

116TH CONGRESS
1ST SESSION

S. 64

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

IN THE SENATE OF THE UNITED STATES

JANUARY 9, 2019

Ms. KLOBUCHAR (for herself and Mr. GRASSLEY) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

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

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”.

1 **SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF**
2 **PURPOSES.**

3 (a) FINDINGS.—Congress finds the following:

4 (1) In 1984, the Drug Price Competition and
5 Patent Term Restoration Act (Public Law 98–417)
6 (referred to in this Act as the “1984 Act”), was en-
7 acted with the intent of facilitating the early entry
8 of generic drugs while preserving incentives for inno-
9 vation.

10 (2) Prescription drugs make up approximately
11 10 percent of the national health care spending.

12 (3) Initially, the 1984 Act was successful in fa-
13 cilitating generic competition to the benefit of con-
14 sumers and health care payers, although 88 percent
15 of all prescriptions dispensed in the United States
16 are generic drugs, they account for only 28 percent
17 of all expenditures.

18 (4) Generic drugs cost substantially less than
19 brand name drugs, with discounts off the brand
20 price averaging 80 to 85 percent.

21 (5) Federal dollars currently account for over
22 40 percent of the \$325,000,000,000 spent on retail
23 prescription drugs, and this share is expected to rise
24 to 47 percent by 2025.

25 (6)(A) In recent years, the intent of the 1984
26 Act has been subverted by certain settlement agree-

1 ments in which brand name companies transfer
2 value to their potential generic competitors to settle
3 claims that the generic company is infringing the
4 branded company’s patents.

5 (B) These “reverse payment” settlement agree-
6 ments—

7 (i) allow a branded company to share its
8 monopoly profits with the generic company as a
9 way to protect the branded company’s monop-
10 oly; and

11 (ii) have unduly delayed the marketing of
12 low-cost generic drugs contrary to free competi-
13 tion, the interests of consumers, and the prin-
14 ciples underlying antitrust law.

15 (C) Because of the price disparity between
16 brand name and generic drugs, such agreements are
17 more profitable for both the brand and generic man-
18 ufacturers than competition and will become increas-
19 ingly common unless prohibited.

20 (D) These agreements result in consumers los-
21 ing the benefits that the 1984 Act was intended to
22 provide.

23 (7) In 2010, the Biologics Price Competition
24 and Innovation Act (Public Law 111–148) (referred
25 to in this Act as the “BPCIA”), was enacted with

1 the intent of facilitating the early entry of biosimilar
2 and interchangeable follow-on versions of branded
3 biological products while preserving incentives for in-
4 novation.

5 (8) Biological drugs play an important role in
6 treating many serious illnesses, from cancers to ge-
7 netic disorders. They are also expensive, rep-
8 resenting more than 40 percent of all prescription
9 drug spending.

10 (9) Competition from biosimilar and inter-
11 changeable biological products promises to lower
12 drug costs and increase patient access to biological
13 medicines. But “reverse payment” settlement agree-
14 ments also threaten to delay the entry of biosimilar
15 and interchangeable biological products, which would
16 undermine the goals of BPCIA.

17 (b) PURPOSES.—The purposes of this Act are—

18 (1) to enhance competition in the pharma-
19 ceutical market by stopping anticompetitive agree-
20 ments between brand name and generic drug and
21 biosimilar biological product manufacturers that
22 limit, delay, or otherwise prevent competition from
23 generic drugs and biosimilar biological products; and

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

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

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

8 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS**
 9 **AND BIOSIMILARS.**

10 “(a) IN GENERAL.—

11 “(1) ENFORCEMENT PROCEEDING.—The Com-
 12 mission may initiate a proceeding to enforce the pro-
 13 visions of this section against the parties to any
 14 agreement resolving or settling, on a final or interim
 15 basis, a patent infringement claim, in connection
 16 with the sale of a drug product or biological product.

17 “(2) PRESUMPTION AND VIOLATION.—

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

22 “(i) an ANDA filer or a biosimilar bi-
 23 ological product application filer receives
 24 anything of value, including an exclusive li-
 25 cense; and

1 “(ii) the ANDA filer or biosimilar bio-
2 logical product application filer agrees to
3 limit or forego research, development,
4 manufacturing, marketing, or sales of the
5 ANDA product or biosimilar biological
6 product, as applicable, for any period of
7 time.

8 “(B) EXCEPTION.—Subparagraph (A)
9 shall not apply if the parties to such agreement
10 demonstrate by clear and convincing evidence
11 that—

12 “(i) the value described in subpara-
13 graph (A)(i) is compensation solely for
14 other goods or services that the ANDA
15 filer or biosimilar biological product appli-
16 cation filer has promised to provide; or

17 “(ii) the procompetitive benefits of the
18 agreement outweigh the anticompetitive ef-
19 fects of the agreement.

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

23 “(1) that entry would not have occurred until
24 the expiration of the relevant patent or statutory ex-
25 clusivity; or

1 “(2) that the agreement’s provision for entry of
2 the ANDA product or biosimilar biological product
3 prior to the expiration of the relevant patent or stat-
4 utory exclusivity means that the agreement is pro-
5 competitive.

6 “(c) EXCLUSIONS.—Nothing in this section shall pro-
7 hibit a resolution or settlement of a patent infringement
8 claim in which the consideration granted by the NDA
9 holder or biological product license holder to the ANDA
10 filer or biosimilar biological product application filer, re-
11 spectively, as part of the resolution or settlement includes
12 only one or more of the following:

13 “(1) The right to market the ANDA product or
14 biosimilar biological product in the United States
15 prior to the expiration of—

16 “(A) any patent that is the basis for the
17 patent infringement claim; or

18 “(B) any patent right or other statutory
19 exclusivity that would prevent the marketing of
20 such ANDA product or biosimilar biological
21 product.

22 “(2) A payment for reasonable litigation ex-
23 penses not to exceed \$7,500,000.

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 a violation of section 5.

7 “(2) JUDICIAL REVIEW.—

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

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

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

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

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

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

25 “(f) PENALTIES.—

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

23 “(2) CEASE AND DESIST.—

24 “(A) IN GENERAL.—If the Commission has
25 issued a cease and desist order with respect to

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

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

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

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

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

1 “(A) the nature, circumstances, extent,
2 and gravity of the violation;

3 “(B) with respect to the violator, the de-
4 gree of culpability, any history of violations, the
5 ability to pay, any effect on the ability to con-
6 tinue doing business, profits earned by the
7 NDA holder or biological product license holder,
8 compensation received by the ANDA filer or
9 biosimilar biological product application filer,
10 and the amount of commerce affected; 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) NDA.—The term ‘NDA’ means a new
21 drug application filed under section 505(b) of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 355(b)).

24 “(14) NDA HOLDER.—The term ‘NDA holder’
25 means—

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

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

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

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

19 “(16) PATENT INFRINGEMENT.—The term
20 ‘patent infringement’ means infringement of any
21 patent or of any filed patent application, extension,
22 reissue, renewal, division, continuation, continuation
23 in part, reexamination, patent term restoration, pat-
24 ents of addition, and extensions thereof.

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

11 “(18) STATUTORY EXCLUSIVITY.—The term
12 ‘statutory exclusivity’ means those prohibitions on
13 the approval of drug applications under clauses (ii)
14 through (iv) of section 505(c)(3)(E) (5- and 3-year
15 data exclusivity), section 527 (orphan drug exclu-
16 sivity), or section 505A (pediatric exclusivity) of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 355(c)(3)(E), 360cc, 355a), or on the licensing of
19 biological product applications under section
20 351(k)(7) (12-year exclusivity) or paragraph (2) or
21 (3) of section 351(m) (pediatric exclusivity) of the
22 Public Health Service Act (42 U.S.C. 262) or under
23 section 527 of the Federal Food, Drug, and Cos-
24 metic Act (orphan drug exclusivity).”.

1 (b) EFFECTIVE DATE.—Section 27 of the Federal
2 Trade Commission Act, as added by this section, shall
3 apply to all agreements described in section 27(a)(1) of
4 that Act entered into after June 17, 2013. Section 27(f)
5 of the Federal Trade Commission Act, as added by this
6 section, shall apply to agreements entered into on or after
7 the date of enactment of this Act.

8 **SEC. 4. CERTIFICATION 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 “(d) CERTIFICATION.—The Chief Executive Officer
13 or the company official responsible for negotiating any
14 agreement under subsection (a) or (b) that is required to
15 be filed under subsection (c), within 30 days after such
16 filing, shall execute and file with the Assistant Attorney
17 General and the Commission a certification as follows: ‘I
18 declare that the following is true, correct, and complete
19 to the best of my knowledge: The materials filed with the
20 Federal Trade Commission and the Department of Justice
21 under section 1112 of subtitle B of title XI of the Medi-
22 care Prescription Drug, Improvement, and Modernization
23 Act of 2003, with respect to the agreement referenced in
24 this certification—’

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

3 “(2) include any ancillary agreements that are
4 contingent upon, provide a contingent condition for,
5 or are otherwise related to, the referenced agree-
6 ment; and

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

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

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

18 **SEC. 6. COMMISSION LITIGATION AUTHORITY.**

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

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

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

1 (3) inserting after subparagraph (E) the fol-
2 lowing:

3 “(F) under section 27;”.

4 **SEC. 7. STATUTE OF LIMITATIONS.**

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

14 **SEC. 8. SEVERABILITY.**

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

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