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119TH CONGRESS
1ST SESSION

S. 1096

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

MARCH 24, 2025

Ms. KLOBUCHAR (for herself, Mr. GRASSLEY, Mr. DURBIN, Mr. CRAMER, Mr. BLUMENTHAL, Ms. ERNST, Mr. WELCH, Mr. KELLY, and Mr. BOOKER) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

APRIL 10, 2025

Reported by Mr. GRASSLEY, 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 11 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 91 percent
 20 of all prescriptions dispensed in the United States
 21 are generic drugs, they account for only 18 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 \$449,700,000,000 spent on retail
3 prescription drugs annually.

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

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

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

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

20 (C) Because of the price disparity between
21 brand name and generic drugs, such agreements are
22 more profitable for both the brand and generic man-
23 ufacturers than competition and will become increas-
24 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 half of all prescription drug
 15 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) PROHIBITION.—

15 “(1) IN GENERAL.—It shall be a violation of
 16 this section for a party to enter into, or be a partici-
 17 pant to, an agreement, resolving or settling, on a
 18 final or interim basis, a patent claim in connection
 19 with the sale of a drug product or biological product,
 20 that has anticompetitive effects.

21 “(2) TREATMENT.—A violation of this section
 22 shall be treated as an unfair method of competition
 23 in violation of section 5(a)(1).

24 “(3) PRESUMPTION.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (B), an agreement described in para-
3 graph (1) shall be presumed to have anti-
4 competitive effects for purposes of such para-
5 graph if—

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

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

17 “(B) EXCEPTION.—Subparagraph (A)
18 shall not apply if the parties to such agreement
19 demonstrate by a preponderance of the evidence
20 that—

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

1 “(ii) the procompetitive benefits of the
2 transfer of value described in subpara-
3 graph (A)(i) and the agreement by the
4 ANDA filer or biosimilar biological product
5 application filer to limit or forgo research,
6 development, manufacturing, marketing, or
7 sales of the ANDA product or biosimilar
8 biological product described in subpara-
9 graph (A)(ii) outweigh the anticompetitive
10 effects of the transfer of value described in
11 subparagraph (A)(i) and the agreement by
12 the ANDA filer or biosimilar biological
13 product application filer to limit or forgo
14 research, development, manufacturing,
15 marketing, or sales of the ANDA product
16 or biosimilar biological product described
17 in subparagraph (A)(ii).

18 “(4) CIVIL ACTION.—In addition to any pro-
19 ceeding under section 5, if the Commission has rea-
20 son to believe that a party has violated this section,
21 the Commission may bring, in its own name by any
22 of its attorneys designated by it for such purpose, a
23 civil action against the party in a district court of
24 the United States to seek to recover any of the rem-
25 edies of civil penalty, mandatory injunctions, and

1 such other and further equitable relief as the court
2 deems appropriate.

3 ~~“(5) CIVIL PENALTY.—~~

4 ~~“(A) IN GENERAL.—Each party that vio-~~
5 ~~lates or assists in the violation of paragraph (1)~~
6 ~~shall forfeit and pay to the United States a civil~~
7 ~~penalty sufficient to deter violations of para-~~
8 ~~graph (1), but in no event greater than 3 times~~
9 ~~the value received by the party that is reason-~~
10 ~~ably attributable to the violation of paragraph~~
11 ~~(1). If no such value has been received by the~~
12 ~~NDA holder, the biological product license hold-~~
13 ~~er, the ANDA filer, or the biosimilar biological~~
14 ~~product application filer, the penalty to the~~
15 ~~NDA holder, the biological product license hold-~~
16 ~~er, the ANDA filer, or the biosimilar biological~~
17 ~~product application filer shall be sufficient to~~
18 ~~deter violations, but in no event shall be greater~~
19 ~~than 3 times the value given to an ANDA filer~~
20 ~~or biosimilar biological product application filer~~
21 ~~reasonably attributable to the violation of this~~
22 ~~section.~~

23 ~~“(B) AMOUNT.—In determining the~~
24 ~~amount of the civil penalty described in sub-~~

1 paragraph (A), the court shall take into ac-
2 count—

3 “(i) the nature, circumstances, extent,
4 and gravity of the violation;

5 “(ii) with respect to the violator, the
6 degree of culpability, any history of prior
7 such conduct, including other agreements
8 resolving or settling a patent infringement
9 claim, the ability to pay, any effect on the
10 ability to continue doing business, profits
11 earned by the NDA holder, the biological
12 product license holder, the ANDA filer, or
13 the biosimilar biological product applica-
14 tion filer, compensation received by the
15 ANDA filer or biosimilar biological product
16 application filer, and the amount of com-
17 merce affected; and

18 “(iii) other matters that justice re-
19 quires.

20 “(C) REMEDIES IN ADDITION.—Remedies
21 provided in this paragraph are in addition to,
22 and not in lieu of, any other remedy provided
23 by Federal law. Nothing in this section shall be
24 construed to limit any authority of the Commis-
25 sion under any other provision of law.

1 “(b) ~~EXCLUSIONS.~~—Nothing in this section shall pro-
 2 hibit a resolution or settlement of a patent infringement
 3 claim in which the consideration that the ANDA filer or
 4 biosimilar biological product application filer, respectively,
 5 receives as part of the resolution or settlement includes
 6 only one or more of the following:

7 “(1) The right to market and secure final ap-
 8 proval in the United States for the ANDA product
 9 or biosimilar biological product at a date, whether
 10 certain or contingent, prior to the expiration of—

11 “(A) any patent that is the basis for the
 12 patent infringement claim; or

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

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

19 “(A) for calendar year 2025, \$7,500,000;
 20 or

21 “(B) for calendar year 2026 and each sub-
 22 sequent calendar year, the amount determined
 23 for the preceding calendar year adjusted to re-
 24 flect the percentage increase (if any) in the
 25 Producer Price Index for Legal Services pub-

1 lished by the Bureau of Labor Statistics of the
2 Department of Labor for the most recent cal-
3 endar year.

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

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

19 ~~“(d) DEFINITIONS.—In this section:~~

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

24 ~~“(2) AGREEMENT RESOLVING OR SETTLING A~~
25 PATENT INFRINGEMENT CLAIM.—The term ‘agree-

1 ment resolving or settling a patent infringement
2 claim² includes any agreement that is entered into
3 within 30 days of the resolution or the settlement of
4 the claim, or any other agreement that is contingent
5 upon, provides a contingent condition for, or is oth-
6 erwise related to the resolution or settlement of the
7 claim.

8 “(3) ANDA.—The term ‘ANDA’ means an ab-
9 breviated new drug application filed under section
10 505(j) of the Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 355(j)) or a new drug application sub-
12 mitted pursuant to section 505(b)(2) of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C.
14 355(b)(2)).

15 “(4) ANDA FILER.—The term ‘ANDA filer’
16 means a party that owns or controls an ANDA filed
17 with the Secretary of Health and Human Services or
18 has the exclusive rights under such ANDA to dis-
19 tribute the ANDA product.

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

24 “(6) BIOLOGICAL PRODUCT.—The term ‘bio-
25 logical product’ has the meaning given such term in

1 section 351(i)(1) of the Public Health Service Act
2 (42 U.S.C. 262(i)(1)).

3 ~~“(7) BIOLOGICAL PRODUCT LICENSE APPLICATION.—~~The term ‘biological product license applica-
4 tion’ means an application under section 351(a) of
5 the Public Health Service Act (42 U.S.C. 262(a)).
6

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

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

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

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

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

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

12 ~~“(11) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-~~
 13 ~~CATION FILER.—The term ‘biosimilar biological~~
 14 ~~product application filer’ means a party that owns or~~
 15 ~~controls a biosimilar biological product application~~
 16 ~~filed with the Secretary of Health and Human Serv-~~
 17 ~~ices or has the exclusive rights under such applica-~~
 18 ~~tion to distribute the biosimilar biological product.~~

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

23 ~~“(13) MARKET.—The term ‘market’ means the~~
 24 ~~promotion, offering for sale, selling, or distribution~~
 25 ~~of a drug product.~~

1 ~~“(14) 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 ~~“(15) 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 ~~“(16) PARTY.—The term ‘party’ means any~~
23 ~~person, partnership, corporation, or other legal enti-~~
24 ~~ty.~~

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

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

19 “(19) STATUTORY EXCLUSIVITY.—The term
20 ‘statutory exclusivity’ means those prohibitions on
21 the submission or the approval of drug applications
22 under clauses (ii) through (iv) of section
23 505(c)(3)(E), clauses (ii) through (iv) of section
24 505(j)(5)(F), section 527, section 505A, or section
25 505E of the Federal Food, Drug, and Cosmetic Act

1 ~~(21 U.S.C. 355(c)(3)(E), 360cc, 355a, 355f), or on~~
 2 ~~the submission or licensing of biological product ap-~~
 3 ~~plications under section 351(k)(7) or paragraph (2)~~
 4 ~~or (3) of section 351(m) of the Public Health Serv-~~
 5 ~~ice Act (42 U.S.C. 262) or under section 527 of the~~
 6 ~~Federal Food, Drug, and Cosmetic Act (21 U.S.C.~~
 7 ~~360cc).”.~~

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

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

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

23 (b) **CERTIFICATION OF AGREEMENTS.**—Section 1112
 24 of the Medicare Prescription Drug, Improvement, and

1 Modernization Act of 2003 (21 U.S.C. 355 note) is
 2 amended by adding at the end the following:

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

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

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

22 “(3) include written descriptions of any oral
 23 agreements, representations, commitments, or prom-
 24 ises between the parties that are responsive to sub-

1 section (a) or (b) of such section 1112 and have not
 2 been reduced to writing.”.

3 **SEC. 5. NOTIFICATION OF AGREEMENTS.**

4 Section 1112 of the Medicare Prescription Drug, Im-
 5 provement, and Modernization Act of 2003 (21 U.S.C.
 6 355 note), as amended by section 4(b), is further amended
 7 by adding at the end the following:

8 “(e) **RULE OF CONSTRUCTION.**—

9 “(1) **IN GENERAL.**—An agreement that is re-
 10 quired under subsection (a) or (b) shall include
 11 agreements resolving any outstanding disputes, in-
 12 cluding agreements resolving or settling a Patent
 13 Trial and Appeal Board proceeding.

14 “(2) **DEFINITION.**—For purposes of subpara-
 15 graph (A), the term ‘Patent Trial and Appeal Board
 16 proceeding’ means a proceeding conducted by the
 17 Patent Trial and Appeal Board of the United States
 18 Patent and Trademark Office, including an inter
 19 partes review instituted under chapter 31 of title 35,
 20 United States Code, a post-grant review instituted
 21 under chapter 32 of that title (including a pro-
 22 ceeding instituted pursuant to the transitional pro-
 23 gram for covered business method patents, as de-
 24 scribed in section 18 of the Leahy-Smith America
 25 Invents Act (35 U.S.C. 321 note)), and a derivation

1 proceeding instituted under section 135 of that
 2 title.”.

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

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

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

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

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

14 (2) in subparagraph (E)—

15 (A) by moving the margin 2 ems to the
 16 left; and

17 (B) by inserting “or” after the semicolon;
 18 and

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

21 “(F) under section 27.”.

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

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

Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a recommendation, and the Commission's basis for such recommendation, regarding a potential amendment to include in section 27(b) of the Federal Trade Commission Act (as added by section 3) an additional exclusion for consideration granted by an NDA holder to a ANDA filer or by a biological product license holder to a biosimilar biological product application filer as part of the resolution or settlement, a release, waiver, or limitation of a claim for damages or other monetary relief.

(2) DEFINITIONS.—In this section, the terms “ANDA filer”, “biological product license holder”, “biosimilar biological product application filer”, and “NDA holder” have the meanings given such terms in section 27(d) of the Federal Trade Commission Act (as added by section 3).

SEC. 9. STATUTE OF LIMITATIONS.

The Federal Trade Commission shall commence any enforcement proceeding described in section 27 of the Federal Trade Commission Act, as added by section 3, not later than 6 years after the date on which the parties to the agreement file the certification under section 1112(d)

1 of the Medicare Prescription Drug Improvement and Mod-
 2 ernization Act of 2003 (21 U.S.C. 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 amend-
 6 ment to any person or circumstance is held to be unconsti-
 7 tutional, the remainder of this Act, the amendments made
 8 by this Act, and the application of the provisions of such
 9 Act or amendments to any person or circumstance shall
 10 not be affected.

11 **SECTION 1. SHORT TITLE.**

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

14 **SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF**
 15 **PURPOSES.**

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

17 (1) *In 1984, the Drug Price Competition and*
 18 *Patent Term Restoration Act of 1984 (Public Law*
 19 *98–417) (referred to in this Act as the “1984 Act”),*
 20 *was enacted with the intent of facilitating the early*
 21 *entry of generic drugs while preserving incentives for*
 22 *innovation.*

23 (2) *Prescription drugs make up approximately*
 24 *11 percent of the national health care spending.*

1 (3) *Initially, the 1984 Act was successful in fa-*
2 *cilitating generic competition to the benefit of con-*
3 *sumers and health care payers. Although 91 percent*
4 *of all prescriptions dispensed in the United States are*
5 *generic drugs, they account for only 18 percent of all*
6 *expenditures.*

7 (4) *Generic drugs cost substantially less than*
8 *brand name drugs, with discounts off the brand price*
9 *averaging 80 to 85 percent.*

10 (5) *Federal dollars currently account for over 40*
11 *percent of the \$449,700,000,000 spent on retail pre-*
12 *scription drugs annually.*

13 (6)(A) *In recent years, the intent of the 1984 Act*
14 *has been subverted by certain settlement agreements*
15 *in which brand name companies transfer value to*
16 *their potential generic competitors to settle claims*
17 *that the generic company is infringing the branded*
18 *company's patents.*

19 (B) *These “reverse payment” settlement agree-*
20 *ments—*

21 (i) *allow a branded company to share its*
22 *monopoly profits with the generic company as a*
23 *way to protect the branded company's monopoly;*
24 *and*

1 (ii) have unduly delayed the marketing of
2 low-cost generic drugs contrary to free competi-
3 tion, the interests of consumers, and the prin-
4 ciples underlying antitrust law.

5 (C) Because of the price disparity between brand
6 name and generic drugs, such agreements are more
7 profitable for both the brand and generic manufactur-
8 ers than competition and will become increasingly
9 common unless prohibited.

10 (D) These agreements result in consumers losing
11 the benefits that the 1984 Act was intended to pro-
12 vide.

13 (7) In 2010, the *Biologics Price Competition and*
14 *Innovation Act of 2009 (Public Law 111–148)* (re-
15 ferred to in this Act as the “BPCIA”), was enacted
16 with the intent of facilitating the early entry of bio-
17 similar and interchangeable follow-on versions of
18 branded biological products while preserving incen-
19 tives for innovation.

20 (8) Biological drugs play an important role in
21 treating many serious illnesses, from cancers to ge-
22 netic disorders. They are also expensive, representing
23 more than half of all prescription drug spending.

24 (9) Competition from biosimilar and inter-
25 changeable biological products promises to lower drug

1 costs and increase patient access to biological medi-
 2 cines. But “reverse payment” settlement agreements
 3 also threaten to delay the entry of biosimilar and
 4 interchangeable biological products, which would un-
 5 dermine the goals of the BPCIA.

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

7 (1) to enhance competition in the pharma-
 8 ceutical market by stopping anticompetitive agree-
 9 ments between brand name and generic drug and bio-
 10 similar biological product manufacturers that limit,
 11 delay, or otherwise prevent competition from generic
 12 drugs and biosimilar biological products; and

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

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

17 (a) *IN GENERAL.*—The Federal Trade Commission Act
 18 (15 U.S.C. 41 et seq.) is amended by inserting after section
 19 26 (15 U.S.C. 57c–2) the following:

20 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS**
 21 **AND BIOSIMILARS.**

22 “(a) *PROHIBITION.*—

23 “(1) *IN GENERAL.*—It shall be a violation of this
 24 section for a party to enter into, or be a participant
 25 to, an agreement, resolving or settling, on a final or

1 *interim basis, a patent claim in connection with the*
 2 *sale of a drug product or biological product, that has*
 3 *anticompetitive effects.*

4 “(2) *TREATMENT.*—*A violation of this section*
 5 *shall be treated as an unfair method of competition*
 6 *in violation of section 5(a)(1).*

7 “(3) *PRESUMPTION.*—

8 “(A) *IN GENERAL.*—*Subject to subpara-*
 9 *graph (B), an agreement described in paragraph*
 10 *(1) shall be presumed to have anticompetitive ef-*
 11 *fects for purposes of such paragraph if—*

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

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

22 “(B) *EXCEPTION.*—*Subparagraph (A) shall*
 23 *not apply if the parties to such agreement dem-*
 24 *onstrate by a preponderance of the evidence*
 25 *that—*

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

6 “(ii) the procompetitive benefits of the
7 transfer of value described in subparagraph
8 (A)(i) and the agreement by the ANDA filer
9 or biosimilar biological product application
10 filer to limit or forgo research, development,
11 manufacturing, marketing, or sales of the
12 ANDA product or biosimilar biological
13 product described in subparagraph (A)(ii)
14 outweigh the anticompetitive effects of the
15 transfer of value described in subparagraph
16 (A)(i) and the agreement by the ANDA filer
17 or biosimilar biological product application
18 filer to limit or forgo research, development,
19 manufacturing, marketing, or sales of the
20 ANDA product or biosimilar biological
21 product described in subparagraph (A)(ii).

22 “(4) CIVIL ACTION.—In addition to any pro-
23 ceeding under section 5, if the Commission has reason
24 to believe that a party has violated this section, the
25 Commission may bring, in its own name by any of

1 *its attorneys designated by it for such purpose, a civil*
2 *action against the party in a district court of the*
3 *United States to seek to recover any of the remedies*
4 *of civil penalty, mandatory injunctions, and such*
5 *other and further equitable relief as the court deems*
6 *appropriate.*

7 “(5) *CIVIL PENALTY.*—

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

1 “(B) *AMOUNT.*—*In determining the amount*
2 *of the civil penalty described in subparagraph*
3 *(A), the court shall take into account—*

4 “(i) *the nature, circumstances, extent,*
5 *and gravity of the violation;*

6 “(ii) *with respect to the violator, the*
7 *degree of culpability, any history of prior*
8 *such conduct, including other agreements re-*
9 *solving or settling a patent infringement*
10 *claim, the ability to pay, any effect on the*
11 *ability to continue doing business, profits*
12 *earned by the NDA holder, the biological*
13 *product license holder, the ANDA filer, or*
14 *the biosimilar biological product applica-*
15 *tion filer, compensation received by the*
16 *ANDA filer or biosimilar biological product*
17 *application filer, and the amount of com-*
18 *merce affected; and*

19 “(iii) *other matters that justice re-*
20 *quires.*

21 “(C) *REMEDIES IN ADDITION.*—*Remedies*
22 *provided in this paragraph are in addition to,*
23 *and not in lieu of, any other remedy provided by*
24 *Federal law. Nothing in this section shall be con-*

1 *strued to limit any authority of the Commission*
 2 *under any other provision of law.*

3 “(b) *EXCLUSIONS.*—*Nothing in this section shall pro-*
 4 *hibit a resolution or settlement of a patent infringement*
 5 *claim in which the consideration that the ANDA filer or*
 6 *biosimilar biological product application filer, respectively,*
 7 *receives as part of the resolution or settlement includes only*
 8 *one or more of the following:*

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

13 “(A) *any patent that is the basis for the*
 14 *patent infringement claim; or*

15 “(B) *any patent right or other statutory ex-*
 16 *clusivity that would prevent the marketing of*
 17 *such ANDA product or biosimilar biological*
 18 *product.*

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

21 “(A) *for calendar year 2025, \$7,500,000; or*

22 “(B) *for calendar year 2026 and each subse-*
 23 *quent calendar year, the amount determined for*
 24 *the preceding calendar year adjusted to reflect*
 25 *the percentage increase (if any) in the Producer*

1 *Price Index for Legal Services published by the*
 2 *Bureau of Labor Statistics of the Department of*
 3 *Labor for the most recent calendar year.*

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

7 “(c) *ANTITRUST LAWS.—Except to the extent this sec-*
 8 *tion establishes an additional basis of liability, nothing in*
 9 *this section shall modify, impair, limit, or supersede the*
 10 *applicability of the antitrust laws as defined in subsection*
 11 *(a) of the first section of the Clayton Act (15 U.S.C. 12(a)),*
 12 *and of section 5 of this Act to the extent that section 5 ap-*
 13 *plies to unfair methods of competition. Nothing in this sec-*
 14 *tion shall modify, impair, limit, or supersede the right of*
 15 *an ANDA filer or biosimilar biological product application*
 16 *filer to assert claims or counterclaims against any person,*
 17 *under the antitrust laws or other laws relating to unfair*
 18 *competition.*

19 “(d) *DEFINITIONS.—In this section:*

20 “(1) *AGREEMENT.—The term ‘agreement’ means*
 21 *anything that would constitute an agreement under*
 22 *section 1 of the Sherman Act (15 U.S.C. 1) or section*
 23 *5 of this Act.*

24 “(2) *AGREEMENT RESOLVING OR SETTLING A*
 25 *PATENT INFRINGEMENT CLAIM.—The term ‘agreement*

1 *resolving or settling a patent infringement claim’ in-*
2 *cludes any agreement that is entered into within 30*
3 *days of the resolution or the settlement of the claim,*
4 *or any other agreement that is contingent upon, pro-*
5 *vides a contingent condition for, or is otherwise re-*
6 *lated to the resolution or settlement of the claim.*

7 “(3) *ANDA*.—The term ‘*ANDA*’ means an abbrev-
8 *viated new drug application filed under section 505(j)*
9 *of the Federal Food, Drug, and Cosmetic Act (21*
10 *U.S.C. 355(j)) or a new drug application submitted*
11 *pursuant to section 505(b)(2) of the Federal Food,*
12 *Drug, 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 Secretary of Health and Human Services or*
16 *has the exclusive rights under such ANDA to dis-*
17 *tribute the ANDA product.*

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

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

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

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

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

10 “(B) *a person owning or controlling en-*
 11 *forcement of any patents that claim the biologi-*
 12 *cal product that is the subject of such approved*
 13 *application; 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 in-*
 19 *direct share ownership of 50 percent or greater),*
 20 *as well as the licensees, licensors, successors, and*
 21 *assigns of each of the entities.*

22 “(9) *BIOSIMILAR BIOLOGICAL PRODUCT.*—*The*
 23 *term ‘biosimilar biological product’ means the prod-*
 24 *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 prod-*
 11 *uct application filer’ means a party that owns or*
 12 *controls a biosimilar biological product application*
 13 *filed with the Secretary of Health and Human Serv-*
 14 *ices or has the exclusive rights under such application*
 15 *to distribute the biosimilar biological product.*

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

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

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

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

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

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

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

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

20 “(17) *PATENT INFRINGEMENT*.—The term ‘pat-
21 *ent infringement’ means infringement of any patent*
22 *or of any filed patent application, including any ex-*
23 *tension, reissue, renewal, division, continuation, con-*
24 *tinuation in part, reexamination, patent term res-*
25 *toration, patents of addition, and extensions thereof.*

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

11 “(19) *STATUTORY EXCLUSIVITY.*—*The term ‘stat-*
 12 *utory exclusivity’ means those prohibitions on the*
 13 *submission or the approval of drug applications*
 14 *under clauses (ii) through (iv) of section 505(c)(3)(E),*
 15 *clauses (ii) through (iv) of section 505(j)(5)(F), sec-*
 16 *tion 527, section 505A, or section 505E of the Federal*
 17 *Food, Drug, and Cosmetic Act (21 U.S.C.*
 18 *355(c)(3)(E), 355(j)(5)(F), 360cc, 355a, 355f), or on*
 19 *the submission or licensing of biological product ap-*
 20 *plications under section 351(k)(7) or paragraph (2)*
 21 *or (3) of section 351(m) of the Public Health Service*
 22 *Act (42 U.S.C. 262) or under section 527 of the Fed-*
 23 *eral Food, Drug, and Cosmetic Act (21 U.S.C.*
 24 *360cc).’.*

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 that
 4 Act entered into on or after the date of enactment of this
 5 Act.

6 **SEC. 4. CERTIFICATION OF AGREEMENTS.**

7 (a) *NOTICE OF ALL AGREEMENTS.*—Section 1111(7)
 8 of the Medicare Prescription Drug, Improvement, and Mod-
 9 ernization Act of 2003 (21 U.S.C. 355 note) is amended
 10 by inserting “, or the owner of a patent for which a claim
 11 of infringement could reasonably be asserted against any
 12 person for making, using, offering to sell, selling, or import-
 13 ing into the United States a biological product that is the
 14 subject of a biosimilar biological product application” be-
 15 fore the period at the end.

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

20 “(d) *CERTIFICATION.*—The Chief Executive Officer or
 21 the company official responsible for negotiating any agree-
 22 ment under subsection (a) or (b) that is required to be filed
 23 under subsection (c), within 30 days after such filing, shall
 24 execute and file with the Assistant Attorney General and
 25 the Commission a certification as follows: ‘I declare that

1 *the following is true, correct, and complete to the best of*
 2 *my knowledge: The materials filed with the Federal Trade*
 3 *Commission and the Department of Justice under section*
 4 *1112 of subtitle B of title XI of the Medicare Prescription*
 5 *Drug, Improvement, and Modernization Act of 2003, with*
 6 *respect to the agreement referenced in this certification—*

7 “(1) *represent the complete, final, and exclusive*
 8 *agreement between the parties;*

9 “(2) *include any ancillary agreements that are*
 10 *contingent upon, provide a contingent condition for,*
 11 *or are otherwise related to, the referenced agreement;*
 12 *and*

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

18 **SEC. 5. NOTIFICATION OF AGREEMENTS.**

19 *Section 1112 of the Medicare Prescription Drug, Im-*
 20 *provement, and Modernization Act of 2003 (21 U.S.C. 355*
 21 *note), as amended by section 4(b), is further amended by*
 22 *adding at the end the following:*

23 “(e) *RULE OF CONSTRUCTION.—*

24 “(1) *IN GENERAL.—An agreement that is re-*
 25 *quired under subsection (a) or (b) shall include agree-*

1 *ments resolving any outstanding disputes, including*
 2 *agreements resolving or settling a Patent Trial and*
 3 *Appeal Board proceeding.*

4 “(2) *DEFINITION.*—For purposes of subpara-
 5 *graph (A), the term ‘Patent Trial and Appeal Board*
 6 *proceeding’ means a proceeding conducted by the Pat-*
 7 *ent Trial and Appeal Board of the United States Pat-*
 8 *ent and Trademark Office, including an inter partes*
 9 *review instituted under chapter 31 of title 35, United*
 10 *States Code, a post-grant review instituted under*
 11 *chapter 32 of that title (including a proceeding insti-*
 12 *tuted pursuant to the transitional program for cov-*
 13 *ered business method patents, as described in section*
 14 *18 of the Leahy-Smith America Invents Act (35*
 15 *U.S.C. 321 note)), and a derivation proceeding insti-*
 16 *tuted under section 135 of that title.”.*

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

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

22 **SEC. 7. COMMISSION LITIGATION AUTHORITY.**

23 *Section 16(a)(2) of the Federal Trade Commission Act*
 24 *(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)—*

4 *(A) by moving the margin 2 ems to the left;*
 5 *and*

6 *(B) by inserting “or” after the semicolon;*
 7 *and*

8 (3) *by inserting after subparagraph (E) the fol-*
 9 *lowing:*
 10 *“(F) under section 27,”.*

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

12 (1) *IN GENERAL.—Not later than 1 year after*
 13 *the date of enactment of this Act, the Federal Trade*
 14 *Commission shall submit to the Committee on the Ju-*
 15 *diary of the Senate and the Committee on the Judi-*
 16 *ciary of the House of Representatives a recommenda-*
 17 *tion, and the Commission’s basis for such rec-*
 18 *ommendation, regarding a potential amendment to*
 19 *include in section 27(b) of the Federal Trade Com-*
 20 *mission Act (as added by section 3) an additional ex-*
 21 *clusion for consideration granted by an NDA holder*
 22 *to a ANDA filer or by a biological product license*
 23 *holder to a biosimilar biological product application*
 24 *filer as part of the resolution or settlement, a release,*

1 *waiver, or limitation of a claim for damages or other*
 2 *monetary relief.*

3 (2) *DEFINITIONS.—In this section, the terms*
 4 *“ANDA filer”, “biological product license holder”,*
 5 *“biosimilar biological product application filer”, and*
 6 *“NDA holder” have the meanings given such terms in*
 7 *section 27(d) of the Federal Trade Commission Act*
 8 *(as added by section 3).*

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

10 *The Federal Trade Commission shall commence any*
 11 *enforcement proceeding described in section 27 of the Fed-*
 12 *eral Trade Commission Act, as added by section 3, not later*
 13 *than 6 years after the date on which the parties to the agree-*
 14 *ment file the certification under section 1112(d) of the*
 15 *Medicare Prescription Drug, Improvement, and Moderniza-*
 16 *tion Act of 2003 (21 U.S.C. 355 note).*

17 **SEC. 10. SEVERABILITY.**

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

Calendar No. 46

119TH CONGRESS
1ST Session

S. 1096

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.

APRIL 10, 2025

Reported with an amendment