

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.

○