110TH CONGRESS 1ST SESSION

H. R. 1432

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.

IN THE HOUSE OF REPRESENTATIVES

March 9, 2007

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

A BILL

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.

- 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 "Preserve Access to Af-
- 5 fordable Generics Act".
- 6 SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF
- 7 PURPOSES.
- 8 (a) FINDINGS.—The Congress finds that—

- 1 (1) prescription drugs make up 11 percent of 2 the national health care spending but are 1 of the 3 largest and fastest growing health care expenditures;
 - (2) 56 percent of all prescriptions dispensed in the United States are generic drugs, yet they account for only 13 percent of all expenditures;
 - (3) generic drugs, on average, cost 63 percent less than their brand-name counterparts;
 - (4) consumers and the health care system would benefit from free and open competition in the pharmaceutical market and the removal of obstacles to the introduction of generic drugs;
 - (5) full and free competition in the pharmaceutical industry, and the full enforcement of antitrust law to prevent anticompetitive practices in this industry, will lead to lower prices, greater innovation, and inure to the general benefit of consumers;
 - (6) the Federal Trade Commission has determined that some brand name pharmaceutical manufacturers collude with generic drug manufacturers to delay the marketing of competing, low-cost, generic drugs;
 - (7) collusion by the brand name pharmaceutical manufacturers is contrary to free competition, to the

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- interests of consumers, and to the principles underlying antitrust law;
 - (8) in 2005, 2 appellate court decisions reversed the Federal Trade Commission's long-standing position, and upheld settlements that include pay-offs by brand name pharmaceutical manufacturers to generic manufacturers designed to keep generic competition off the market;
 - (9) in the 6 months following the March 2005 court decisions, the Federal Trade Commission found there were three settlement agreements in which the generic received compensation and agreed to a restriction on its ability to market the product;
 - (10) the Federal Trade Commission found that more than 2/3 of the approximately ten settlement agreements made in 2006 include a pay-off from the brand in exchange for a promise by the generic company to delay entry into the market; and
 - (11) settlements which include a payment from a brand name manufacturer to a generic manufacturer to delay entry by generic drugs are anti-competitive and contrary to the interests of consumers.
 - (b) Purposes.—The purposes of this Act are—
 - (1) to enhance competition in the pharmaceutical market by prohibiting anticompetitive agree-

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1	ments and collusion between brand name and ge-
2	neric drug manufacturers intended to keep generic
3	drugs off the market;
4	(2) to support the purpose and intent of anti-
5	trust law by prohibiting anticompetitive agreements
6	and collusion in the pharmaceutical industry; and
7	(3) to clarify the law to prohibit payments from
8	brand name to generic drug manufacturers with the
9	purpose to prevent or delay the entry of competition
10	from generic drugs.
11	SEC. 3. UNLAWFUL COMPENSATION FOR DELAY.
12	The Clayton Act (15 U.S.C. 12 et seq.) is amended—
13	(1) by redesignating section 28 as section 29
14	and
15	(2) by inserting after section 27 the following
16	"SEC. 28. UNLAWFUL INTERFERENCE WITH GENERIC MAR
17	KETING.
18	"(a) It shall be unlawful under this Act for any per-
19	son, in connection with the sale of a drug product, to di-
20	rectly or indirectly be a party to any agreement resolving
21	or settling a patent infringement claim which—
22	"(1) an ANDA filer receives anything of value
23	and

1 "(2) the ANDA filer agrees not to research, de-2 velop, manufacture, market, or sell the ANDA prod-3 uct for any period of time. "(b) Nothing in this section shall prohibit a resolu-4 5 tion or settlement of patent infringement claim in which the value paid by the NDA holder to the ANDA filer as 6 a part of the resolution or settlement of the patent in-8 fringement claim includes no more than the right to market the ANDA product prior to the expiration of the pat-10 ent that is the basis for the patent infringement claim. 11 "(c) In this section: 12 "(1) The term 'agreement' means anything that 13 would constitute an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of the 14 15 Federal Trade Commission Act (15 U.S.C. 45). "(2) The term 'agreement resolving or settling 16 17 a patent infringement claim' includes, any agree-18 ment that is contingent upon, provides a contingent 19 condition for, or is otherwise related to the resolu-20 tion or settlement of the claim. 21 "(3) The term 'ANDA' means an abbreviated 22 new drug application, as defined under section 23 505(j) of the Federal Food, Drug, and Cosmetic Act 24 (21 U.S.C. 355(j)).

1	"(4) The term 'ANDA filer' means a party who
2	has filed an ANDA with the Federal Drug Adminis-
3	tration.
4	"(5) The term 'ANDA product' means the
5	product to be manufactured under the ANDA that
6	is the subject of the patent infringement claim.
7	"(6) The term 'drug product' means a finished
8	dosage form (e.g., tablet, capsule, or solution) that
9	contains a drug substance, generally, but not nec-
10	essarily, in association with 1 or more other ingredi-
11	ents, as defined in section 314.3(b) of title 21, Code
12	of Federal Regulations.
13	"(7) The term 'NDA' means a new drug appli-
14	cation, as defined under section 505(b) of the Fed-
15	eral Food, Drug, and Cosmetic Act (21 U.S.C.
16	355(b)).
17	"(8) The term 'NDA holder' means—
18	"(A) the party that received FDA approval
19	to market a drug product pursuant to an NDA;
20	"(B) a party owning or controlling enforce-
21	ment of the patent listed in the Approved Drug
22	Products With Therapeutic Equivalence Eval-
23	uations (commonly known as the 'FDA Orange
24	Book') in connection with the NDA: or

"(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of
the entities described in subclauses (i) and (ii)
(such control to be presumed by direct or indirect share ownership of 50 percent or greater),
as well as the licensees, licensors, successors,
and assigns of each of the entities.

- "(9) The term 'patent infringement' means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.
- "(10) The term 'patent infringement claim' means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product may infringe any patent held by, or exclusively licensed to, the NDA holder of the drug product.".

21 SEC. 4. NOTICE AND CERTIFICATION OF AGREEMENTS.

- 22 (a) NOTICE OF ALL AGREEMENTS.—Section 23 1112(c)(2) of the Medicare Prescription Drug, Improve-24 ment, and Modernization Act of 2003 (21 U.S.C. 3155)
- 25 note) is amended by—

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- 1 (1) striking "the Commission the" and insert-2 ing "the Commission (1) the"; and
- 3 (2) inserting before the period at the end the 4 following: "; and (2) a description of the subject 5 matter of any other agreement the parties enter into 6 within 30 days of an entering into an agreement 7 covered by subsection (a) or (b)".
- 8 (b) CERTIFICATION OF AGREEMENTS.—Section 1112 9 of such Act is amended by adding at the end the following:
- 10 "(d) CERTIFICATION.—The Chief Executive Officer 11 or the company official responsible for negotiating any
- 12 agreement required to be filed under subsection (a), (b),
- 13 or (c) shall execute and file with the Assistant Attorney
- 14 General and the Commission a certification as follows: 'I
- 15 declare under penalty of perjury that the following is true
- 16 and correct: The materials filed with the Federal Trade
- 17 Commission and the Department of Justice under section
- 18 1112 of subtitle B of title XI of the Medicare Prescription
- 19 Drug, Improvement, and Modernization Act of 2003, with
- 20 respect to the agreement referenced in this certification:
- 21 (1) represent the complete, final, and exclusive agreement
- 22 between the parties; (2) include any ancillary agreements
- 23 that are contingent upon, provide a contingent condition
- 24 for, or are otherwise related to, the referenced agreement;
- 25 and (3) include written descriptions of any oral agree-

- 1 ments, representations, commitments, or promises be-
- 2 tween the parties that are responsive to subsection (a) or
- 3 (b) of such section 1112 and have not been reduced to
- 4 writing.'.''.

5 SEC. 5. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

- 6 Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug
- 7 and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is
- 8 amended by inserting "section 28 of the Clayton Act or"
- 9 after "that the agreement has violated".

10 SEC. 6. AUTHORIZATION OF APPROPRIATIONS.

- There are authorized to be appropriated to the Fed-
- 12 eral Trade Commission such sums as may be necessary
- 13 to carry out the provisions of this Act.

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