

Union Calendar No. 576

116TH CONGRESS
2^D SESSION

H. R. 2375

[Report No. 116–693, Part I]

To prohibit prescription drug companies from compensating other prescription drug companies to delay the entry of a generic drug, biosimilar biological product, or interchangeable biological product into the market.

IN THE HOUSE OF REPRESENTATIVES

APRIL 29, 2019

Mr. NADLER (for himself, Mr. COLLINS of Georgia, and Mr. CICILLINE) introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committee on Energy and Commerce, 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

DECEMBER 24, 2020

Additional sponsors: Mr. COHEN and Mr. MEADOWS

DECEMBER 24, 2020

Reported from the Committee on the Judiciary

DECEMBER 24, 2020

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

A BILL

To prohibit prescription drug companies from compensating other prescription drug companies to delay the entry of a generic drug, biosimilar biological product, or interchangeable biological product 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 and Biosimilars Act”.

6 **SEC. 2. DECLARATION OF PURPOSES.**

7 The purposes of this Act are—

8 (1) to enhance competition in the pharma-
9 ceutical market by stopping anticompetitive agree-
10 ments between manufacturers of brand name and
11 generic drug products or biosimilar biological prod-
12 ucts, or among manufacturers of generic drug prod-
13 ucts or biosimilar biological products, that limit,
14 delay, or otherwise prevent competition from generic
15 drugs and biosimilar biological products; and

16 (2) to support the purpose and intent of anti-
17 trust law by prohibiting anticompetitive practices in
18 the pharmaceutical industry that harm consumers.

19 **SEC. 3. UNLAWFUL COMPENSATION FOR DELAY.**

20 (a) IN GENERAL.—The Federal Trade Commission
21 Act (15 U.S.C. 44 et seq.) is amended by inserting after
22 section 26 (15 U.S.C. 57c–2) the following:

23 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS**
24 **AND BIOSIMILARS.**

25 “(a) IN GENERAL.—

1 “(1) ENFORCEMENT PROCEEDING.—The Com-
 2 mission may initiate a proceeding to enforce the pro-
 3 visions of this section against the parties to any
 4 agreement resolving or settling, on a final or interim
 5 basis, a patent claim, in connection with the sale of
 6 a drug product or biological product.

7 “(2) PRESUMPTION AND VIOLATION.—

8 “(A) IN GENERAL.—Subject to subpara-
 9 graph (B), in such a proceeding, an agreement
 10 shall be presumed to have anticompetitive ef-
 11 fects and shall be a violation of this section if—

12 “(i) an ANDA filer or a biosimilar bi-
 13 ological product application filer receives
 14 anything of value, including an exclusive li-
 15 cense; and

16 “(ii) the ANDA filer or biosimilar bio-
 17 logical product application filer agrees to
 18 limit or forgo research, development, man-
 19 ufacturing, marketing, or sales of the
 20 ANDA product or biosimilar biological
 21 product, as applicable, for any period of
 22 time.

23 “(B) EXCEPTION.—Subparagraph (A)
 24 shall not apply if the parties to such agreement

1 demonstrate by clear and convincing evidence
2 that—

3 “(i) the value described in subpara-
4 graph (A)(i) is compensation solely for
5 other goods or services that the ANDA
6 filer or biosimilar biological product appli-
7 cation filer has promised to provide; or

8 “(ii) the procompetitive benefits of the
9 agreement outweigh the anticompetitive ef-
10 fects of the agreement.

11 “(b) LIMITATIONS.—In determining whether the set-
12 tling parties have met their burden under subsection
13 (a)(2)(B), the fact finder shall not presume—

14 “(1) that entry would not have occurred until
15 the expiration of the relevant patent or statutory ex-
16 clusivity; or

17 “(2) that the agreement’s provision for entry of
18 the ANDA product or biosimilar biological product
19 prior to the expiration of the relevant patent or stat-
20 utory exclusivity means that the agreement is pro-
21 competitive.

22 “(c) EXCLUSIONS.—Nothing in this section shall pro-
23 hibit a resolution or settlement of a patent infringement
24 claim in which the consideration that the ANDA filer or
25 biosimilar biological product application filer receives as

1 part of the resolution or settlement includes only one or
2 more of the following:

3 “(1) The right to market and secure final regu-
4 latory approval for the ANDA product or biosimilar
5 biological product at a date, whether certain or con-
6 tingent, in the United States prior to the expiration
7 of—

8 “(A) any patent that is the basis for the
9 patent infringement claim; or

10 “(B) any patent right or other statutory
11 exclusivity that would prevent the marketing of
12 such ANDA product or biosimilar biological
13 product.

14 “(2) A payment for reasonable litigation ex-
15 penses not to exceed—

16 “(A) for calendar year 2019, \$7,500,000;
17 and

18 “(B) for calendar year 2020 and each cal-
19 endar year thereafter, the amount determined
20 for the preceding calendar year adjusted to re-
21 flect the percentage increase (if any) in the
22 Producer Price Index for Legal Services pub-
23 lished by the Bureau of Labor Statistics of the
24 Department of Labor for the then most recent
25 12-month period ending December 31.

1 “(3) A covenant not to sue on any claim that
2 the ANDA product or biosimilar biological product
3 infringes a United States patent.

4 “(d) ENFORCEMENT.—

5 “(1) ENFORCEMENT.—A violation of this sec-
6 tion shall be treated as an unfair method of competi-
7 tion under section 5(a)(1) of the Federal Trade
8 Commission Act (15 U.S.C. 45(a)(1)).

9 “(2) JUDICIAL REVIEW.—

10 “(A) IN GENERAL.—Any party that is sub-
11 ject to a final order of the Commission, issued
12 in an administrative adjudicative proceeding
13 under the authority of subsection (a)(1), may,
14 within 30 days of the issuance of such order,
15 petition for review of such order in—

16 “(i) the United States Court of Ap-
17 peals for the District of Columbia Circuit;

18 “(ii) the United States Court of Ap-
19 peals for the circuit in which the ultimate
20 parent entity, as defined in section
21 801.1(a)(3) of title 16, Code of Federal
22 Regulations, or any successor thereto, of
23 the NDA holder or biological product li-
24 cense holder is incorporated as of the date
25 that the NDA or biological product license

1 application, as applicable, is filed with the
2 Commissioner of Food and Drugs; or

3 “(iii) the United States Court of Ap-
4 peals for the circuit in which the ultimate
5 parent entity of the ANDA filer or bio-
6 similar biological product application filer
7 is incorporated as of the date that the
8 ANDA or biosimilar biological product ap-
9 plication is filed with the Commissioner of
10 Food and Drugs.

11 “(B) TREATMENT OF FINDINGS.—In a
12 proceeding for judicial review of a final order of
13 the Commission, the findings of the Commis-
14 sion as to the facts, if supported by evidence,
15 shall be conclusive.

16 “(e) ANTITRUST LAWS.—Nothing in this section
17 shall modify, impair, limit, or supersede the applicability
18 of the antitrust laws as defined in subsection (a) of the
19 first section of the Clayton Act (15 U.S.C. 12(a)), and
20 of section 5 of this Act to the extent that section 5 applies
21 to unfair methods of competition. Nothing in this section
22 shall modify, impair, limit, or supersede the right of an
23 ANDA filer or biosimilar biological product application
24 filer to assert claims or counterclaims against any person,

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

3 “(f) PENALTIES.—

4 “(1) FORFEITURE.—Each party that violates or
5 assists in the violation of this section shall forfeit
6 and pay to the United States a civil penalty suffi-
7 cient to deter violations of this section, but in no
8 event greater than 3 times the value received by the
9 party that is reasonably attributable to the violation
10 of this section. If no such value has been received by
11 the NDA holder, biological product license holder,
12 the ANDA filer, or biosimilar biological product ap-
13 plication filer the penalty to the NDA holder, bio-
14 logical product license holder, the ANDA filer, or
15 biosimilar biological product application filer shall be
16 sufficient to deter violations, but in no event greater
17 than 3 times the value given to an ANDA filer or
18 biosimilar biological product application filer reason-
19 ably attributable to the violation of this section.
20 Such penalty shall accrue to the United States and
21 may be recovered in a civil action brought by the
22 Commission, in its own name by any of its attorneys
23 designated by it for such purpose, in a district court
24 of the United States against any party that violates
25 this section. In such actions, the United States dis-

1 trict courts are empowered to grant mandatory in-
2 junctions and such other and further equitable relief
3 as they deem appropriate.

4 “(2) CEASE AND DESIST.—

5 “(A) IN GENERAL.—If the Commission has
6 issued a cease and desist order with respect to
7 a party in an administrative adjudicative pro-
8 ceeding under the authority of subsection
9 (a)(1), an action brought pursuant to para-
10 graph (1) may be commenced against such
11 party at any time before the expiration of 1
12 year after such order becomes final pursuant to
13 section 5(g).

14 “(B) EXCEPTION.—In an action under
15 subparagraph (A), the findings of the Commis-
16 sion as to the material facts in the administra-
17 tive adjudicative proceeding with respect to the
18 violation of this section by a party shall be con-
19 clusive unless—

20 “(i) the terms of such cease and de-
21 sist order expressly provide that the Com-
22 mission’s findings shall not be conclusive;
23 or

24 “(ii) the order became final by reason
25 of section 5(g)(1), in which case such find-

1 ing shall be conclusive if supported by evi-
2 dence.

3 “(3) CIVIL PENALTY.—In determining the
4 amount of the civil penalty described in this section,
5 the court shall take into account—

6 “(A) the nature, circumstances, extent,
7 and gravity of the violation;

8 “(B) with respect to the violator, the de-
9 gree of culpability, any history of violations, the
10 ability to pay, any effect on the ability to con-
11 tinue doing business, profits earned by the
12 NDA holder, biological product license holder,
13 the ANDA filer, or biosimilar biological product
14 application filer, compensation received by the
15 ANDA filer or biosimilar biological product ap-
16 plication filer, and the amount of commerce af-
17 fected; and

18 “(C) other matters that justice requires.

19 “(4) REMEDIES IN ADDITION.—Remedies pro-
20 vided in this subsection are in addition to, and not
21 in lieu of, any other remedy provided by Federal
22 law. Nothing in this paragraph shall be construed to
23 affect any authority of the Commission under any
24 other provision of law.

25 “(g) DEFINITIONS.—In this section:

1 “(1) AGREEMENT.—The term ‘agreement’
2 means anything that would constitute an agreement
3 under section 1 of the Sherman Act (15 U.S.C. 1)
4 or section 5 of this Act.

5 “(2) AGREEMENT RESOLVING OR SETTLING A
6 PATENT INFRINGEMENT CLAIM.—The term ‘agree-
7 ment resolving or settling a patent infringement
8 claim’ includes any agreement that is entered into
9 within 30 days of the resolution or the settlement of
10 the claim, or any other agreement that is contingent
11 upon, provides a contingent condition for, or is oth-
12 erwise related to the resolution or settlement of the
13 claim.

14 “(3) ANDA.—The term ‘ANDA’ means an ab-
15 breviated new drug application filed under section
16 505(j) of the Federal Food, Drug, and Cosmetic Act
17 (21 U.S.C. 355(j)) or a new drug application filed
18 under section 505(b)(2) of the Federal Food, Drug,
19 and Cosmetic Act (21 U.S.C. 355(b)(2)).

20 “(4) ANDA FILER.—The term ‘ANDA filer’
21 means a party that owns or controls an ANDA filed
22 with the Food and Drug Administration or has the
23 exclusive rights under such ANDA to distribute the
24 ANDA product.

1 “(5) ANDA PRODUCT.—The term ‘ANDA
2 product’ means the product to be manufactured
3 under the ANDA that is the subject of the patent
4 infringement claim.

5 “(6) BIOLOGICAL PRODUCT.—The term ‘bio-
6 logical product’ has the meaning given such term in
7 section 351(i)(1) of the Public Health Service Act
8 (42 U.S.C. 262(i)(1)).

9 “(7) BIOLOGICAL PRODUCT LICENSE APPLICA-
10 TION.—The term ‘biological product license applica-
11 tion’ means an application under section 351(a) of
12 the Public Health Service Act (42 U.S.C. 262(a)).

13 “(8) BIOLOGICAL PRODUCT LICENSE HOLD-
14 ER.—The term ‘biological product license holder’
15 means—

16 “(A) the holder of an approved biological
17 product license application for a biological prod-
18 uct;

19 “(B) a person owning or controlling en-
20 forcement of any patents that claim the biologi-
21 cal product that is the subject of such approved
22 application; or

23 “(C) the predecessors, subsidiaries, divi-
24 sions, groups, and affiliates controlled by, con-
25 trolling, or under common control with any of

1 the entities described in subparagraphs (A) and
2 (B) (such control to be presumed by direct or
3 indirect share ownership of 50 percent or great-
4 er), as well as the licensees, licensors, succes-
5 sors, and assigns of each of the entities.

6 “(9) BIOSIMILAR BIOLOGICAL PRODUCT.—The
7 term ‘biosimilar biological product’ means the prod-
8 uct to be manufactured under the biosimilar biologi-
9 cal product application that is the subject of the pat-
10 ent infringement claim.

11 “(10) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
12 CATION.—The term ‘biosimilar biological product ap-
13 plication’ means an application under section 351(k)
14 of the Public Health Service Act (42 U.S.C. 262(k))
15 for licensure of a biological product as biosimilar to,
16 or interchangeable with, a reference product.

17 “(11) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
18 CATION FILER.—The term ‘biosimilar biological
19 product application filer’ means a party that owns or
20 controls a biosimilar biological product application
21 filed with the Food and Drug Administration or has
22 the exclusive rights under such application to dis-
23 tribute the biosimilar biological product.

24 “(12) DRUG PRODUCT.—The term ‘drug prod-
25 uct’ has the meaning given such term in section

1 314.3(b) of title 21, Code of Federal Regulations (or
2 any successor regulation).

3 “(13) MARKET.—The term ‘market’ means the
4 promote, offer for sale, sell, or distribute a drug
5 product.

6 “(14) NDA.—The term ‘NDA’ means a new
7 drug application filed under section 505(b) of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 355(b)).

10 “(15) NDA HOLDER.—The term ‘NDA holder’
11 means—

12 “(A) the holder of an approved NDA appli-
13 cation for a drug product;

14 “(B) a person owning or controlling en-
15 forcement of the patent listed in the Approved
16 Drug Products With Therapeutic Equivalence
17 Evaluations (commonly known as the ‘FDA Or-
18 ange Book’) in connection with the NDA; or

19 “(C) the predecessors, subsidiaries, divi-
20 sions, groups, and affiliates controlled by, con-
21 trolling, or under common control with any of
22 the entities described in subparagraphs (A) and
23 (B) (such control to be presumed by direct or
24 indirect share ownership of 50 percent or great-

1 er), as well as the licensees, licensors, succes-
2 sors, and assigns of each of the entities.

3 “(16) PARTY.—The term ‘party’ means any
4 person, partnership, corporation, or other legal enti-
5 ty.

6 “(17) PATENT INFRINGEMENT.—The term
7 ‘patent infringement’ means infringement of any
8 patent or of any filed patent application, including
9 any extension, reissue, renewal, division, continu-
10 ation, continuation in part, reexamination, patent
11 term restoration, patents of addition, and extensions
12 thereof.

13 “(18) PATENT INFRINGEMENT CLAIM.—The
14 term ‘patent infringement claim’ means any allega-
15 tion made to an ANDA filer or biosimilar biological
16 product application filer, whether or not included in
17 a complaint filed with a court of law, that its ANDA
18 or ANDA product, or biological product license ap-
19 plication or biological product, may infringe any pat-
20 ent held by, or exclusively licensed to, the NDA
21 holder or biological product license holder, biological
22 product license holder, the ANDA filer, or biosimilar
23 biological product application filer of the drug prod-
24 uct or biological product, as applicable.

1 “(19) STATUTORY EXCLUSIVITY.—The term
 2 ‘statutory exclusivity’ means those prohibitions on
 3 the approval of drug applications under clauses (ii)
 4 through (iv) of section 505(c)(3)(E) (5- and 3-year
 5 data exclusivity), section 527 (orphan drug exclu-
 6 sivity), or section 505A (pediatric exclusivity) of the
 7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 8 355(c)(3)(E), 360cc, 355a), or on the licensing of
 9 biological product applications under section
 10 351(k)(7) (12-year exclusivity) or paragraph (2) or
 11 (3) of section 351(m) (pediatric exclusivity) of the
 12 Public Health Service Act (42 U.S.C. 262) or under
 13 section 527 of the Federal Food, Drug, and Cos-
 14 metic Act (orphan drug exclusivity).”.

15 (b) EFFECTIVE DATE.—Section 27 of the Federal
 16 Trade Commission Act, as added by this section, shall
 17 apply to all agreements described in section 27(a)(1) of
 18 that Act entered into on or after the date of enactment
 19 of this Act.

20 **SEC. 4. NOTICE AND CERTIFICATION OF AGREEMENTS.**

21 (a) NOTICE OF ALL AGREEMENTS.—Section 1111(7)
 22 of the Medicare Prescription Drug, Improvement, and
 23 Modernization Act of 2003 (21 U.S.C. 355 note) is
 24 amended by inserting “or the owner of a patent for which
 25 a claim of infringement could reasonably be asserted

1 against any person for making, using, offering to sell, sell-
2 ing, or importing into the United States a biological prod-
3 uct that is the subject of a biosimilar biological product
4 application” before the period at the end.

5 (b) CERTIFICATION OF AGREEMENTS.—Section 1112
6 of the Medicare Prescription Drug, Improvement, and
7 Modernization Act of 2003 (21 U.S.C. 355 note) is
8 amended by adding at the end the following:

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

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

24 ““(2) include any ancillary agreements that are
25 contingent upon, provide a contingent condition for,

1 or are otherwise related to, the referenced agree-
2 ment; and

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

8 **SEC. 5. NOTIFICATION OF AGREEMENTS.**

9 Section 1112 of the Medicare Prescription Drug, Im-
10 provement, and Modernization Act of 2003 (21 U.S.C.
11 355 note) is amended by adding at the end the following:

12 “(4) RULE OF CONSTRUCTION.—

13 “(A) An agreement that is required in sub-
14 section (a) or (b) shall include agreements re-
15 solving any outstanding disputes, including
16 agreements resolving or settling a Patent Trial
17 and Appeal Board proceeding.

18 “(B) For purposes of subparagraph (A),
19 the term ‘Patent Trial and Appeal Board pro-
20 ceeding’ means a proceeding conducted by the
21 United States Patent and Trademark Office
22 Patent Trial and Appeal Board, including but
23 not limited to inter parties review, post-grant
24 review, the transitional program for covered

1 business method patents, and derivation pro-
2 ceedings.”.

3 **SEC. 6. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

4 Section 505(j)(5)(D)(i)(V) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))
6 is amended by inserting “section 27 of the Federal Trade
7 Commission Act or” after “that the agreement has vio-
8 lated”.

9 **SEC. 7. COMMISSION LITIGATION AUTHORITY.**

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

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

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

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

18 “(F) under section 27;”.

19 **SEC. 8. REPORT ON ADDITIONAL EXCLUSION.**

20 Within 1 year of enactment, the Federal Trade Com-
21 mission shall provide a recommendation, and the Commis-
22 sion’s basis for it, to the Committee on the Judiciary of
23 the House of Representatives and the Committee on the
24 Judiciary of the Senate regarding a potential amendment
25 to include in section 27(c) of the Federal Trade Commis-

1 sion Act, an additional exclusion for consideration granted
2 by an NDA holder or biological product license holder to
3 the ANDA filer or biosimilar biological product application
4 filer, respectively, as part of the resolution or settlement,
5 a release, waiver, or limitation of a claim for damages or
6 other monetary relief.

7 **SEC. 9. STATUTE OF LIMITATIONS.**

8 The Federal Trade Commission shall commence any
9 enforcement proceeding described in section 27 of the
10 Federal Trade Commission Act, as added by section 3, ex-
11 cept for an action described in section 27(f)(2) of the Fed-
12 eral Trade Commission Act, not later than 6 years after
13 the date on which the parties to the agreement file the
14 certification under section 1112(d) of the Medicare Pre-
15 scription Drug, Improvement, and Modernization Act of
16 2003 (21 U.S.C. 355 note).

17 **SEC. 10. SEVERABILITY.**

18 If any provision of this Act, an amendment made by
19 this Act, or the application of such provision or amend-
20 ment to any person or circumstance is held to be unconsti-
21 tutional, the remainder of this Act, the amendments made
22 by this Act, and the application of the provisions of such
23 Act or amendments to any person or circumstance shall
24 not be affected.

Union Calendar No. 576

116TH CONGRESS
2^D Session

H. R. 2375

[Report No. 116-693, Part I]

A BILL

To prohibit prescription drug companies from compensating other prescription drug companies to delay the entry of a generic drug, biosimilar biological product, or interchangeable biological product into the market.

DECEMBER 24, 2020

Reported from the Committee on the Judiciary

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