2 Drug, and Cosmetic Act (21 U.S.C. 355(j)).

3 (4) ANDA FILER.—The term “ANDA filer”  
4 means a party that has filed an ANDA with the  
5 Food and Drug Administration.

6 (5) PATENT INFRINGEMENT.—The term “pat-  
7 ent infringement” means infringement of any patent  
8 or of any filed patent application, extension,  
9 reissuance, renewal, division, continuation, continu-  
10 ation in part, reexamination, patent term restora-  
11 tion, patent of addition, or extension thereof.

12 (6) PATENT INFRINGEMENT CLAIM.—The term  
13 “patent infringement claim” means any allegation  
14 made to an ANDA filer, whether or not included in  
15 a complaint filed with a court of law, that its ANDA  
16 or drug to be manufactured under such ANDA may  
17 infringe any patent.

18 **SEC. 3. FTC RULEMAKING.**

19 The Federal Trade Commission may, by rule promul-  
20 gated under section 553 of title 5, United States Code,  
21 exempt certain agreements described in section 2 if the  
22 Commission finds such agreements to be in furtherance  
23 of market competition and for the benefit of consumers.  
24 Consistent with the authority of the Commission, such  
25 rules may include interpretive rules and general state-

1 ments of policy with respect to the practices prohibited  
2 under section 2.

3 **SEC. 4. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD**  
4 **UNDER THE FFDCA.**

5 Section 505(j)(5)(D)(i) of the Federal Food, Drug,  
6 and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)) is amended  
7 in subclause (V) by inserting “section 2 of the Protecting  
8 Consumer Access to Generic Drugs Act of 2012 or” after  
9 “that the agreement has violated”.

10 **SEC. 5. NOTICE AND CERTIFICATION OF AGREEMENTS.**

11 (a) NOTICE OF ALL AGREEMENTS.—Section  
12 1112(c)(2) of the Medicare Prescription Drug, Improve-  
13 ment, and Modernization Act of 2003 (21 U.S.C. 3155  
14 note) is amended by—

15 (1) striking “the Commission the” and insert-  
16 ing “the Commission (1) the”; and

17 (2) inserting before the period at the end the  
18 following: “; and (2) a description of the subject  
19 matter of any other agreement the parties enter into  
20 within 30 days of an entering into an agreement  
21 covered by subsection (a) or (b)”.

22 (b) CERTIFICATION OF AGREEMENTS.—Section 1112  
23 of such Act is amended by adding at the end the following:

24 “(d) CERTIFICATION.—The Chief Executive Officer  
25 or the company official responsible for negotiating any

1 agreement required to be filed under subsection (a), (b),  
2 or (c) shall execute and file with the Assistant Attorney  
3 General and the Commission a certification as follows: ‘I  
4 declare under penalty of perjury that the following is true  
5 and correct: The materials filed with the Federal Trade  
6 Commission and the Department of Justice under section  
7 1112 of subtitle B of title XI of the Medicare Prescription  
8 Drug, Improvement, and Modernization Act of 2003, with  
9 respect to the agreement referenced in this certification:  
10 (1) represent the complete, final, and exclusive agreement  
11 between the parties; (2) include any ancillary agreements  
12 that are contingent upon, provide a contingent condition  
13 for, or are otherwise related to, the referenced agreement;  
14 and (3) include written descriptions of any oral agree-  
15 ments, representations, commitments, or promises be-  
16 tween the parties that are responsive to subsection (a) or  
17 (b) of such section 1112 and have not been reduced to  
18 writing.’”.

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