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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.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 9, 2015

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

A BILL

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.

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 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)

1 (referred to in this Act as the “1984 Act”), was en-
2 acted with the intent of facilitating the early entry
3 of generic drugs while preserving incentives for inno-
4 vation.

5 (2) Prescription drugs make up approximately
6 10 percent of the national health care spending.

7 (3) Until recently, the 1984 Act was successful
8 in facilitating generic competition to the benefit of
9 consumers and health care payers, although 86 per-
10 cent of all prescriptions dispensed in the United
11 States are generic drugs, they account for only 27
12 percent of all expenditures.

13 (4) Generic drugs cost substantially less than
14 brand name drugs, with discounts off the brand
15 price averaging 80 to 85 percent.

16 (5) Federal dollars currently account for an es-
17 timated 38.6 percent of the \$271,000,000,000 spent
18 on prescription drugs, and this share is expected to
19 rise to 47 percent by 2023.

20 (6)(A) In recent years, the intent of the 1984
21 Act has been subverted by certain settlement agree-
22 ments in which brand name companies transfer
23 value to their potential generic competitors to settle
24 claims that the generic company is infringing the
25 branded company’s patents.

1 (B) These “reverse payment” settlement agree-
2 ments—

3 (i) allow a branded company to share its
4 monopoly profits with the generic company as a
5 way to protect the branded company’s monop-
6 oly; and

7 (ii) have unduly delayed the marketing of
8 low-cost generic drugs contrary to free competi-
9 tion, the interests of consumers, and the prin-
10 ciples underlying antitrust law.

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

16 (D) These agreements result in consumers los-
17 ing the benefits that the 1984 Act was intended to
18 provide.

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

20 (1) to enhance competition in the pharma-
21 ceutical market by stopping anticompetitive agree-
22 ments between brand name and generic drug manu-
23 facturers that limit, delay, or otherwise prevent com-
24 petition from generic drugs; and

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

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

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

8 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE**
 9 **GENERICIS.**

10 “(a) IN GENERAL.—

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

17 “(2) PRESUMPTION AND VIOLATION.—

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

22 “(i) an ANDA filer receives anything
 23 of value, including an exclusive license; and

24 “(ii) the ANDA filer agrees to limit or
 25 forego research, development, manufac-

1 turing, marketing, or sales of the ANDA
2 product for any period of time.

3 “(B) EXCEPTION.—Subparagraph (A)
4 shall not apply if the parties to such agreement
5 demonstrate by clear and convincing evidence
6 that—

7 “(i) the value described in subpara-
8 graph (A)(i) is compensation solely for
9 other goods or services that the ANDA
10 filer has promised to provide; or

11 “(ii) the procompetitive benefits of the
12 agreement outweigh the anticompetitive ef-
13 fects of the agreement.

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

17 “(1) that entry would not have occurred until
18 the expiration of the relevant patent or statutory ex-
19 clusivity; or

20 “(2) that the agreement’s provision for entry of
21 the ANDA product prior to the expiration of the rel-
22 evant patent or statutory exclusivity means that the
23 agreement is procompetitive.

24 “(c) EXCLUSIONS.—Nothing in this section shall pro-
25 hibit a resolution or settlement of a patent infringement

1 claim in which the consideration granted by the NDA
2 holder to the ANDA filer as part of the resolution or set-
3 tlement includes only one or more of the following:

4 “(1) The right to market the ANDA product in
5 the United States prior to the expiration of—

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

8 “(B) any patent right or other statutory
9 exclusivity that would prevent the marketing of
10 such drug.

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

13 “(3) A covenant not to sue on any claim that
14 the ANDA product infringes a United States patent.

15 “(d) ENFORCEMENT.—

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

18 “(2) JUDICIAL REVIEW.—

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

1 “(i) the United States Court of Ap-
 2 peals 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
 7 Regulations, or any successor thereto, of
 8 the NDA holder is incorporated as of the
 9 date that the NDA is filed with the Com-
 10 missioner of Food and Drugs; or

11 “(iii) the United States Court of Ap-
 12 peals for the circuit in which the ultimate
 13 parent entity of the ANDA filer is incor-
 14 porated as of the date that the ANDA is
 15 filed with the Commissioner of Food and
 16 Drugs.

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

22 “(e) ANTITRUST LAWS.—Nothing in this section
 23 shall be construed to modify, impair, or supersede the ap-
 24 plicability of the antitrust laws as defined in subsection
 25 (a) of the first section of the Clayton Act (15 U.S.C.

1 12(a)), and of section 5 of this Act to the extent that sec-
2 tion 5 applies to unfair methods of competition. Nothing
3 in this section shall modify, impair, limit, or supersede the
4 right of an ANDA filer to assert claims or counterclaims
5 against any person, under the antitrust laws or other laws
6 relating to unfair competition.

7 “(f) PENALTIES.—

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

15 “(C) other matters that justice requires.

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

22 “(g) DEFINITIONS.—In this section:

23 “(1) AGREEMENT.—The term ‘agreement’
24 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 Commission of Food and Drugs 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) DRUG PRODUCT.—The term ‘drug prod-
4 uct’ has the meaning given such term in section
5 314.3(b) of title 21, Code of Federal Regulations (or
6 any successor regulation).

7 “(7) NDA.—The term ‘NDA’ means a new
8 drug application filed under section 505(b) of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 355(b)).

11 “(8) NDA HOLDER.—The term ‘NDA holder’
12 means—

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

15 “(B) a person owning or controlling en-
16 forcement of the patent listed in the Approved
17 Drug Products With Therapeutic Equivalence
18 Evaluations (commonly known as the ‘FDA Or-
19 ange Book’) in connection with the NDA; or

20 “(C) the predecessors, subsidiaries, divi-
21 sions, groups, and affiliates controlled by, con-
22 trolling, or under common control with any of
23 the entities described in subparagraphs (A) and
24 (B) (such control to be presumed by direct or
25 indirect share ownership of 50 percent or great-

1 er), as well as the licensees, licensors, succes-
2 sors, and assigns of each of the entities.

3 “(9) PARTY.—The term ‘party’ means any per-
4 son, partnership, corporation, or other legal entity.

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

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

18 “(12) STATUTORY EXCLUSIVITY.—The term
19 ‘statutory exclusivity’ means those prohibitions on
20 the approval of drug applications under clauses (ii)
21 through (iv) of section 505(c)(3)(E) (5- and 3-year
22 data exclusivity), section 527 (orphan drug exclu-
23 sivity), or section 505A (pediatric exclusivity) of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 355(c)(3)(E), 360cc, 355a).”.

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

8 **SEC. 4. NOTICE AND CERTIFICATION OF AGREEMENTS.**

9 (a) NOTICE OF ALL AGREEMENTS.—Section
 10 1112(c)(2) of the Medicare Prescription Drug, Improve-
 11 ment, and Modernization Act of 2003 (21 U.S.C. 355
 12 note) is amended by—

13 (1) striking “the Commission the” and insert-
 14 ing the following: “the Commission—

15 “(A) the”;

16 (2) striking the period and inserting “; and”;
 17 and

18 (3) inserting at the end the following:

19 “(B) any other agreement the parties enter
 20 into within 30 days of entering into an agree-
 21 ment covered by subsection (a) or (b).”.

22 (b) CERTIFICATION OF AGREEMENTS.—Section 1112
 23 of such Act is 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) shall execute and file with
 3 the Assistant Attorney General and the Commission a cer-
 4 tification as follows: ‘I declare that the following is true,
 5 correct, and complete to the best of my knowledge: The
 6 materials filed with the Federal Trade Commission and
 7 the Department of Justice under section 1112 of subtitle
 8 B of title XI of the Medicare Prescription Drug, Improve-
 9 ment, and Modernization Act of 2003, with respect to the
 10 agreement referenced in this certification—

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

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

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

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

23 Section 505(j)(5)(D)(i)(V) of the Federal Food,
 24 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))
 25 is amended by inserting “section 27 of the Federal Trade

1 Commission Act or” after “that the agreement has vio-
2 lated”.

3 **SEC. 6. COMMISSION LITIGATION AUTHORITY.**

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

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

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

10 (3) inserting after subparagraph (E) the fol-
11 lowing:

12 “(F) under section 27;”.

13 **SEC. 7. STATUTE OF LIMITATIONS.**

14 The Federal Trade Commission shall commence any
15 enforcement proceeding described in section 27 of the
16 Federal Trade Commission Act, as added by section 3, ex-
17 cept for an action described in section 27(f)(2) of the Fed-
18 eral Trade Commission Act, not later than 6 years after
19 the date on which the parties to the agreement file the
20 Notice of Agreement as provided by sections 1112(c)(2)
21 and (d) of the Medicare Prescription Drug Improvement
22 and Modernization Act of 2003 (21 U.S.C. 355 note).

23 **SEC. 8. SEVERABILITY.**

24 If any provision of this Act, an amendment made by
25 this Act, or the application of such provision or amend-

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

