

116TH CONGRESS
1ST SESSION

H. R. 1499

To prohibit brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 5, 2019

Mr. RUSH 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 manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Protecting Consumer
3 Access to Generic Drugs Act of 2019”.

4 **SEC. 2. UNLAWFUL AGREEMENTS.**

5 (a) **AGREEMENTS PROHIBITED.**—Subject to sub-
6 sections (b) and (c), it shall be unlawful for an NDA or
7 BLA holder and a subsequent filer to enter into, or carry
8 out, an agreement resolving or settling a covered patent
9 infringement claim on a final or interim basis if under
10 such agreement—

11 (1) a subsequent filer directly or indirectly re-
12 ceives from such holder anything of value, including
13 an exclusive license; and

14 (2) the subsequent filer agrees to limit or fore-
15 go research on, or development, manufacturing,
16 marketing, or sales, for any period of time, of the
17 covered product that is the subject of the application
18 described in subparagraph (A) or (B) of subsection
19 (f)(8).

20 (b) **EXCLUSION.**—It shall not be unlawful under sub-
21 section (a) if a party to an agreement described in such
22 subsection demonstrates by clear and convincing evidence
23 that the value described in subsection (a)(1) is compensa-
24 tion solely for other goods or services that the subsequent
25 filer has promised to provide.

1 (c) LIMITATION.—Nothing in this section shall pro-
2 hibit an agreement resolving or settling a covered patent
3 infringement claim in which the consideration granted by
4 the NDA or BLA holder to the subsequent filer as part
5 of the resolution or settlement includes only one or more
6 of the following:

7 (1) The right to market the covered product
8 that is the subject of the application described in
9 subparagraph (A) or (B) of subsection (f)(8) in the
10 United States before the expiration of—

11 (A) any patent that is the basis of the cov-
12 ered patent infringement claim; or

13 (B) any patent right or other statutory ex-
14 clusivity that would prevent the marketing of
15 such covered product.

16 (2) A payment for reasonable litigation ex-
17 penses not to exceed \$7,500,000 in the aggregate.

18 (3) A covenant not to sue on any claim that
19 such covered product infringes a patent.

20 (d) ENFORCEMENT BY FEDERAL TRADE COMMIS-
21 SION.—

22 (1) GENERAL APPLICATION.—The requirements
23 of this section apply, according to their terms, to an
24 NDA or BLA holder or subsequent filer that is—

1 (A) a person, partnership, or corporation
2 over which the Commission has authority pur-
3 suant to section 5(a)(2) of the Federal Trade
4 Commission Act (15 U.S.C. 45(a)(2)); or

5 (B) a person, partnership, or corporation
6 over which the Commission would have author-
7 ity pursuant to such section but for the fact
8 that such person, partnership, or corporation is
9 not organized to carry on business for its own
10 profit or that of its members.

11 (2) UNFAIR OR DECEPTIVE ACTS OR PRACTICES
12 ENFORCEMENT AUTHORITY.—

13 (A) IN GENERAL.—A violation of this sec-
14 tion shall be treated as an unfair or deceptive
15 act or practice in violation of section 5(a)(1) of
16 the Federal Trade Commission Act (15 U.S.C.
17 45(a)(1)).

18 (B) POWERS OF COMMISSION.—Except as
19 provided in subparagraph (C) and paragraphs
20 (1)(B) and (3)—

21 (i) the Commission shall enforce this
22 section in the same manner, by the same
23 means, and with the same jurisdiction,
24 powers, and duties as though all applicable
25 terms and provisions of the Federal Trade

1 Commission Act (15 U.S.C. 41 et seq.)
2 were incorporated into and made a part of
3 this section; and

4 (ii) any NDA or BLA holder or subse-
5 quent filer that violates this section shall
6 be subject to the penalties and entitled to
7 the privileges and immunities provided in
8 the Federal Trade Commission Act.

9 (C) JUDICIAL REVIEW.—In the case of a
10 cease and desist order issued by the Commis-
11 sion under section 5 of the Federal Trade Com-
12 mission Act (15 U.S.C. 45) for violation of this
13 section, a party to such order may obtain judi-
14 cial review of such order as provided in such
15 section 5, except that—

16 (i) such review may only be obtained
17 in—

18 (I) the United States Court of
19 Appeals for the District of Columbia
20 Circuit;

21 (II) the United States Court of
22 Appeals for the circuit in which the
23 ultimate parent entity, as defined in
24 section 801.1(a)(3) of title 16, Code
25 of Federal Regulations, or any suc-

1 cessor thereto, of the NDA or BLA
2 holder is incorporated as of the date
3 that the application described in sub-
4 paragraph (A) or (B) of subsection
5 (f)(8) is submitted to the Commis-
6 sioner of Food and Drugs; or

7 (III) the United States Court of
8 Appeals for the circuit in which the
9 ultimate parent entity, as so defined,
10 of the subsequent filer is incorporated
11 as of the date that the application de-
12 scribed in subparagraph (A) or (B) of
13 subsection (f)(8) is submitted to the
14 Commissioner of Food and Drugs;
15 and

16 (ii) the petition for review shall be
17 filed in the court not later than 30 days
18 after such order is served on the party
19 seeking review.

20 (3) ADDITIONAL ENFORCEMENT AUTHORITY.—

21 (A) CIVIL PENALTY.—The Commission
22 may commence a civil action to recover a civil
23 penalty in a district court of the United States
24 against any NDA or BLA holder or subsequent
25 filer that violates this section.

1 (B) SPECIAL RULE FOR RECOVERY OF
2 PENALTY IF CEASE AND DESIST ORDER
3 ISSUED.—

4 (i) IN GENERAL.—If the Commission
5 has issued a cease and desist order in a
6 proceeding under section 5 of the Federal
7 Trade Commission Act (15 U.S.C. 45) for
8 violation of this section—

9 (I) the Commission may com-
10 mence a civil action under subpara-
11 graph (A) to recover a civil penalty
12 against any party to such order at
13 any time before the expiration of the
14 1-year period beginning on the date
15 on which such order becomes final
16 under section 5(g) of such Act (15
17 U.S.C. 45(g)); and

18 (II) in such civil action, the find-
19 ings of the Commission as to the ma-
20 terial facts in such proceeding shall be
21 conclusive, unless—

22 (aa) the terms of such order
23 expressly provide that the Com-
24 mission's findings shall not be
25 conclusive; or

1 (bb) such order became final
2 by reason of section 5(g)(1) of
3 such Act (15 U.S.C. 45(g)(1)), in
4 which case such findings shall be
5 conclusive if supported by evi-
6 dence.

7 (ii) RELATIONSHIP TO PENALTY FOR
8 VIOLATION OF AN ORDER.—The penalty
9 provided in clause (i) for violation of this
10 section is separate from and in addition to
11 any penalty that may be incurred for viola-
12 tion of an order of the Commission under
13 section 5(l) of the Federal Trade Commis-
14 sion Act (15 U.S.C. 45(l)).

15 (C) AMOUNT OF PENALTY.—

16 (i) IN GENERAL.—The amount of a
17 civil penalty imposed in a civil action under
18 subparagraph (A) on a party to an agree-
19 ment described in subsection (a) shall be
20 sufficient to deter violations of this section,
21 but in no event greater than—

22 (I) if such party is the NDA or
23 BLA holder, the greater of—

24 (aa) 3 times the value re-
25 ceived by such NDA or BLA

1 holder that is reasonably attrib-
2 utable to the violation of this sec-
3 tion; or

4 (bb) 3 times the value given
5 to the subsequent filer reasonably
6 attributable to the violation of
7 this section; and

8 (II) if such party is the subse-
9 quent filer, 3 times the value received
10 by such subsequent filer that is rea-
11 sonably attributable to the violation of
12 this section.

13 (ii) FACTORS FOR CONSIDERATION.—
14 In determining such amount, the court
15 shall take into account—

16 (I) the nature, circumstances, ex-
17 tent, and gravity of the violation;

18 (II) with respect to the violator,
19 the degree of culpability, any history
20 of violations, the ability to pay, any
21 effect on the ability to continue doing
22 business, profits earned by the NDA
23 or BLA holder, compensation received
24 by the subsequent filer, and the
25 amount of commerce affected; and

1 (III) other matters that justice
2 requires.

3 (D) INJUNCTIONS AND OTHER EQUITABLE
4 RELIEF.—In a civil action under subparagraph
5 (A), the United States district courts are em-
6 powered to grant mandatory injunctions and
7 such other and further equitable relief as they
8 deem appropriate.

9 (4) REMEDIES IN ADDITION.—Remedies pro-
10 vided in this subsection are in addition to, and not
11 in lieu of, any other remedy provided by Federal
12 law.

13 (5) PRESERVATION OF AUTHORITY OF COMMIS-
14 SION.—Nothing in this section shall be construed to
15 affect any authority of the Commission under any
16 other provision of law.

17 (e) ANTITRUST LAWS.—Nothing in this section shall
18 modify, impair, limit, or supersede the applicability of the
19 antitrust laws as defined in subsection (a) of the first sec-
20 tion of the Clayton Act (15 U.S.C. 12(a)), and of section
21 5 of the Federal Trade Commission Act (15 U.S.C. 45)
22 to the extent that such section 5 applies to unfair methods
23 of competition. Nothing in this section shall modify, im-
24 pair, limit, or supersede the right of a subsequent filer
25 to assert claims or counterclaims against any person,

1 under the antitrust laws or other laws relating to unfair
2 competition.

3 (f) DEFINITIONS.—In this section:

4 (1) AGREEMENT RESOLVING OR SETTLING A
5 COVERED PATENT INFRINGEMENT CLAIM.—The
6 term “agreement resolving or settling a covered pat-
7 ent infringement claim” means any agreement
8 that—

9 (A) resolves or settles a covered patent in-
10 fringement claim; or

11 (B) is contingent upon, provides for a con-
12 tingent condition for, or is otherwise related to
13 the resolution or settlement of a covered patent
14 infringement claim.

15 (2) COMMISSION.—The term “Commission”
16 means the Federal Trade Commission.

17 (3) COVERED PATENT INFRINGEMENT CLAIM.—
18 The term “covered patent infringement claim”
19 means an allegation made by the NDA or BLA hold-
20 er to a subsequent filer, whether or not included in
21 a complaint filed with a court of law, that—

22 (A) the submission of the application de-
23 scribed in clause (i) or (ii) of paragraph (5)(A),
24 or the manufacture, use, offering for sale, sale,
25 or importation into the United States of a cov-

1 ered product that is the subject of such an ap-
2 plication, infringes any patent owned by, or ex-
3 clusively licensed to, the NDA or BLA holder of
4 the covered product; or

5 (B) the covered product to be manufac-
6 tured under such application uses a covered
7 product as claimed in a published patent appli-
8 cation.

9 (4) COVERED PRODUCT.—The term “covered
10 product” means—

11 (A) a new drug (as defined in section
12 201(p) of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 321(p))); or

14 (B) a biological product (as defined in sec-
15 tion 351(i) of the Public Health Service Act (42
16 U.S.C. 262(i))).

17 (5) NDA OR BLA HOLDER.—The term “NDA
18 or BLA holder” means—

19 (A) the holder of—

20 (i) an approved new drug application
21 filed under section 505(b)(1) of the Fed-
22 eral Food, Drug, and Cosmetic Act (21
23 U.S.C. 355(b)(1)) for a covered product;

24 or

1 (ii) an application approved under sec-
2 tion 351(a) of the Public Health Service
3 Act (42 U.S.C. 262(a)) with respect to a
4 biological product;

5 (B) a person owning or controlling enforce-
6 ment of the patent on—

7 (i) the list published under section
8 505(j)(7) of the Federal Food, Drug, and
9 Cosmetic Act (21 U.S.C. 355(j)(7)) in con-
10 nection with the application described in
11 subparagraph (A)(i); or

12 (ii) the equivalent list published under
13 section 351 of the Public Health Service
14 Act (42 U.S.C. 262) comprised of patents
15 associated with applications filed under
16 section 351(a) of such Act (42 U.S.C.
17 262(a)); or

18 (C) the predecessors, subsidiaries, divi-
19 sions, groups, and affiliates controlled by, con-
20 trolling, or under common control with any en-
21 tity described in subparagraph (A) or (B) (such
22 control to be presumed by direct or indirect
23 share ownership of 50 percent or greater), as
24 well as the licensees, licensors, successors, and
25 assigns of each of the entities.

1 (6) PATENT.—The term “patent” means a pat-
2 ent issued by the United States Patent and Trade-
3 mark Office.

4 (7) STATUTORY EXCLUSIVITY.—The term
5 “statutory exclusivity” means those prohibitions on
6 the approval of drug applications under clauses (ii)
7 through (iv) of section 505(c)(3)(E) (5- and 3-year
8 data exclusivity), section 505(j)(5)(B)(iv) (180-day
9 exclusivity), section 527 (orphan drug exclusivity),
10 section 505A (pediatric exclusivity), or section 505E
11 (qualified infectious disease product exclusivity) of
12 the Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 360cc, 355a,
14 355f), or section 351(k)(6) (interchangeable biologi-
15 cal product exclusivity) or section 351(k)(7) (biologi-
16 cal product reference product exclusivity) of the
17 Public Health Service Act (42 U.S.C. 262(k)(6),
18 (7)).

19 (8) SUBSEQUENT FILER.—The term “subse-
20 quent filer” means—

21 (A) in the case of a drug, a party that
22 owns or controls an abbreviated new drug appli-
23 cation filed under section 505(j) of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C.
25 355(j)) or a new drug application filed under

1 section 505(b)(2) of such Act (21 U.S.C.
2 355(b)(2)) or has the exclusive rights to dis-
3 tribute the covered product that is the subject
4 of such application; or

5 (B) in the case of a biological product, a
6 party that owns or controls an application filed
7 with the Food and Drug Administration under
8 section 351(k) of the Public Health Service Act
9 (42 U.S.C. 262(k)) or has the exclusive rights
10 to distribute the biological product that is the
11 subject of such application.

12 (g) EFFECTIVE DATE.—This section shall apply to
13 all agreements described in subsection (a) entered into
14 after June 17, 2013, except that a civil penalty may only
15 be obtained under subsection (d)(3)(A) with respect to
16 such an agreement entered into on or after the date of
17 enactment of this Act.

18 **SEC. 3. NOTICE AND CERTIFICATION OF AGREEMENTS.**

19 (a) NOTICE OF ALL AGREEMENTS.—Section 1111(7)
20 of the Medicare Prescription Drug, Improvement, and
21 Modernization Act of 2003 (21 U.S.C. 355 note) is
22 amended by inserting “or the owner of a patent for which
23 a claim of infringement could reasonably be asserted
24 against any person for making, using, offering to sell, sell-
25 ing, or importing into the United States a biological prod-

1 uct that is the subject of a biosimilar biological product
2 application” before the period at the end.

3 (b) CERTIFICATION OF AGREEMENTS.—Section 1112
4 of such Act (21 U.S.C. 355 note) is amended by adding
5 at the end the following:

6 “(d) CERTIFICATION.—The Chief Executive Officer
7 or the company official responsible for negotiating any
8 agreement under subsection (a) or (b) that is required to
9 be filed under subsection (c) shall, within 30 days of such
10 filing, execute and file with the Assistant Attorney General
11 and the Commission a certification as follows: ‘I declare
12 that the following is true, correct, and complete to the best
13 of my knowledge: The materials filed with the Federal
14 Trade Commission and the Department of Justice under
15 section 1112 of the Medicare Prescription Drug, Improve-
16 ment, and Modernization Act of 2003, with respect to the
17 agreement referenced in this certification—

18 ““(1) represent the complete, final, and exclu-
19 sive agreement between the parties;

20 ““(2) include any ancillary agreements that are
21 contingent upon, provide a contingent condition for,
22 were entered into within 30 days of, or are otherwise
23 related to, the referenced agreement; and

24 ““(3) include written descriptions of any oral
25 agreements, representations, commitments, or prom-

1 ises between the parties that are responsive to sub-
2 section (a) or (b) of such section 1112 and have not
3 been reduced to writing.’.”.

4 **SEC. 4. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

5 Section 505(j)(5)(D)(i)(V) of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))
7 is amended by inserting “section 2 of the Protecting Con-
8 sumer Access to Generic Drugs Act of 2019 or” after
9 “that the agreement has violated”.

10 **SEC. 5. COMMISSION LITIGATION AUTHORITY.**

11 Section 16(a)(2) of the Federal Trade Commission
12 Act (15 U.S.C. 56(a)(2)) is amended—

13 (1) in subparagraph (D), by striking “or” after
14 the semicolon;

15 (2) in subparagraph (E), by inserting “or”
16 after the semicolon; and

17 (3) by inserting after subparagraph (E) the fol-
18 lowing:

19 “(F) under section 2(d)(3)(A) of the Pro-
20 tecting Consumer Access to Generic Drugs Act
21 of 2019;”.

22 **SEC. 6. STATUTE OF LIMITATIONS.**

23 (a) IN GENERAL.—Except as provided in subsection
24 (b), the Commission shall commence any administrative
25 proceeding or civil action to enforce section 2 of this Act

1 not later than 6 years after the date on which the parties
2 to the agreement file the Notice of Agreement as provided
3 by section 1112(c)(2) and (d) of the Medicare Prescription
4 Drug Improvement and Modernization Act of 2003 (21
5 U.S.C. 355 note).

6 (b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND
7 DESIST ORDER.—If the Commission has issued a cease
8 and desist order under section 5 of the Federal Trade
9 Commission Act (15 U.S.C. 45) for violation of section
10 2 of this Act and the proceeding for the issuance of such
11 order was commenced within the period required by sub-
12 section (a) of this section, such subsection does not pro-
13 hibit the commencement, after such period, of a civil ac-
14 tion under section 2(d)(3)(A) against a party to such
15 order or a civil action under subsection (l) of such section
16 5 for violation of such order.

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