

Union Calendar No. 30

116TH CONGRESS
1ST SESSION

H. R. 1499

[Report No. 116–52, Part I]

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 bio-similar 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

MAY 10, 2019

Additional sponsors: Mr. PALLONE, Mr. RUIZ, Mrs. DINGELL, Mrs. CRAIG, Ms. ESHOO, Mr. KENNEDY, Ms. MATSUI, Mr. VAN DREW, Ms. CLARKE of New York, Mr. KHANNA, Ms. SCHAKOWSKY, Mr. PAPPAS, Mr. COHEN, Mr. WELCH, Mr. LARSON of Connecticut, Mr. HASTINGS, Mr. NEGUSE, Ms. FINKENAUER, Mr. CASE, Mr. QUIGLEY, Ms. WILD, Mr. LANGEVIN, Mr. COOPER, Mr. RASKIN, Mr. DAVID SCOTT of Georgia, Ms. MUCARSEL-POWELL, Mr. THOMPSON of Mississippi, Ms. STEVENS, Mr. CISNEROS, Ms. KELLY of Illinois, Mr. CASTEN of Illinois, Ms. HOULAHAN, Mr. CARSON of Indiana, Mr. CARBAJAL, Ms. DAVIDS of Kansas, Mr. SMITH of Washington, Mr. CONNOLLY, and Ms. UNDERWOOD

MAY 10, 2019

Reported from the Committee on Energy and Commerce with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

MAY 10, 2019

Committee on the Judiciary discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on March 5, 2019]

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,*

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “Protecting Consumer*
5 *Access to Generic Drugs Act of 2019”.*

6 **SEC. 2. UNLAWFUL AGREEMENTS.**

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

13 *(1) a subsequent filer directly or indirectly re-*
14 *ceives from such holder (or in the case of such an*
15 *agreement between two subsequent filers, the other*
16 *subsequent filer) anything of value, including a li-*
17 *cence; and*

18 *(2) the subsequent filer agrees to limit or forego*
19 *research on, or development, manufacturing, mar-*
20 *keting, or sales, for any period of time, of the covered*
21 *product that is the subject of the application described*
22 *in subparagraph (A) or (B) of subsection (g)(8).*

23 *(b) EXCLUSION.—It shall not be unlawful under sub-*
24 *section (a) if a party to an agreement described in such*
25 *subsection demonstrates by clear and convincing evidence*

1 *that the value described in subsection (a)(1) is compensa-*
2 *tion solely for other goods or services that the subsequent*
3 *filer has promised to provide.*

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

10 (1) *The right to market the covered product that*
11 *is the subject of the application described in subpara-*
12 *graph (A) or (B) of subsection (g)(8) in the United*
13 *States before the expiration of—*

14 (A) *any patent that is the basis of the cov-*
15 *ered patent infringement claim; or*

16 (B) *any patent right or other statutory ex-*
17 *clusivity that would prevent the marketing of*
18 *such covered product.*

19 (2) *A payment for reasonable litigation expenses*
20 *not to exceed \$7,500,000 in the aggregate.*

21 (3) *A covenant not to sue on any claim that such*
22 *covered product infringes a patent.*

23 (d) *ENFORCEMENT BY FEDERAL TRADE COMMIS-*
24 *SION.—*

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

4 (A) *a person, partnership, or corporation*
5 *over which the Commission has authority pursu-*
6 *ant to section 5(a)(2) of the Federal Trade Com-*
7 *mission Act (15 U.S.C. 45(a)(2)); or*

8 (B) *a person, partnership, or corporation*
9 *over which the Commission would have authority*
10 *pursuant to such section but for the fact that*
11 *such person, partnership, or corporation is not*
12 *organized to carry on business for its own profit*
13 *or that of its members.*

14 (2) *UNFAIR OR DECEPTIVE ACTS OR PRACTICES*
15 *ENFORCEMENT AUTHORITY.*—

16 (A) *IN GENERAL.*—*A violation of this sec-*
17 *tion shall be treated as an unfair or deceptive*
18 *act or practice in violation of section 5(a)(1) of*
19 *the Federal Trade Commission Act (15 U.S.C.*
20 *45(a)(1)).*

21 (B) *POWERS OF COMMISSION.*—*Except as*
22 *provided in subparagraph (C) and paragraphs*
23 *(1)(B) and (3)—*

24 (i) *the Commission shall enforce this*
25 *section in the same manner, by the same*

1 *means, and with the same jurisdiction,*
2 *powers, and duties as though all applicable*
3 *terms and provisions of the Federal Trade*
4 *Commission Act (15 U.S.C. 41 et seq.) were*
5 *incorporated into and made a part of this*
6 *section; and*

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

12 *(C) JUDICIAL REVIEW.—In the case of a*
13 *cease and desist order issued by the Commission*
14 *under section 5 of the Federal Trade Commission*
15 *Act (15 U.S.C. 45) for violation of this section,*
16 *a party to such order may obtain judicial review*
17 *of such order as provided in such section 5, ex-*
18 *cept that—*

19 *(i) such review may only be obtained*
20 *in—*

21 *(I) the United States Court of Ap-*
22 *peals for the District of Columbia Cir-*
23 *cuit;*

24 *(II) the United States Court of*
25 *Appeals for the circuit in which the ul-*

1 *timate parent entity, as defined in sec-*
2 *tion 801.1(a)(3) of title 16, Code of*
3 *Federal Regulations, or any successor*
4 *thereto, of the NDA or BLA holder (if*
5 *any such holder is a party to such*
6 *order) is incorporated as of the date*
7 *that the application described in sub-*
8 *paragraph (A) or (B) of subsection*
9 *(g)(8) or an approved application that*
10 *is deemed to be a license for a biologi-*
11 *cal product under section 351(k) of the*
12 *Public Health Service Act (42 U.S.C.*
13 *262(k)) pursuant to section 7002(e)(4)*
14 *of the Biologics Price Competition and*
15 *Innovation Act of 2009 (Public Law*
16 *111–148; 124 Stat. 817) is submitted*
17 *to the Commissioner of Food and*
18 *Drugs; or*

19 *(III) the United States Court of*
20 *Appeals for the circuit in which the ul-*
21 *timate parent entity, as so defined, of*
22 *any subsequent filer that is a party to*
23 *such order is incorporated as of the*
24 *date that the application described in*
25 *subparagraph (A) or (B) of subsection*

1 (g)(8) is submitted to the Commis-
2 sioner of Food and Drugs; and

3 (ii) the petition for review shall be
4 filed in the court not later than 30 days
5 after such order is served on the party seek-
6 ing review.

7 (3) *ADDITIONAL ENFORCEMENT AUTHORITY.*—

8 (A) *CIVIL PENALTY.*—*The Commission may*
9 *commence a civil action to recover a civil pen-*
10 *alty in a district court of the United States*
11 *against any NDA or BLA holder or subsequent*
12 *filer that violates this section.*

13 (B) *SPECIAL RULE FOR RECOVERY OF PEN-*
14 *ALTY IF CEASE AND DESIST ORDER ISSUED.*—

15 (i) *IN GENERAL.*—*If the Commission*
16 *has issued a cease and desist order in a pro-*
17 *ceeding under section 5 of the Federal Trade*
18 *Commission Act (15 U.S.C. 45) for viola-*
19 *tion of this section—*

20 (I) *the Commission may com-*
21 *mence a civil action under subpara-*
22 *graph (A) to recover a civil penalty*
23 *against any party to such order at any*
24 *time before the expiration of the 1-year*
25 *period beginning on the date on which*

1 *such order becomes final under section*
2 *5(g) of such Act (15 U.S.C. 45(g)); and*

3 *(II) in such civil action, the find-*
4 *ings of the Commission as to the mate-*
5 *rial facts in such proceeding shall be*
6 *conclusive, unless—*

7 *(aa) the terms of such order*
8 *expressly provide that the Com-*
9 *mission's findings shall not be*
10 *conclusive; or*

11 *(bb) such order became final*
12 *by reason of section 5(g)(1) of*
13 *such Act (15 U.S.C. 45(g)(1)), in*
14 *which case such findings shall be*
15 *conclusive if supported by evi-*
16 *dence.*

17 *(i) RELATIONSHIP TO PENALTY FOR*
18 *VIOLATION OF AN ORDER.—The penalty*
19 *provided in clause (i) for violation of this*
20 *section is separate from and in addition to*
21 *any penalty that may be incurred for viola-*
22 *tion of an order of the Commission under*
23 *section 5(l) of the Federal Trade Commis-*
24 *sion Act (15 U.S.C. 45(l)).*

25 *(C) AMOUNT OF PENALTY.—*

1 (i) *IN GENERAL.*—*The amount of a*
2 *civil penalty imposed in a civil action*
3 *under subparagraph (A) on a party to an*
4 *agreement described in subsection (a) shall*
5 *be sufficient to deter violations of this sec-*
6 *tion, but in no event greater than—*

7 (I) *if such party is the NDA or*
8 *BLA holder (or, in the case of an*
9 *agreement between two subsequent fil-*
10 *ers, the subsequent filer who gave the*
11 *value described in subsection (a)(1)),*
12 *the greater of—*

13 (aa) *3 times the value re-*
14 *ceived by such NDA or BLA hold-*
15 *er (or by such subsequent filer)*
16 *that is reasonably attributable to*
17 *the violation of this section; or*

18 (bb) *3 times the value given*
19 *to the subsequent filer (or to the*
20 *other subsequent filer) reasonably*
21 *attributable to the violation of*
22 *this section; and*

23 (II) *if such party is the subse-*
24 *quent filer (or, in the case of an agree-*
25 *ment between two subsequent filers, the*

1 *subsequent filer who received the value*
2 *described in subsection (a)(1)), 3 times*
3 *the value received by such subsequent*
4 *filer that is reasonably attributable to*
5 *the violation of this section.*

6 *(ii) FACTORS FOR CONSIDERATION.—*

7 *In determining such amount, the court shall*
8 *take into account—*

9 *(I) the nature, circumstances, ex-*
10 *tent, and gravity of the violation;*

11 *(II) with respect to the violator,*
12 *the degree of culpability, any history of*
13 *violations, the ability to pay, any effect*
14 *on the ability to continue doing busi-*
15 *ness, profits earned by the NDA or*
16 *BLA holder (or, in the case of an*
17 *agreement between two subsequent fil-*
18 *ers, the subsequent filer who gave the*
19 *value described in subsection (a)(1)),*
20 *compensation received by the subse-*
21 *quent filer (or, in the case of an agree-*
22 *ment between two subsequent filers, the*
23 *subsequent filer who received the value*
24 *described in subsection (a)(1)), and the*
25 *amount of commerce affected; and*

1 (III) *other matters that justice re-*
2 *quires.*

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

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

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

16 (e) *FEDERAL TRADE COMMISSION RULEMAKING.—The*
17 *Commission may, in its discretion, by rule promulgated*
18 *under section 553 of title 5, United States Code, exempt*
19 *from this section certain agreements described in subsection*
20 *(a) if the Commission finds such agreements to be in fur-*
21 *therance of market competition and for the benefit of con-*
22 *sumers.*

23 (f) *ANTITRUST LAWS.—Nothing in this section shall*
24 *modify, impair, limit, or supersede the applicability of the*
25 *antitrust laws as defined in subsection (a) of the first sec-*

1 *tion of the Clayton Act (15 U.S.C. 12(a)), and of section*
2 *5 of the Federal Trade Commission Act (15 U.S.C. 45) to*
3 *the extent that such section 5 applies to unfair methods of*
4 *competition. Nothing in this section shall modify, impair,*
5 *limit, or supersede the right of a subsequent filer to assert*
6 *claims or counterclaims against any person, under the anti-*
7 *trust laws or other laws relating to unfair competition.*

8 *(g) DEFINITIONS.—In this section:*

9 *(1) AGREEMENT RESOLVING OR SETTTLING A COV-*
10 *ERED PATENT INFRINGEMENT CLAIM.—The term*
11 *“agreement resolving or settling a covered patent in-*
12 *fringement claim” means any agreement that—*

13 *(A) resolves or settles a covered patent in-*
14 *fringement claim; or*

15 *(B) is contingent upon, provides for a con-*
16 *tingent condition for, or is otherwise related to*
17 *the resolution or settlement of a covered patent*
18 *infringement claim.*

19 *(2) COMMISSION.—The term “Commission”*
20 *means the Federal Trade Commission.*

21 *(3) COVERED PATENT INFRINGEMENT CLAIM.—*
22 *The term “covered patent infringement claim” means*
23 *an allegation made by the NDA or BLA holder to a*
24 *subsequent filer (or, in the case of an agreement be-*
25 *tween two subsequent filers, by one subsequent filer to*

1 another), whether or not included in a complaint filed
2 with a court of law, that—

3 (A) the submission of the application de-
4 scribed in subparagraph (A) or (B) of paragraph
5 (9), or the manufacture, use, offering for sale,
6 sale, or importation into the United States of a
7 covered product that is the subject of such an ap-
8 plication—

9 (i) in the case of an agreement between
10 an NDA or BLA holder and a subsequent
11 filer, infringes any patent owned by, or ex-
12 clusively licensed to, the NDA or BLA hold-
13 er of the covered product; or

14 (ii) in the case of an agreement be-
15 tween two subsequent filers, infringes any
16 patent owned by the subsequent filer; or

17 (B) in the case of an agreement between an
18 NDA or BLA holder and a subsequent filer, the
19 covered product to be manufactured under such
20 application uses a covered product as claimed in
21 a published patent application.

22 (4) COVERED PRODUCT.—The term “covered
23 product” means a drug (as defined in section 201(g)
24 of the Federal Food, Drug, and Cosmetic Act (21
25 U.S.C. 321(g))), including a biological product (as

1 *defined in section 351(i) of the Public Health Service*
2 *Act (42 U.S.C. 262(i)).*

3 (5) *NDA OR BLA HOLDER.—The term “NDA or*
4 *BLA holder” means—*

5 (A) *the holder of—*

6 (i) *an approved new drug application*
7 *filed under section 505(b)(1) of the Federal*
8 *Food, Drug, and Cosmetic Act (21 U.S.C.*
9 *355(b)(1)) for a covered product; or*

10 (ii) *a biologics license application filed*
11 *under section 351(a) of the Public Health*
12 *Service Act (42 U.S.C. 262(a)) with respect*
13 *to a biological product;*

14 (B) *a person owning or controlling enforce-*
15 *ment of the patent on—*

16 (i) *the list published under section*
17 *505(j)(7) of the Federal Food, Drug, and*
18 *Cosmetic Act (21 U.S.C. 355(j)(7)) in con-*
19 *nection with the application described in*
20 *subparagraph (A)(i); or*

21 (ii) *any list published under section*
22 *351 of the Public Health Service Act (42*
23 *U.S.C. 262) comprised of patents associated*
24 *with biologics license applications filed*

1 under section 351(a) of such Act (42 U.S.C.
2 262(a)); or

3 (C) the predecessors, subsidiaries, divisions,
4 groups, and affiliates controlled by, controlling,
5 or under common control with any entity de-
6 scribed in subparagraph (A) or (B) (such control
7 to be presumed by direct or indirect share owner-
8 ship of 50 percent or greater), as well as the li-
9 censees, licensors, successors, and assigns of each
10 of the entities.

11 (6) *PATENT*.—The term “patent” means a pat-
12 ent issued by the United States Patent and Trade-
13 mark Office.

14 (7) *STATUTORY EXCLUSIVITY*.—The term “statu-
15 tory exclusivity” means those prohibitions on the sub-
16 mission or approval of drug applications under
17 clauses (ii) through (iv) of section 505(c)(3)(E) (5-
18 and 3-year exclusivity), clauses (ii) through (iv) of
19 section 505(j)(5)(F) (5-year and 3-year exclusivity),
20 section 505(j)(5)(B)(iv) (180-day exclusivity), section
21 527 (orphan drug exclusivity), section 505A (pedi-
22 atric exclusivity), or section 505E (qualified infec-
23 tious disease product exclusivity) of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E),
25 355(j)(5)(B)(iv), 355(j)(5)(F), 360cc, 355a, 355f), or

1 *prohibitions on the submission or licensing of bio-*
2 *logics license applications under section 351(k)(6)*
3 *(interchangeable biological product exclusivity) or sec-*
4 *tion 351(k)(7) (biological product reference product*
5 *exclusivity) of the Public Health Service Act (42*
6 *U.S.C. 262(k)(6), (7)).*

7 (8) *SUBSEQUENT FILER.*—*The term “subsequent*
8 *filer” means—*

9 (A) *in the case of a drug, a party that owns*
10 *or controls an abbreviated new drug application*
11 *submitted pursuant to section 505(j) of the Fed-*
12 *eral Food, Drug, and Cosmetic Act (21 U.S.C.*
13 *355(j)) or a new drug application submitted*
14 *pursuant to section 505(b)(2) of the Federal*
15 *Food, Drug, and Cosmetic Act (21U.S.C.*
16 *355(b)(2)) and filed under section 505(b)(1) of*
17 *such Act (21 U.S.C. 355(b)(1)) or has the exclu-*
18 *sive rights to distribute the covered product that*
19 *is the subject of such application; or*

20 (B) *in the case of a biological product, a*
21 *party that owns or controls an application filed*
22 *with the Food and Drug Administration under*
23 *section 351(k) of the Public Health Service Act*
24 *(42 U.S.C. 262(k)) or has the exclusive rights to*

1 *distribute the biological product that is the sub-*
2 *ject of such application.*

3 *(h) EFFECTIVE DATE.—This section applies with re-*
4 *spect to agreements described in subsection (a) entered into*
5 *on or after the date of the enactment of this Act.*

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

7 *(a) NOTICE OF ALL AGREEMENTS.—Section 1111(7)*
8 *of the Medicare Prescription Drug, Improvement, and Mod-*
9 *ernization Act of 2003 (21 U.S.C. 355 note) is amended*
10 *by inserting “or the owner of a patent for which a claim*
11 *of infringement could reasonably be asserted against any*
12 *person for making, using, offering to sell, selling, or import-*
13 *ing into the United States a biological product that is the*
14 *subject of a biosimilar biological product application” be-*
15 *fore the period at the end.*

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

19 *“(d) CERTIFICATION.—The Chief Executive Officer or*
20 *the company official responsible for negotiating any agree-*
21 *ment under subsection (a) or (b) that is required to be filed*
22 *under subsection (c) shall, within 30 days of such filing,*
23 *execute and file with the Assistant Attorney General and*
24 *the Commission a certification as follows: ‘I declare that*
25 *the following is true, correct, and complete to the best of*

1 *my knowledge: The materials filed with the Federal Trade*
2 *Commission and the Department of Justice under section*
3 *1112 of the Medicare Prescription Drug, Improvement, and*
4 *Modernization Act of 2003, with respect to the agreement*
5 *referenced in this certification—*

6 “‘(1) represent the complete, final, and exclusive
7 agreement between the parties;

8 “‘(2) include any ancillary agreements that are
9 contingent upon, provide a contingent condition for,
10 were entered into within 30 days of, or are otherwise
11 related to, the referenced agreement; and

12 “‘(3) include written descriptions of any oral
13 agreements, representations, commitments, or prom-
14 ises between the parties that are responsive to sub-
15 section (a) or (b) of such section 1112 and have not
16 been reduced to writing.’”.

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

18 Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug,
19 and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amend-
20 ed by inserting “section 2 of the Protecting Consumer Access
21 to Generic Drugs Act of 2019 or” after “that the agreement
22 has violated”.

23 **SEC. 5. COMMISSION LITIGATION AUTHORITY.**

24 Section 16(a)(2) of the Federal Trade Commission Act
25 (15 U.S.C. 56(a)(2)) is amended—

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

3 (2) *in subparagraph (E), by inserting “or” after*
4 *the semicolon; and*

5 (3) *by inserting after subparagraph (E) the fol-*
6 *lowing:*

7 *“(F) under section 2(d)(3)(A) of the Pro-*
8 *tecting Consumer Access to Generic Drugs Act of*
9 *2019;”.*

10 **SEC. 6. STATUTE OF LIMITATIONS.**

11 (a) *IN GENERAL.—Except as provided in subsection*
12 *(b), the Commission shall commence any administrative*
13 *proceeding or civil action to enforce section 2 of this Act*
14 *not later than 6 years after the date on which the parties*
15 *to the agreement file the Notice of Agreement as provided*
16 *by section 1112(c)(2) and (d) of the Medicare Prescription*
17 *Drug, Improvement, and Modernization Act of 2003 (21*
18 *U.S.C. 355 note).*

19 (b) *CIVIL ACTION AFTER ISSUANCE OF CEASE AND*
20 *DESIST ORDER.—If the Commission has issued a cease and*
21 *desist order under section 5 of the Federal Trade Commis-*
22 *sion Act (15 U.S.C. 45) for violation of section 2 of this*
23 *Act and the proceeding for the issuance of such order was*
24 *commenced within the period required by subsection (a) of*
25 *this section, such subsection does not prohibit the commence-*

1 *ment, after such period, of a civil action under section*
2 *2(d)(3)(A) against a party to such order or a civil action*
3 *under subsection (l) of such section 5 for violation of such*
4 *order.*

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