

113TH CONGRESS
1ST SESSION

S. _____

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

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

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 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “Preserve Access to Af-
3 fordable Generics 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-

1 acted with the intent of facilitating the early entry
2 of generic drugs while preserving incentives for inno-
3 vation.

4 (2) Prescription drugs make up 10 percent of
5 the national health care spending but for the past
6 decade have been one of the fastest growing seg-
7 ments of health care expenditures.

8 (3) Until recently, the 1984 Act was successful
9 in facilitating generic competition to the benefit of
10 consumers and health care payers—although 67 per-
11 cent of all prescriptions dispensed in the United
12 States are generic drugs, they account for only 20
13 percent of all expenditures.

14 (4) Generic drugs cost substantially less than
15 brand name drugs, with discounts off the brand
16 price sometimes exceeding 90 percent.

17 (5) Federal dollars currently account for an es-
18 timated 35 percent of the \$263,000,000,000 spent
19 on prescription drugs, and this share is expected to
20 rise to 42 percent by 2021.

21 (6)(A) In recent years, the intent of the 1984
22 Act has been subverted by certain settlement agree-
23 ments between brand companies and their potential
24 generic competitors that make “reverse payments”

1 which are payments by the brand company to the
2 generic company.

3 (B) These settlement agreements have unduly
4 delayed the marketing of low-cost generic drugs con-
5 trary to free competition, the interests of consumers,
6 and the principles underlying antitrust law.

7 (C) Because of the price disparity between
8 brand name and generic drugs, such agreements are
9 more profitable for both the brand and generic man-
10 ufacturers than competition, and will become in-
11 creasingly common unless prohibited.

12 (D) These agreements result in consumers los-
13 ing the benefits that the 1984 Act was intended to
14 provide.

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

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

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

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

2 The Federal Trade Commission Act (15 U.S.C. 44
3 et seq.) is amended by—

- 4 (1) redesignating section 28 as section 29; and
5 (2) inserting before section 29, as redesignated,
6 the following:

7 **“SEC. 28. PRESERVING ACCESS TO AFFORDABLE**
8 **GENERICS.**

9 “(a) IN GENERAL.—

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

16 “(2) PRESUMPTION.—

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

21 “(i) an ANDA filer receives anything
22 of value; and

23 “(ii) the ANDA filer agrees to limit or
24 forego research, development, manufac-
25 turing, marketing, or sales of the ANDA
26 product for any period of time.

1 “(B) EXCEPTION.—The presumption in
2 subparagraph (A) shall not apply if the parties
3 to such agreement demonstrate by clear and
4 convincing evidence that the procompetitive
5 benefits of the agreement outweigh the anti-
6 competitive effects of the agreement.

7 “(b) COMPETITIVE FACTORS.—In determining
8 whether the settling parties have met their burden under
9 subsection (a)(2)(B), the fact finder shall consider—

10 “(1) the length of time remaining until the end
11 of the life of the relevant patent, compared with the
12 agreed upon entry date for the ANDA product;

13 “(2) the value to consumers of the competition
14 from the ANDA product allowed under the agree-
15 ment;

16 “(3) the form and amount of consideration re-
17 ceived by the ANDA filer in the agreement resolving
18 or settling the patent infringement claim;

19 “(4) the revenue the ANDA filer would have re-
20 ceived by winning the patent litigation;

21 “(5) the reduction in the NDA holder’s reve-
22 nues if it had lost the patent litigation;

23 “(6) the time period between the date of the
24 agreement conveying value to the ANDA filer and

1 the date of the settlement of the patent infringement
2 claim; and

3 “(7) any other factor that the fact finder, in its
4 discretion, deems relevant to its determination of
5 competitive effects under this subsection.

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

9 “(1) that entry would not have occurred until
10 the expiration of the relevant patent or statutory ex-
11 clusivity; or

12 “(2) that the agreement’s provision for entry of
13 the ANDA product prior to the expiration of the rel-
14 evant patent or statutory exclusivity means that the
15 agreement is pro-competitive, although such evidence
16 may be relevant to the fact finder’s determination
17 under this section.

18 “(d) EXCLUSIONS.—Nothing in this section shall pro-
19 hibit a resolution or settlement of a patent infringement
20 claim in which the consideration granted by the NDA
21 holder to the ANDA filer as part of the resolution or set-
22 tlement includes only one or more of the following:

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

1 “(A) any patent that is the basis for the
2 patent infringement claim; or

3 “(B) any patent right or other statutory
4 exclusivity that would prevent the marketing of
5 such drug.

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

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

10 “(e) REGULATIONS AND ENFORCEMENT.—

11 “(1) REGULATIONS.—The Federal Trade Com-
12 mission may issue, in accordance with section 553 of
13 title 5, United States Code, regulations imple-
14 menting and interpreting this section. These regula-
15 tions may exempt certain types of agreements de-
16 scribed in subsection (a) if the Commission deter-
17 mines such agreements will further market competi-
18 tion and benefit consumers. Judicial review of any
19 such regulation shall be in the United States Dis-
20 trict Court for the District of Columbia pursuant to
21 section 706 of title 5, United States Code.

22 “(2) ENFORCEMENT.—A violation of this sec-
23 tion shall be treated as a violation of section 5.

24 “(3) JUDICIAL REVIEW.—Any person, partner-
25 ship or corporation that is subject to a final order

1 of the Commission, issued in an administrative adju-
2 dicative proceeding under the authority of subsection
3 (a)(1), may, within 30 days of the issuance of such
4 order, petition for review of such order in the United
5 States Court of Appeals for the District of Columbia
6 Circuit or the United States Court of Appeals for
7 the circuit in which the ultimate parent entity, as
8 defined at 16 CFR 801.1(a)(3), of the NDA holder
9 is incorporated as of the date that the NDA is filed
10 with the Secretary of the Food and Drug Adminis-
11 tration, or the United States Court of Appeals for
12 the circuit in which the ultimate parent entity of the
13 ANDA filer is incorporated as of the date that the
14 ANDA is filed with the Secretary of the Food and
15 Drug Administration. In such a review proceeding,
16 the findings of the Commission as to the facts, if
17 supported by evidence, shall be conclusive.

18 “(f) ANTITRUST LAWS.—Nothing in this section shall
19 be construed to modify, impair or supersede the applica-
20 bility of the antitrust laws as defined in subsection (a)
21 of the 1st section of the Clayton Act (15 U.S.C. 12(a))
22 and of section 5 of this Act to the extent that section 5
23 applies to unfair methods of competition. Nothing in this
24 section shall modify, impair, limit or supersede the right
25 of an ANDA filer to assert claims or counterclaims against

1 any person, under the antitrust laws or other laws relating
2 to unfair competition.

3 “(g) PENALTIES.—

4 “(1) FORFEITURE.—Each person, partnership
5 or corporation that violates or assists in the violation
6 of this section shall forfeit and pay to the United
7 States a civil penalty sufficient to deter violations of
8 this section, but in no event greater than 3 times the
9 value received by the party that is reasonably attrib-
10 utable to a violation of this section. If no such value
11 has been received by the NDA holder, the penalty to
12 the NDA holder shall be shall be sufficient to deter
13 violations, but in no event greater than 3 times the
14 value given to the ANDA filer reasonably attrib-
15 utable to the violation of this section. Such penalty
16 shall accrue to the United States and may be recov-
17 ered in a civil action brought by the Federal Trade
18 Commission, in its own name by any of its attorneys
19 designated by it for such purpose, in a district court
20 of the United States against any person, partnership
21 or corporation that violates this section. In such ac-
22 tions, the United States district courts are empow-
23 ered to grant mandatory injunctions and such other
24 and further equitable relief as they deem appro-
25 priate.

1 “(2) CEASE AND DESIST.—

2 “(A) IN GENERAL.—If the Commission has
3 issued a cease and desist order with respect to
4 a person, partnership or corporation in an ad-
5 ministrative adjudicative proceeding under the
6 authority of subsection (a)(1), an action
7 brought pursuant to paragraph (1) may be
8 commenced against such person, partnership or
9 corporation at any time before the expiration of
10 one year after such order becomes final pursu-
11 ant to section 5(g).

12 “(B) EXCEPTION.—In an action under
13 subparagraph (A), the findings of the Commis-
14 sion as to the material facts in the administra-
15 tive adjudicative proceeding with respect to
16 such person’s, partnership’s or corporation’s
17 violation of this section shall be conclusive un-
18 less—

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 “(h) 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, as defined under
14 section 505(j) of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 355(j)).

16 “(4) ANDA FILER.—The term ‘ANDA filer’
17 means a party who has filed an ANDA with the
18 Food and Drug Administration.

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

23 “(6) DRUG PRODUCT.—The term ‘drug prod-
24 uct’ means a finished dosage form (e.g., tablet, cap-
25 sule, or solution) that contains a drug substance,

1 generally, but not necessarily, in association with 1
2 or more other ingredients, as defined in section
3 314.3(b) of title 21, Code of Federal Regulations.

4 “(7) NDA.—The term ‘NDA’ means a new
5 drug application, as defined under section 505(b) of
6 the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 355(b)).

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

10 “(A) the party that received FDA approval
11 to market a drug product pursuant to an NDA;

12 “(B) a party owning or controlling enforce-
13 ment of the patent listed in the Approved Drug
14 Products With Therapeutic Equivalence Eval-
15 uations (commonly known as the ‘FDA Orange
16 Book’) in connection with the NDA; 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) PATENT INFRINGEMENT.—The term ‘pat-
2 ent infringement’ means infringement of any patent
3 or of any filed patent application, extension, reissue,
4 renewal, division, continuation, continuation in part,
5 reexamination, patent term restoration, patents of
6 addition and extensions thereof.

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

14 “(11) STATUTORY EXCLUSIVITY.—The term
15 ‘statutory exclusivity’ means those prohibitions on
16 the approval of drug applications under clauses (ii)
17 through (iv) of section 505(c)(3)(E) (5- and 3-year
18 data exclusivity), section 527 (orphan drug exclu-
19 sivity), or section 505A (pediatric exclusivity) of the
20 Federal Food, Drug, and Cosmetic Act.”.

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

22 (a) NOTICE OF ALL AGREEMENTS.—Section
23 1112(c)(2) of the Medicare Prescription Drug, Improve-
24 ment, and Modernization Act of 2003 (21 U.S.C. 355
25 note) is amended by—

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

3 “(1) the”;

4 (2) striking the period and inserting “; and”;
5 and

6 (3) inserting at the end the following:

7 “(2) any other agreement the parties enter into
8 within 30 days of entering into an agreement cov-
9 ered by subsection (a) or (b).”.

10 (b) CERTIFICATION OF AGREEMENTS.—Section 1112
11 of such Act is amended by adding at the end the following:

12 “(d) CERTIFICATION.—The Chief Executive Officer
13 or the company official responsible for negotiating any
14 agreement required to be filed under subsection (a), (b),
15 or (c) shall execute and file with the Assistant Attorney
16 General and the Commission a certification as follows: ‘I
17 declare that the following is true, correct, and complete
18 to the best of my knowledge: The materials filed with the
19 Federal Trade Commission and the Department of Justice
20 under section 1112 of subtitle B of title XI of the Medi-
21 care Prescription Drug, Improvement, and Modernization
22 Act of 2003, with respect to the agreement referenced in
23 this certification: (1) represent the complete, final, and ex-
24 clusive agreement between the parties; (2) include any an-
25 cillary agreements that are contingent upon, provide a

1 contingent condition for, or are otherwise related to, the
2 referenced agreement; and (3) include written descriptions
3 of any oral agreements, representations, commitments, or
4 promises between the parties that are responsive to sub-
5 section (a) or (b) of such section 1112 and have not been
6 reduced to writing.’.’.

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

8 Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug
9 and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is
10 amended by inserting “section 28 of the Federal Trade
11 Commission Act or” after “that the agreement has vio-
12 lated”.

13 **SEC. 6. COMMISSION LITIGATION AUTHORITY.**

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

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

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

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

22 “(F) under section 28;”.

23 **SEC. 7. STATUTE OF LIMITATIONS.**

24 The Commission shall commence any enforcement
25 proceeding described in section 28 of the Federal Trade

1 Commission Act, as added by section 3, except for an ac-
2 tion described in section 28(g)(2) of the Federal Trade
3 Commission Act, not later than 3 years after the date on
4 which the parties to the agreement file the Notice of
5 Agreement as provided by sections 1112(c)(2) and (d) of
6 the Medicare Prescription Drug Improvement and Mod-
7 ernization Act of 2003 (21 U.S.C. 355 note).

8 **SEC. 8. SEVERABILITY.**

9 If any provision of this Act, an amendment made by
10 this Act, or the application of such provision or amend-
11 ment to any person or circumstance is held to be unconsti-
12 tutional, the remainder of this Act, the amendments made
13 by this Act, and the application of the provisions of such
14 Act or amendments to any person or circumstance shall
15 not be affected thereby.