

Calendar No. 180117TH CONGRESS
1ST SESSION**S. 1428**

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

APRIL 28, 2021

Ms. KLOBUCHAR (for herself, Mr. GRASSLEY, Mr. DURBIN, Ms. ERNST, Mr. LEAHY, Ms. COLLINS, Mr. VAN HOLLEN, Mr. CRAMER, Mrs. BLACKBURN, Mr. BLUMENTHAL, Mr. OSSOFF, and Mr. BOOKER) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

DECEMBER 9, 2021

Reported by Mr. DURBIN, with an amendment

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

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*”.

6 **SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF**
7 **PURPOSES.**

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

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

15 (2) Prescription drugs make up approximately
16 10 percent of the national health care spending.

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

23 (4) Generic drugs cost substantially less than
24 brand name drugs, with discounts off the brand
25 price averaging 80 to 85 percent.

1 (5) Federal dollars currently account for over
2 40 percent of the \$325,000,000,000 spent on retail
3 prescription drugs, and this share is expected to rise
4 to 47 percent by 2025.

5 (6)(A) In recent years, the intent of the 1984
6 Act has been subverted by certain settlement agree-
7 ments in which brand name companies transfer
8 value to their potential generic competitors to settle
9 claims that the generic company is infringing the
10 branded company's patents.

11 (B) These "reverse payment" settlement agree-
12 ments—

13 (i) allow a branded company to share its
14 monopoly profits with the generic company as a
15 way to protect the branded company's monop-
16 oly; and

17 (ii) have unduly delayed the marketing of
18 low-cost generic drugs contrary to free competi-
19 tion, the interests of consumers, and the prin-
20 ciples underlying antitrust law.

21 (C) Because of the price disparity between
22 brand name and generic drugs, such agreements are
23 more profitable for both the brand and generic man-
24 ufacturers than competition and will become increas-
25 ingly common unless prohibited.

1 (D) These agreements result in consumers los-
2 ing the benefits that the 1984 Act was intended to
3 provide.

4 (7) In 2010, the Biologics Price Competition
5 and Innovation Act (Public Law 111–148) (referred
6 to in this Act as the “BPCIA”), was enacted with
7 the intent of facilitating the early entry of biosimilar
8 and interchangeable follow-on versions of branded
9 biological products while preserving incentives for in-
10 novation.

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

16 (9) Competition from biosimilar and inter-
17 changeable biological products promises to lower
18 drug costs and increase patient access to biological
19 medicines. But “reverse payment” settlement agree-
20 ments also threaten to delay the entry of biosimilar
21 and interchangeable biological products, which would
22 undermine the goals of BPCIA.

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

24 (1) to enhance competition in the pharma-
25 ceutical market by stopping anticompetitive agree-

1 ments between brand name and generic drug and
 2 biosimilar biological product manufacturers that
 3 limit, delay, or otherwise prevent competition from
 4 generic drugs and biosimilar biological products; and

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

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

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

12 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS**
 13 **AND BIOSIMILARS.**

14 “(a) IN GENERAL.—

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

21 “(2) PRESUMPTION AND VIOLATION.—

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

1 “(i) an ANDA filer or a biosimilar bi-
2 ological product application filer receives
3 anything of value, including an exclusive li-
4 cense; and

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

12 “(B) EXCEPTION.—Subparagraph (A)
13 shall not apply if the parties to such agreement
14 demonstrate by clear and convincing evidence
15 that—

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

21 “(ii) the procompetitive benefits of the
22 agreement outweigh the anticompetitive ef-
23 fects of the agreement.

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

4 “(1) that entry would not have occurred until
5 the expiration of the relevant patent or statutory ex-
6 clusivity; or

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

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

19 “(1) The right to market the ANDA product or
20 biosimilar biological product in the United States
21 prior to the expiration of—

22 “(A) any patent that is the basis for the
23 patent infringement claim; or

24 “(B) any patent right or other statutory
25 exclusivity that would prevent the marketing of

1 such ANDA product or biosimilar biological
2 product.

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

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

8 “(d) ENFORCEMENT.—

9 “(1) ENFORCEMENT.—A violation of this sec-
10 tion shall be treated as a violation of section 5.

11 “(2) JUDICIAL REVIEW.—

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

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

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

1 cense holder is incorporated as of the date
2 that the NDA or biological product license
3 application, as applicable, is filed with the
4 Commissioner of Food and Drugs; or

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

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

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

1 filer to assert claims or counterclaims against any person;
2 under the antitrust laws or other laws relating to unfair
3 competition.

4 “(f) PENALTIES.—

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

1 mandatory injunctions and such other and further
 2 equitable relief as they deem appropriate.

3 “(2) CEASE AND DESIST.—

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

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

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

23 “(ii) the order became final by reason
 24 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 or biological product license holder,
13 compensation received by the ANDA filer or
14 biosimilar biological product application filer,
15 and the amount of commerce affected; and

16 “(C) other matters that justice requires.

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

23 “(g) DEFINITIONS.—In this section:

24 “(1) AGREEMENT.—The term ‘agreement’
25 means anything that would constitute an agreement

1 under section 1 of the Sherman Act (15 U.S.C. 1)
2 or section 5 of this Act.

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

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

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

23 “(5) ANDA PRODUCT.—The term ‘ANDA
24 product’ means the product to be manufactured

1 under the ANDA that is the subject of the patent
2 infringement claim.

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

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

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

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

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

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

1 indirect share ownership of 50 percent or great-
2 er), as well as the licensees, licensors, succes-
3 sors, and assigns of each of the entities.

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

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

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

22 “(12) DRUG PRODUCT.—The term ‘drug prod-
23 uct’ has the meaning given such term in section
24 314.3(b) of title 21, Code of Federal Regulations (or
25 any successor regulation).

1 “(13) NDA.—The term ‘NDA’ means a new
2 drug application filed under section 505(b) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 355(b)).

5 “(14) NDA HOLDER.—The term ‘NDA holder’
6 means—

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

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

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

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

1 “(16) PATENT INFRINGEMENT.—The term
2 ‘patent infringement’ means infringement of any
3 patent or of any filed patent application, extension,
4 reissue, renewal, division, continuation, continuation
5 in part, reexamination, patent term restoration, pat-
6 ents of addition, and extensions thereof.

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

17 “(18) 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(e)(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(e)(3)(E), 360ee, 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 (orphan drug exclusivity) of the Federal~~
 5 ~~Food, Drug, and Cosmetic Act (21 U.S.C. 360ee).”.~~

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 after June 17, 2013. Section 27(f)~~
 10 ~~of the Federal Trade Commission Act, as added by this~~
 11 ~~section, shall apply to agreements entered into on or after~~
 12 ~~the date of enactment of this Act.~~

13 **SEC. 4. CERTIFICATION OF AGREEMENTS.**

14 ~~Section 1112 of the Medicare Prescription Drug, Im-~~
 15 ~~provement, and Modernization Act of 2003 (21 U.S.C.~~
 16 ~~355 note) is amended by adding at the end the following:~~

17 ~~“(d) CERTIFICATION.—The Chief Executive Officer~~
 18 ~~or the company official responsible for negotiating any~~
 19 ~~agreement under subsection (a) or (b) that is required to~~
 20 ~~be filed under subsection (c), within 30 days after such~~
 21 ~~filing, shall execute and file with the Assistant Attorney~~
 22 ~~General and the Commission a certification as follows: “I~~
 23 ~~declare that the following is true, correct, and complete~~
 24 ~~to the best of my knowledge. The materials filed with the~~
 25 ~~Federal Trade Commission and the Department of Justice~~

1 under section 1112 of subtitle B of title XI of the Medi-
2 care Prescription Drug, Improvement, and Modernization
3 Act of 2003, with respect to the agreement referenced in
4 this certification—

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

7 “(2) include any ancillary agreements that are
8 contingent upon, provide a contingent condition for,
9 or are otherwise related to, the referenced agree-
10 ment; and

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

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

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

22 **SEC. 6. COMMISSION LITIGATION AUTHORITY.**

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

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

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

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

7 “(F) under section 27.”

8 **SEC. 7. STATUTE OF LIMITATIONS.**

9 The Federal Trade Commission shall commence any
10 enforcement proceeding described in section 27 of the
11 Federal Trade Commission Act, as added by section 3, ex-
12 cept for an action described in section 27(f)(2) of the Fed-
13 eral Trade Commission Act, not later than 6 years after
14 the date on which the parties to the agreement file the
15 certification under section 1112(d) of the Medicare Pre-
16 scription Drug Improvement and Modernization Act of
17 2003 (21 U.S.C. 355 note).

18 **SEC. 8. SEVERABILITY.**

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

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Preserve Access to Af-*
3 *fordable Generics and Biosimilars Act”.*

4 **SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF**
5 **PURPOSES.**

6 (a) *FINDINGS.—Congress finds the following:*

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8 *Patent Term Restoration Act (Public Law 98–417)*
9 *(referred to in this Act as the “1984 Act”), was en-*
10 *acted with the intent of facilitating the early entry of*
11 *generic drugs while preserving incentives for innova-*
12 *tion.*

13 (2) *Prescription drugs make up approximately*
14 *10 percent of the national health care spending.*

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

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22 *brand name drugs, with discounts off the brand price*
23 *averaging 80 to 85 percent.*

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25 *percent of the \$325,000,000,000 spent on retail pre-*

1 *scription drugs, and this share is expected to rise to*
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4 *has been subverted by certain settlement agreements*
5 *in which brand name companies transfer value to*
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7 *that the generic company is infringing the branded*
8 *company's patents.*

9 *(B) These "reverse payment" settlement agree-*
10 *ments—*

11 *(i) allow a branded company to share its*
12 *monopoly profits with the generic company as a*
13 *way to protect the branded company's monopoly;*
14 *and*

15 *(ii) have unduly delayed the marketing of*
16 *low-cost generic drugs contrary to free competi-*
17 *tion, the interests of consumers, and the prin-*
18 *ciples underlying antitrust law.*

19 *(C) Because of the price disparity between brand*
20 *name and generic drugs, such agreements are more*
21 *profitable for both the brand and generic manufactur-*
22 *ers than competition and will become increasingly*
23 *common unless prohibited.*

1 (D) *These agreements result in consumers losing*
2 *the benefits that the 1984 Act was intended to pro-*
3 *vide.*

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5 *Innovation Act (Public Law 111–148) (referred to in*
6 *this Act as the “BPCIA”), was enacted with the in-*
7 *tent of facilitating the early entry of biosimilar and*
8 *interchangeable follow-on versions of branded biologi-*
9 *cal products while preserving incentives for innova-*
10 *tion.*

11 (8) *Biological drugs play an important role in*
12 *treating many serious illnesses, from cancers to ge-*
13 *netic disorders. They are also expensive, representing*
14 *more than 40 percent of all prescription drug spend-*
15 *ing.*

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17 *changeable biological products promises to lower drug*
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20 *also threaten to delay the entry of biosimilar and*
21 *interchangeable biological products, which would un-*
22 *dermine the goals of BPCIA.*

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

24 (1) *to enhance competition in the pharma-*
25 *ceutical market by stopping anticompetitive agree-*

1 *ments between brand name and generic drug and bio-*
 2 *similar biological product manufacturers that limit,*
 3 *delay, or otherwise prevent competition from generic*
 4 *drugs and biosimilar biological products; and*

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

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 17 *visions of this section against the parties to any*
 18 *agreement resolving or settling, on a final or interim*
 19 *basis, a patent claim, in connection with the sale of*
 20 *a drug product or biological product.*

21 *“(2) PRESUMPTION AND VIOLATION.—*

22 *“(A) IN GENERAL.—Subject to subpara-*
 23 *graph (B), in such a proceeding, an agreement*
 24 *shall be presumed to have anticompetitive effects*
 25 *and shall be a violation of this section if—*

1 “(i) an ANDA filer or a biosimilar bi-
2 logical product application filer receives
3 anything of value, including an exclusive li-
4 cense; and

5 “(ii) the ANDA filer or biosimilar bio-
6 logical product application filer agrees to
7 limit or forgo research, development, manu-
8 facturing, marketing, or sales of the ANDA
9 product or biosimilar biological product, as
10 applicable, for any period of time.

11 “(B) EXCEPTION.—Subparagraph (A) shall
12 not apply if the parties to such agreement dem-
13 onstrate by clear and convincing evidence that—

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

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

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

1 “(1) that entry would not have occurred until the
2 expiration of the relevant patent or statutory exclu-
3 sivity; or

4 “(2) that the agreement’s provision for entry of
5 the ANDA product or biosimilar biological product
6 prior to the expiration of the relevant patent or statu-
7 tory exclusivity means that the agreement is procom-
8 petitive.

9 “(c) *EXCLUSIONS.*—Nothing in this section shall pro-
10 hibit a resolution or settlement of a patent infringement
11 claim in which the consideration that the ANDA filer or
12 biosimilar biological product application filer, respectively,
13 receives as part of the resolution or settlement includes only
14 one or more of the following:

15 “(1) The right to market and secure final ap-
16 proval in the United States for the ANDA product or
17 biosimilar biological product at a date, whether cer-
18 tain or contingent, prior to the expiration of—

19 “(A) any patent that is the basis for the
20 patent infringement claim; or

21 “(B) any patent right or other statutory ex-
22 clusivity that would prevent the marketing of
23 such ANDA product or biosimilar biological
24 product.

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

3 “(A) *for calendar year 2021, \$7,500,000; or*

4 “(B) *for calendar year 2022 and each subse-*
5 *quent calendar year, the amount determined for*
6 *the preceding calendar year adjusted to reflect*
7 *the percentage increase (if any) in the Producer*
8 *Price Index for Legal Services published by the*
9 *Bureau of Labor Statistics of the Department of*
10 *Labor for the most recent calendar year.*

11 “(3) *A covenant not to sue on any claim that the*
12 *ANDA product or biosimilar biological product in-*
13 *fringes a United States patent.*

14 “(d) *ENFORCEMENT.—*

15 “(1) *ENFORCEMENT.—A violation of this section*
16 *shall be treated as an unfair method of competition*
17 *under section 5(a)(1).*

18 “(2) *JUDICIAL REVIEW.—*

19 “(A) *IN GENERAL.—Any party that is sub-*
20 *ject to a final order of the Commission, issued in*
21 *an administrative adjudicative proceeding under*
22 *the authority of subsection (a)(1), may, within*
23 *30 days of the issuance of such order, petition for*
24 *review of such order in—*

1 “(i) the United States Court of Appeals
2 for the District of Columbia Circuit;

3 “(ii) the United States Court of Ap-
4 peals for the circuit in which the ultimate
5 parent entity, as defined in section
6 801.1(a)(3) of title 16, Code of Federal Reg-
7 ulations, or any successor thereto, of the
8 NDA holder or biological product license
9 holder is incorporated as of the date that the
10 NDA or biological product license applica-
11 tion, as applicable, is filed with the Com-
12 missioner of Food and Drugs; or

13 “(iii) the United States Court of Ap-
14 peals for the circuit in which the ultimate
15 parent entity of the ANDA filer or bio-
16 similar biological product application filer
17 is incorporated as of the date that the
18 ANDA or biosimilar biological product ap-
19 plication is filed with the Commissioner of
20 Food and Drugs.

21 “(B) TREATMENT OF FINDINGS.—In a pro-
22 ceeding for judicial review of a final order of the
23 Commission, the findings of the Commission as
24 to the facts, if supported by evidence, shall be
25 conclusive.

1 “(e) *ANTITRUST LAWS.*—*Nothing in this section shall*
2 *modify, impair, limit, or supersede the applicability of the*
3 *antitrust laws as defined in subsection (a) of the first sec-*
4 *tion of the Clayton Act (15 U.S.C. 12(a)), and of section*
5 *5 of this Act to the extent that section 5 applies to unfair*
6 *methods of competition. Nothing in this section shall mod-*
7 *ify, impair, limit, or supersede the right of an ANDA filer*
8 *or biosimilar biological product application filer to assert*
9 *claims or counterclaims against any person, under the anti-*
10 *trust laws or other laws relating to unfair competition.*

11 “(f) *PENALTIES.*—

12 “(1) *FORFEITURE.*—*Each party that violates or*
13 *assists in the violation of this section shall forfeit and*
14 *pay to the United States a civil penalty sufficient to*
15 *deter violations of this section, but in no event greater*
16 *than 3 times the value received by the party that is*
17 *reasonably attributable to the violation of this section.*
18 *If no such value has been received by the NDA holder,*
19 *the biological product license holder, the ANDA filer,*
20 *or the biosimilar biological product application filer,*
21 *the penalty to the NDA holder, the biological product*
22 *license holder, the ANDA filer, or the biosimilar bio-*
23 *logical product application filer shall be sufficient to*
24 *deter violations, but in no event shall be greater than*
25 *3 times the value given to an ANDA filer or bio-*

1 *similar biological product application filer reasonably*
2 *attributable to the violation of this section. Such pen-*
3 *alty shall accrue to the United States and may be re-*
4 *covered in a civil action brought by the Commission,*
5 *in its own name by any of its attorneys designated*
6 *by it for such purpose, in a district court of the*
7 *United States against any party that violates this*
8 *section. In such actions, the United States district*
9 *courts are empowered to grant mandatory injunctions*
10 *and such other and further equitable relief as they*
11 *deem appropriate.*

12 *“(2) CEASE AND DESIST.—*

13 *“(A) IN GENERAL.—If the Commission has*
14 *issued a cease and desist order with respect to a*
15 *party in an administrative adjudicative pro-*
16 *ceeding under the authority of subsection (a)(1),*
17 *an action brought pursuant to paragraph (1)*
18 *may be commenced against such party at any*
19 *time before the expiration of 1 year after such*
20 *order becomes final pursuant to section 5(g).*

21 *“(B) EXCEPTION.—In an action under sub-*
22 *paragraph (A), the findings of the Commission*
23 *as to the material facts in the administrative ad-*
24 *judicative proceeding with respect to the viola-*

1 *tion of this section by a party shall be conclusive*
2 *unless—*

3 *“(i) the terms of such cease and desist*
4 *order expressly provide that the Commis-*
5 *sion’s findings shall not be conclusive; or*

6 *“(ii) the order became final by reason*
7 *of section 5(g)(1), in which case such find-*
8 *ing shall be conclusive if supported by evi-*
9 *dence.*

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

13 *“(A) the nature, circumstances, extent, and*
14 *gravity of the violation;*

15 *“(B) with respect to the violator, the degree*
16 *of culpability, any history of violations, the abil-*
17 *ity to pay, any effect on the ability to continue*
18 *doing business, profits earned by the NDA hold-*
19 *er, the biological product license holder, the*
20 *ANDA filer, or the biosimilar biological product*
21 *application filer, compensation received by the*
22 *ANDA filer or biosimilar biological product ap-*
23 *plication filer, and the amount of commerce af-*
24 *ected; and*

25 *“(C) other matters that justice requires.*

1 “(4) *REMEDIES IN ADDITION.*—*Remedies pro-*
2 *vided in this subsection are in addition to, and not*
3 *in lieu of, any other remedy provided by Federal law.*
4 *Nothing in this paragraph shall be construed to affect*
5 *any authority of the Commission under any other*
6 *provision of law.*

7 “(g) *DEFINITIONS.*—*In this section:*

8 “(1) *AGREEMENT.*—*The term ‘agreement’ means*
9 *anything that would constitute an agreement under*
10 *section 1 of the Sherman Act (15 U.S.C. 1) or section*
11 *5 of this Act.*

12 “(2) *AGREEMENT RESOLVING OR SETTLING A*
13 *PATENT INFRINGEMENT CLAIM.*—*The term ‘agreement*
14 *resolving or settling a patent infringement claim’ in-*
15 *cludes any agreement that is entered into within 30*
16 *days of the resolution or the settlement of the claim,*
17 *or any other agreement that is contingent upon, pro-*
18 *vides a contingent condition for, or is otherwise re-*
19 *lated to the resolution or settlement of the claim.*

20 “(3) *ANDA.*—*The term ‘ANDA’ means an abbre-*
21 *viated new drug application filed under section 505(j)*
22 *of the Federal Food, Drug, and Cosmetic Act (21*
23 *U.S.C. 355(j)) or a new drug application filed under*
24 *section 505(b)(2) of the Federal Food, Drug, and Cos-*
25 *metic Act (21 U.S.C. 355(b)(2)).*

1 “(4) *ANDA FILER*.—*The term ‘ANDA filer’*
2 *means a party that owns or controls an ANDA filed*
3 *with the Food and Drug Administration or has the*
4 *exclusive rights under such ANDA to distribute the*
5 *ANDA product.*

6 “(5) *ANDA PRODUCT*.—*The term ‘ANDA prod-*
7 *uct’ means the product to be manufactured under the*
8 *ANDA that is the subject of the patent infringement*
9 *claim.*

10 “(6) *BIOLOGICAL PRODUCT*.—*The term ‘biologi-*
11 *cal product’ has the meaning given such term in sec-*
12 *tion 351(i)(1) of the Public Health Service Act (42*
13 *U.S.C. 262(i)(1)).*

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

18 “(8) *BIOLOGICAL PRODUCT LICENSE HOLDER*.—
19 *The term ‘biological product license holder’ means—*

20 “(A) *the holder of an approved biological*
21 *product license application for a biological prod-*
22 *uct;*

23 “(B) *a person owning or controlling en-*
24 *forcement of any patents that claim the biologi-*

1 *cal product that is the subject of such approved*
2 *application; or*

3 “(C) *the predecessors, subsidiaries, divi-*
4 *sions, groups, and affiliates controlled by, con-*
5 *trolling, or under common control with any of*
6 *the entities described in subparagraphs (A) and*
7 *(B) (such control to be presumed by direct or in-*
8 *direct share ownership of 50 percent or greater),*
9 *as well as the licensees, licensors, successors, and*
10 *assigns of each of the entities.*

11 “(9) *BIOSIMILAR BIOLOGICAL PRODUCT.—The*
12 *term ‘biosimilar biological product’ means the prod-*
13 *uct to be manufactured under the biosimilar biologi-*
14 *cal product application that is the subject of the pat-*
15 *ent infringement claim.*

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

22 “(11) *BIOSIMILAR BIOLOGICAL PRODUCT APPLI-*
23 *CATION FILER.—The term ‘biosimilar biological prod-*
24 *uct application filer’ means a party that owns or*
25 *controls a biosimilar biological product application*

1 *filed with the Food and Drug Administration or has*
2 *the exclusive rights under such application to dis-*
3 *tribute the biosimilar biological product.*

4 “(12) *DRUG PRODUCT.*—*The term ‘drug product’*
5 *has the meaning given such term in section 314.3(b)*
6 *of title 21, Code of Federal Regulations (or any suc-*
7 *cessor regulation).*

8 “(13) *MARKET.*—*The term ‘market’ means the*
9 *promotion, offering for sale, selling, or distribution of*
10 *a drug product.*

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

14 “(15) *NDA HOLDER.*—*The term ‘NDA holder’*
15 *means—*

16 “(A) *the holder of an approved NDA appli-*
17 *cation for a drug product;*

18 “(B) *a person owning or controlling en-*
19 *forcement of the patent listed in the Approved*
20 *Drug Products With Therapeutic Equivalence*
21 *Evaluations (commonly known as the ‘FDA Or-*
22 *ange Book’)* *in connection with the NDA; 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 in-*
3 *direct share ownership of 50 percent or greater),*
4 *as well as the licensees, licensors, successors, and*
5 *assigns of each of the entities.*

6 “(16) *PARTY.*—*The term ‘party’ means any per-*
7 *son, partnership, corporation, or other legal entity.*

8 “(17) *PATENT INFRINGEMENT.*—*The term ‘pat-*
9 *ent infringement’ means infringement of any patent*
10 *or of any filed patent application, including any ex-*
11 *tension, reissue, renewal, division, continuation, con-*
12 *tinuation in part, reexamination, patent term res-*
13 *toration, patents of addition, and extensions thereof.*

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

1 “(19) *STATUTORY EXCLUSIVITY*.—The term ‘stat-
2 *utory exclusivity*’ means those prohibitions on the ap-
3 *proval of drug applications under clauses (ii) through*
4 *(iv) of section 505(c)(3)(E) (5- and 3-year data exclu-*
5 *sivity), section 527 (orphan drug exclusivity), or sec-*
6 *tion 505A (pediatric exclusivity) of the Federal Food,*
7 *Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E),*
8 *360cc, 355a), or on the licensing of biological product*
9 *applications under section 351(k)(7) (12-year exclu-*
10 *sivity) or paragraph (2) or (3) of section 351(m) (pe-*
11 *diatric exclusivity) of the Public Health Service Act*
12 *(42 U.S.C. 262) or under section 527 of the Federal*
13 *Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) (or-*
14 *phan 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 that*
18 *Act entered into on or after the date of enactment of this*
19 *Act.*

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

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

1 *person for making, using, offering to sell, selling, or import-*
 2 *ing into the United States a biological product that is the*
 3 *subject of a biosimilar biological product application” be-*
 4 *fore the period at the end.*

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

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

22 **“(1) represent the complete, final, and exclusive**
 23 *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 agreement;
2 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. 355
11 note), as amended by section 4(b), is further amended by
12 adding at the end the following:

13 “(e) *RULE OF CONSTRUCTION.*—

14 “(1) *IN GENERAL.*—An agreement that is re-
15 quired under subsection (a) or (b) shall include agree-
16 ments resolving any outstanding disputes, including
17 agreements resolving or settling a Patent Trial and
18 Appeal Board proceeding.

19 “(2) *DEFINITION.*—For purposes of subpara-
20 graph (A), the term ‘Patent Trial and Appeal Board
21 proceeding’ means a proceeding conducted by the Pat-
22 ent Trial and Appeal Board of the United States Pat-
23 ent and Trademark Office, including an *inter partes*
24 review instituted under chapter 31 of title 35, United
25 States Code, a post-grant review instituted under

1 *chapter 32 of that title (including a proceeding insti-*
 2 *tuted pursuant to the transitional program for cov-*
 3 *ered business method patents, as described in section*
 4 *18 of the Leahy-Smith America Invents Act (35*
 5 *U.S.C. 321 note)), and a derivation proceeding insti-*
 6 *tuted under section 135 of that title.”.*

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

8 *Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug,*
 9 *and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amend-*
 10 *ed by inserting “section 27 of the Federal Trade Commis-*
 11 *sion Act or” after “that the agreement has violated”.*

12 **SEC. 7. COMMISSION LITIGATION AUTHORITY.**

13 *Section 16(a)(2) of the Federal Trade Commission Act*
 14 *(15 U.S.C. 56(a)(2)) is amended—*

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

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

19 *(3) inserting after subparagraph (E) the fol-*
 20 *lowing:*

21 *“(F) under section 27,”.*

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

23 *(a) IN GENERAL.—Not later than 1 year after the date*
 24 *of enactment of this Act, the Federal Trade Commission*
 25 *shall submit to the Committee on the Judiciary of the Sen-*

1 ate and the Committee on the Judiciary of the House of
2 Representatives a recommendation, and the Commission's
3 basis for such recommendation, regarding a potential
4 amendment to include in section 27(c) of the Federal Trade
5 Commission Act (as added by section 3 of this Act) an addi-
6 tional exclusion for consideration granted by an NDA hold-
7 er to a ANDA filer or by a biological product license holder
8 to a biosimilar biological product application filer as part
9 of the resolution or settlement, a release, waiver, or limita-
10 tion of a claim for damages or other monetary relief.

11 (b) *DEFINITIONS.*—In this section, the terms “ANDA
12 filer”, “biological product license holder”, “biosimilar bio-
13 logical product application filer”, and “NDA holder” have
14 the meanings given such terms in section 27(g) of the Fed-
15 eral Trade Commission Act (as added by section 3 of this
16 Act).

17 **SEC. 9. STATUTE OF LIMITATIONS.**

18 The Federal Trade Commission shall commence any
19 enforcement proceeding described in section 27 of the Fed-
20 eral Trade Commission Act, as added by section 3, except
21 for an action described in section 27(f)(2) of the Federal
22 Trade Commission Act, not later than 6 years after the date
23 on which the parties to the agreement file the certification
24 under section 1112(d) of the Medicare Prescription Drug

1 *Improvement and Modernization Act of 2003 (21 U.S.C.*
2 *355 note).*

3 **SEC. 10. SEVERABILITY.**

4 *If any provision of this Act, an amendment made by*
5 *this Act, or the application of such provision or amendment*
6 *to any person or circumstance is held to be unconstitu-*
7 *tional, the remainder of this Act, the amendments made by*
8 *this Act, and the application of the provisions of such Act*
9 *or amendments to any person or circumstance shall not be*
10 *affected.*

Calendar No. 180

117TH CONGRESS
1ST Session
S. 1428

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.

DECEMBER 9, 2021

Reported with an amendment