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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

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,*

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:

7 (1) In 1984, the Drug Price Competition and
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
11 of generic drugs while preserving incentives for inno-
12 vation.

13 (2) Prescription drugs make up approximately
14 11 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 91 percent
18 of all prescriptions dispensed in the United States
19 are generic drugs, they account for only 18 percent
20 of all expenditures.

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

24 (5) Federal dollars currently account for over
25 40 percent of the \$449,700,000,000 spent on retail
26 prescription drugs annually.

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

7 (B) These "reverse payment" settlement agree-
8 ments—

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

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

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

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

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

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

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

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

21 (1) to enhance competition in the pharma-
22 ceutical market by stopping anticompetitive agree-
23 ments between brand name and generic drug and
24 biosimilar biological product manufacturers that

1 limit, delay, or otherwise prevent competition from
 2 generic drugs and biosimilar biological products; and
 3 (2) to support the purpose and intent of anti-
 4 trust law by prohibiting anticompetitive practices in
 5 the pharmaceutical industry that harm consumers.

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

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

10 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS**
 11 **AND BIOSIMILARS.**

12 “(a) PROHIBITION.—

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

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

22 “(3) PRESUMPTION.—

23 “(A) IN GENERAL.—Subject to subpara-
 24 graph (B), an agreement described in para-
 25 graph (1) shall be presumed to have anti-

1 competitive effects for purposes of such para-
2 graph if—

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

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

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

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

23 “(ii) the procompetitive benefits of the
24 transfer of value described in subpara-
25 graph (A)(i) and the agreement by the

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

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

25 “(5) CIVIL PENALTY.—

“(A) IN GENERAL.—Each party that violates or assists in the violation of paragraph (1) shall forfeit and pay to the United States a civil penalty sufficient to deter violations of paragraph (1), but in no event greater than 3 times the value received by the party that is reasonably attributable to the violation of paragraph (1). If no such value has been received by the NDA holder, the biological product license holder, the ANDA filer, or the biosimilar biological product application filer, the penalty to the NDA holder, the biological product license holder, the ANDA filer, or the biosimilar biological product application filer shall be sufficient to deter violations, but in no event shall be greater than 3 times the value given to an ANDA filer or biosimilar biological product application filer reasonably attributable to the violation of this section.

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

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

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

14 “(iii) other matters that justice re-
15 quires.

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

22 “(b) EXCLUSIONS.—Nothing in this section shall pro-
23 hibit a resolution or settlement of a patent infringement
24 claim in which the consideration that the ANDA filer or
25 biosimilar biological product application filer, respectively,

1 receives as part of the resolution or settlement includes
2 only one or more of the following:

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

7 “(A) any patent that is the basis for the
8 patent infringement claim; or

9 “(B) any patent right or other statutory
10 exclusivity that would prevent the marketing of
11 such ANDA product or biosimilar biological
12 product.

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

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

17 “(B) for calendar year 2026 and each sub-
18 sequent calendar year, the amount determined
19 for the preceding calendar year adjusted to re-
20 flect the percentage increase (if any) in the
21 Producer Price Index for Legal Services pub-
22 lished by the Bureau of Labor Statistics of the
23 Department of Labor for the most recent cal-
24 endar year.

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

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

16 “(d) DEFINITIONS.—In this section:

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

21 “(2) AGREEMENT RESOLVING OR SETTling A
22 PATENT INFRINGEMENT CLAIM.—The term ‘agree-
23 ment resolving or settling a patent infringement
24 claim’ includes any agreement that is entered into
25 within 30 days of the resolution or the settlement of

1 the claim, or any other agreement that is contingent
2 upon, provides a contingent condition for, or is oth-
3 erwise related to the resolution or settlement of the
4 claim.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 “(19) STATUTORY EXCLUSIVITY.—The term
17 ‘statutory exclusivity’ means those prohibitions on
18 the submission or the approval of drug applications
19 under clauses (ii) through (iv) of section
20 505(c)(3)(E), clauses (ii) through (iv) of section
21 505(j)(5)(F), section 527, section 505A, or section
22 505E of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 355(c)(3)(E), 360cc, 355a, 355f), or on
24 the submission or licensing of biological product ap-
25 plications under section 351(k)(7) or paragraph (2)

1 or (3) of section 351(m) of the Public Health Serv-
 2 ice Act (42 U.S.C. 262) or under section 527 of the
 3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 4 360cc).”.

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

10 **SEC. 4. CERTIFICATION OF AGREEMENTS.**

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

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

24 “(d) CERTIFICATION.—The Chief Executive Officer
 25 or the company official responsible for negotiating any

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

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

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

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

23 **SEC. 5. NOTIFICATION OF AGREEMENTS.**

24 Section 1112 of the Medicare Prescription Drug, Im-
 25 provement, and Modernization Act of 2003 (21 U.S.C.

1 355 note), as amended by section 4(b), is further amended
 2 by adding at the end the following:

3 “(e) RULE OF CONSTRUCTION.—

4 “(1) IN GENERAL.—An agreement that is re-
 5 quired under subsection (a) or (b) shall include
 6 agreements resolving any outstanding disputes, in-
 7 cluding agreements resolving or settling a Patent
 8 Trial and Appeal Board proceeding.

9 “(2) DEFINITION.—For purposes of subpara-
 10 graph (A), the term ‘Patent Trial and Appeal Board
 11 proceeding’ means a proceeding conducted by the
 12 Patent Trial and Appeal Board of the United States
 13 Patent and Trademark Office, including an inter
 14 partes review instituted under chapter 31 of title 35,
 15 United States Code, a post-grant review instituted
 16 under chapter 32 of that title (including a pro-
 17 ceeding instituted pursuant to the transitional pro-
 18 gram for covered business method patents, as de-
 19 scribed in section 18 of the Leahy-Smith America
 20 Invents Act (35 U.S.C. 321 note)), and a derivation
 21 proceeding instituted under section 135 of that
 22 title.”.

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

24 Section 505(j)(5)(D)(i)(V) of the Federal Food,
 25 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))

1 is amended by inserting “section 27 of the Federal Trade
 2 Commission Act or” after “that the agreement has vio-
 3 lated”.

4 **SEC. 7. COMMISSION LITIGATION AUTHORITY.**

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

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

9 (2) in subparagraph (E)—

10 (A) by moving the margin 2 ems to the
 11 left; and

12 (B) by inserting “or” after the semicolon;
 13 and

14 (3) inserting after subparagraph (E) the fol-
 15 lowing:

16 “(F) under section 27,”.

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

18 (1) IN GENERAL.—Not later than 1 year after
 19 the date of enactment of this Act, the Federal Trade
 20 Commission shall submit to the Committee on the
 21 Judiciary of the Senate and the Committee on the
 22 Judiciary of the House of Representatives a rec-
 23 ommendation, and the Commission’s basis for such
 24 recommendation, regarding a potential amendment
 25 to include in section 27(b) of the Federal Trade

1 Commission Act (as added by section 3) an addi-
2 tional exclusion for consideration granted by an
3 NDA holder to a ANDA filer or by a biological prod-
4 uct license holder to a biosimilar biological product
5 application filer as part of the resolution or settle-
6 ment, a release, waiver, or limitation of a claim for
7 damages or other monetary relief.

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

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

15 The Federal Trade Commission shall commence any
16 enforcement proceeding described in section 27 of the
17 Federal Trade Commission Act, as added by section 3, not
18 later than 6 years after the date on which the parties to
19 the agreement file the certification under section 1112(d)
20 of the Medicare Prescription Drug Improvement and Mod-
21 ernization Act of 2003 (21 U.S.C. 355 note).

22 **SEC. 10. SEVERABILITY.**

23 If any provision of this Act, an amendment made by
24 this Act, or the application of such provision or amend-
25 ment to any person or circumstance is held to be unconsti-

1 tutional, the remainder of this Act, the amendments made
2 by this Act, and the application of the provisions of such
3 Act or amendments to any person or circumstance shall
4 not be affected.

