

.....
(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R.

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

Mr. NADLER (for himself and ____) introduced the following bill; which was referred to the Committee on _____

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—

1 (1) to enhance competition in the pharma-
2 ceutical market by stopping anticompetitive agree-
3 ments between manufacturers of brand name and
4 generic drug products or biosimilar biological prod-
5 ucts, or among manufacturers of generic drug prod-
6 ucts or biosimilar biological products, that limit,
7 delay, or otherwise prevent competition from generic
8 drugs and biosimilar biological products; and

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

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

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

16 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS**
17 **AND BIOSIMILARS.**

18 “(a) IN GENERAL.—

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

25 “(2) PRESUMPTION AND VIOLATION.—

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

5 “(i) an ANDA filer or a biosimilar bi-
6 ological product application filer receives
7 anything of value, including an exclusive li-
8 cense; and

9 “(ii) the ANDA filer or biosimilar bio-
10 logical product application filer agrees to
11 limit or forgo research, development, man-
12 ufacturing, marketing, or sales of the
13 ANDA product or biosimilar biological
14 product, as applicable, for any period of
15 time.

16 “(B) EXCEPTION.—Subparagraph (A)
17 shall not apply if the parties to such agreement
18 demonstrate by clear and convincing evidence
19 that—

20 “(i) the value described in subpara-
21 graph (A)(i) is compensation solely for
22 other goods or services that the ANDA
23 filer or biosimilar biological product appli-
24 cation filer has promised to provide; or

1 “(ii) the procompetitive benefits of the
2 agreement outweigh the anticompetitive ef-
3 fects of the agreement.

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

7 “(1) that entry would not have occurred until
8 the expiration of the relevant patent or statutory ex-
9 clusivity; or

10 “(2) that the agreement’s provision for entry of
11 the ANDA product or biosimilar biological product
12 prior to the expiration of the relevant patent or stat-
13 utory exclusivity means that the agreement is pro-
14 competitive.

15 “(c) EXCLUSIONS.—Nothing in this section shall pro-
16 hibit a resolution or settlement of a patent infringement
17 claim in which the consideration that the ANDA filer or
18 biosimilar biological product application filer receives as
19 part of the resolution or settlement includes only one or
20 more of the following:

21 “(1) The right to market and secure final regu-
22 latory approval for the ANDA product or biosimilar
23 biological product at a date, whether certain or con-
24 tingent, in the United States prior to the expiration
25 of—

1 “(A) any patent that is the basis for the
2 patent infringement claim; or

3 “(B) any patent right or other statutory
4 exclusivity that would prevent the marketing of
5 such ANDA product or biosimilar biological
6 product.

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

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

11 “(B) for calendar year 2020 and each cal-
12 endar year thereafter, the amount determined
13 for the preceding calendar year adjusted to re-
14 flect the percentage increase (if any) in the
15 Producer Price Index for Legal Services pub-
16 lished by the Bureau of labor Statistics of the
17 Department of Labor for the then most recent
18 12-month period ending December 31.

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

22 “(d) ENFORCEMENT.—

23 “(1) ENFORCEMENT.—A violation of this sec-
24 tion shall be treated as an unfair method of competi-

1 tion under section 5(a)(1) of the Federal Trade
2 Commission Act (15 U.S.C. 45(a)(1)).

3 “(2) JUDICIAL REVIEW.—

4 “(A) IN GENERAL.—Any party that is sub-
5 ject to a final order of the Commission, issued
6 in an administrative adjudicative proceeding
7 under the authority of subsection (a)(1), may,
8 within 30 days of the issuance of such order,
9 petition for review of such order in—

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

12 “(ii) the United States Court of Ap-
13 peals for the circuit in which the ultimate
14 parent entity, as defined in section
15 801.1(a)(3) of title 16, Code of Federal
16 Regulations, or any successor thereto, of
17 the NDA holder or biological product li-
18 cense holder is incorporated as of the date
19 that the NDA or biological product license
20 application, as applicable, is filed with the
21 Commissioner of Food and Drugs; or

22 “(iii) the United States Court of Ap-
23 peals for the circuit in which the ultimate
24 parent entity of the ANDA filer or bio-
25 similar biological product application filer

1 is incorporated as of the date that the
2 ANDA or biosimilar biological product ap-
3 plication is filed with the Commissioner of
4 Food and Drugs.

5 “(B) TREATMENT OF FINDINGS.—In a
6 proceeding for judicial review of a final order of
7 the Commission, the findings of the Commis-
8 sion as to the facts, if supported by evidence,
9 shall be conclusive.

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

21 “(f) PENALTIES.—

22 “(1) FORFEITURE.—Each party that violates or
23 assists in the violation of this section shall forfeit
24 and pay to the United States a civil penalty suffi-
25 cient to deter violations of this section, but in no

1 event greater than 3 times the value received by the
2 party that is reasonably attributable to the violation
3 of this section. If no such value has been received by
4 the NDA holder, biological product license holder,
5 the ANDA filer, or biosimilar biological product ap-
6 plication filer the penalty to the NDA holder, bio-
7 logical product license holder, the ANDA filer, or
8 biosimilar biological product application filer shall be
9 sufficient to deter violations, but in no event greater
10 than 3 times the value given to an ANDA filer or
11 biosimilar biological product application filer reason-
12 ably attributable to the violation of this section.
13 Such penalty shall accrue to the United States and
14 may be recovered in a civil action brought by the
15 Commission, in its own name by any of its attorneys
16 designated by it for such purpose, in a district court
17 of the United States against any party that violates
18 this section. In such actions, the United States dis-
19 trict courts are empowered to grant mandatory in-
20 junctions and such other and further equitable relief
21 as they deem appropriate.

22 “(2) CEASE AND DESIST.—

23 “(A) IN GENERAL.—If the Commission has
24 issued a cease and desist order with respect to
25 a party in an administrative adjudicative pro-

1 ceeding under the authority of subsection
2 (a)(1), an action brought pursuant to para-
3 graph (1) may be commenced against such
4 party at any time before the expiration of 1
5 year after such order becomes final pursuant to
6 section 5(g).

7 “(B) EXCEPTION.—In an action under
8 subparagraph (A), the findings of the Commis-
9 sion as to the material facts in the administra-
10 tive adjudicative proceeding with respect to the
11 violation of this section by a party shall be con-
12 clusive unless—

13 “(i) the terms of such cease and de-
14 sist order expressly provide that the Com-
15 mission’s findings shall not be conclusive;
16 or

17 “(ii) the order became final by reason
18 of section 5(g)(1), in which case such find-
19 ing shall be conclusive if supported by evi-
20 dence.

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

24 “(A) the nature, circumstances, extent,
25 and gravity of the violation;

1 “(B) with respect to the violator, the de-
2 gree of culpability, any history of violations, the
3 ability to pay, any effect on the ability to con-
4 tinue doing business, profits earned by the
5 NDA holder, biological product license holder,
6 the ANDA filer, or biosimilar biological product
7 application filer, compensation received by the
8 ANDA filer or biosimilar biological product ap-
9 plication filer, and the amount of commerce af-
10 fected; and

11 “(C) other matters that justice requires.

12 “(4) REMEDIES IN ADDITION.—Remedies pro-
13 vided in this subsection are in addition to, and not
14 in lieu of, any other remedy provided by Federal
15 law. Nothing in this paragraph shall be construed to
16 affect any authority of the Commission under any
17 other provision of law.

18 “(g) DEFINITIONS.—In this section:

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

23 “(2) AGREEMENT RESOLVING OR SETTLING A
24 PATENT INFRINGEMENT CLAIM.—The term ‘agree-
25 ment resolving or settling a patent infringement

1 claim' includes any agreement that is entered into
2 within 30 days of the resolution or the settlement of
3 the claim, or any other agreement that is contingent
4 upon, provides a contingent condition for, or is oth-
5 erwise related to the resolution or settlement of the
6 claim.

7 “(3) ANDA.—The term ‘ANDA’ means an ab-
8 breviated new drug application filed under section
9 505(j) of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 355(j)) or a new drug application filed
11 under section 505(b)(2) of the Federal Food, Drug,
12 and Cosmetic Act (21 U.S.C. 355(b)(2)).

13 “(4) ANDA FILER.—The term ‘ANDA filer’
14 means a party that owns or controls an ANDA filed
15 with the Food and Drug Administration or has the
16 exclusive rights under such ANDA to distribute the
17 ANDA product.

18 “(5) ANDA PRODUCT.—The term ‘ANDA
19 product’ means the product to be manufactured
20 under the ANDA that is the subject of the patent
21 infringement claim.

22 “(6) BIOLOGICAL PRODUCT.—The term ‘bio-
23 logical product’ has the meaning given such term in
24 section 351(i)(1) of the Public Health Service Act
25 (42 U.S.C. 262(i)(1)).

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

5 “(8) BIOLOGICAL PRODUCT LICENSE HOLD-
6 ER.—The term ‘biological product license holder’
7 means—

8 “(A) the holder of an approved biological
9 product license application for a biological prod-
10 uct;

11 “(B) a person owning or controlling en-
12 forcement of any patents that claim the biologi-
13 cal product that is the subject of such approved
14 application; or

15 “(C) the predecessors, subsidiaries, divi-
16 sions, groups, and affiliates controlled by, con-
17 trolling, or under common control with any of
18 the entities described in subparagraphs (A) and
19 (B) (such control to be presumed by direct or
20 indirect share ownership of 50 percent or great-
21 er), as well as the licensees, licensors, succes-
22 sors, and assigns of each of the entities.

23 “(9) BIOSIMILAR BIOLOGICAL PRODUCT.—The
24 term ‘biosimilar biological product’ means the prod-
25 uct to be manufactured under the biosimilar biologi-

1 cal product application that is the subject of the pat-
2 ent infringement claim.

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

9 “(11) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
10 CATION FILER.—The term ‘biosimilar biological
11 product application filer’ means a party that owns or
12 controls a biosimilar biological product application
13 filed with the Food and Drug Administration or has
14 the exclusive rights under such application to dis-
15 tribute the biosimilar biological product.

16 “(12) DRUG PRODUCT.—The term ‘drug prod-
17 uct’ has the meaning given such term in section
18 314.3(b) of title 21, Code of Federal Regulations (or
19 any successor regulation).

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

23 “(14) NDA.—The term ‘NDA’ means a new
24 drug application filed under section 505(b) of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 355(b)).

3 “(15) NDA HOLDER.—The term ‘NDA holder’
4 means—

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

7 “(B) a person owning or controlling en-
8 forcement of the patent listed in the Approved
9 Drug Products With Therapeutic Equivalence
10 Evaluations (commonly known as the ‘FDA Or-
11 ange Book’) in connection with the NDA; or

12 “(C) the predecessors, subsidiaries, divi-
13 sions, groups, and affiliates controlled by, con-
14 trolling, or under common control with any of
15 the entities described in subparagraphs (A) and
16 (B) (such control to be presumed by direct or
17 indirect share ownership of 50 percent or great-
18 er), as well as the licensees, licensors, succes-
19 sors, and assigns of each of the entities.

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

23 “(17) PATENT INFRINGEMENT.—The term
24 ‘patent infringement’ means infringement of any
25 patent or of any filed patent application, including

1 any extension, reissue, renewal, division, continu-
2 ation, continuation in part, reexamination, patent
3 term restoration, patents of addition, and extensions
4 thereof.

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

17 “(19) STATUTORY EXCLUSIVITY.—The term
18 ‘statutory exclusivity’ means those prohibitions on
19 the approval of drug applications under clauses (ii)
20 through (iv) of section 505(c)(3)(E) (5- and 3-year
21 data exclusivity), section 527 (orphan drug exclu-
22 sivity), or section 505A (pediatric exclusivity) of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 355(c)(3)(E), 360cc, 355a), or on the licensing of
25 biological product applications under section

1 351(k)(7) (12-year exclusivity) or paragraph (2) or
2 (3) of section 351(m) (pediatric exclusivity) of the
3 Public Health Service Act (42 U.S.C. 262) or under
4 section 527 of the Federal Food, Drug, and Cos-
5 metic Act (orphan drug exclusivity).”.

6 (b) EFFECTIVE DATE.—Section 27 of the Federal
7 Trade Commission Act, as added by this section, shall
8 apply to all agreements described in section 27(a)(1) of
9 that Act entered into on or after the date of enactment
10 of this Act.

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

12 (a) NOTICE OF ALL AGREEMENTS.—Section 1111(7)
13 of the Medicare Prescription Drug, Improvement, and
14 Modernization Act of 2003 (21 U.S.C. 355 note) is
15 amended by inserting “or the owner of a patent for which
16 a claim of infringement could reasonably be asserted
17 against any person for making, using, offering to sell, sell-
18 ing, or importing into the United States a biological prod-
19 uct that is the subject of a biosimilar biological product
20 application” before the period at the end.

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

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

14 “(1) represent the complete, final, and exclusive
15 agreement between the parties;

16 “(2) include any ancillary agreements that are
17 contingent upon, provide a contingent condition for,
18 or are otherwise related to, the referenced agree-
19 ment; and

20 “(3) include written descriptions of any oral
21 agreements, representations, commitments, or prom-
22 ises between the parties that are responsive to sub-
23 section (a) or (b) of such section 1112 and have not
24 been reduced to writing.”.

1 **SEC. 5. NOTIFICATION OF AGREEMENTS.**

2 Section 1112 of the Medicare Prescription Drug, Im-
3 provement, and Modernization Act of 2003 (21 U.S.C.
4 355 note) is amended by adding at the end the following:

5 “(4) RULE OF CONSTRUCTION.—

6 “(A) An agreement that is required in sub-
7 section (a) or (b) shall include agreements re-
8 solving any outstanding disputes, including
9 agreements resolving or settling a Patent Trial
10 and Appeal Board proceeding.

11 “(B) For purposes of subparagraph (A),
12 the term ‘Patent Trial and Appeal Board pro-
13 ceeding’ means a proceeding conducted by the
14 United States Patent and Trademark Office
15 Patent Trial and Appeal Board, including but
16 not limited to inter parties review, post-grant
17 review, the transitional program for covered
18 business method patents, and derivation pro-
19 ceedings.”.

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

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

1 **SEC. 7. COMMISSION LITIGATION AUTHORITY.**

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

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

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

8 (3) inserting after subparagraph (E) the fol-
9 lowing:

10 “(F) under section 27;”.

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

12 Within 1 year of enactment, the Federal Trade Com-
13 mission shall provide a recommendation, and the Commis-
14 sion’s basis for it, to the Committee on the Judiciary of
15 the House of Representatives and the Committee on the
16 Judiciary of the Senate regarding a potential amendment
17 to include in section 27 (c) of the Federal Trade Commis-
18 sion Act, an additional exclusion for consideration granted
19 by an NDA holder or biological product license holder to
20 the ANDA filer or biosimilar biological product application
21 filer, respectively, as part of the resolution or settlement,
22 a release, waiver, or limitation of a claim for damages or
23 other monetary relief.

24 **SEC. 9. STATUTE OF LIMITATIONS.**

25 The Federal Trade Commission shall commence any
26 enforcement proceeding described in section 27 of the

1 Federal Trade Commission Act, as added by section 3, ex-
2 cept for an action described in section 27(f)(2) of the Fed-
3 eral Trade Commission Act, not later than 6 years after
4 the date on which the parties to the agreement file the
5 certification under section 1112(d) of the Medicare Pre-
6 scription Drug, Improvement, and Modernization Act of
7 2003 (21 U.S.C. 355 note).

8 **SEC. 10. SEVERABILITY.**

9 If any provision of this Act, an amendment made by
10 this Act, or the application of such provision or amend-
11 ment to any person or circumstance is held to be unconsti-
12 tutional, the remainder of this Act, the amendments made
13 by this Act, and the application of the provisions of such
14 Act or amendments to any person or circumstance shall
15 not be affected.