

114TH CONGRESS
1ST SESSION

S. _____

To ensure greater affordability of prescription drugs.

IN THE SENATE OF THE UNITED STATES

Mr. SANDERS introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To ensure greater affordability of prescription drugs.

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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Prescription Drug Affordability Act of 2015”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—DRUGS UNDER THE MEDICARE PROGRAM

Sec. 101. Negotiation of lower covered part D drug prices on behalf of Medicare beneficiaries.

Sec. 102. Acceleration of the closing of the Medicare Part D donut hole.

TITLE II—PRESCRIPTION DRUG IMPORTATION

Sec. 201. Prescription drug importation.

Sec. 202. Sense of the Senate regarding trade agreements.

TITLE III—MEDICARE AND MEDICAID REBATES

Sec. 301. Requiring drug manufacturers to provide drug rebates for drugs dispensed to low-income individuals.

Sec. 302. Applying the medicaid additional rebate requirement to generic drugs.

TITLE IV—PAY-FOR-DELAY BLOCKING

Sec. 401. Preserving access to affordable generics.

TITLE V—FRAUD

Sec. 501. Conditions on award of drug exclusivity.

TITLE VI—TRANSPARENCY

Sec. 601. Drug manufacturer reporting.

1 **TITLE I—DRUGS UNDER THE**
 2 **MEDICARE PROGRAM**

3 **SEC. 101. NEGOTIATION OF LOWER COVERED PART D DRUG**
 4 **PRICES ON BEHALF OF MEDICARE BENE-**
 5 **FICIARIES.**

6 (a) NEGOTIATION BY SECRETARY.—Section 1860D–
 7 11 of the Social Security Act (42 U.S.C. 1395w–111) is
 8 amended by striking subsection (i) (relating to noninter-
 9 ference) and inserting the following:

10 “(i) NEGOTIATION OF LOWER DRUG PRICES.—

11 “(1) IN GENERAL.—Notwithstanding any other
 12 provision of law, the Secretary shall negotiate with
 13 pharmaceutical manufacturers the prices (including
 14 discounts, rebates, and other price concessions) that
 15 may be charged to PDP sponsors and MA organiza-
 16 tions for covered part D drugs for part D eligible in-

1 individuals who are enrolled under a prescription drug
2 plan or under an MA–PD plan.

3 “(2) NO CHANGE IN RULES FOR
4 FORMULARIES.—

5 “(A) IN GENERAL.—Nothing in paragraph
6 (1) shall be construed to authorize the Sec-
7 retary to establish or require a particular for-
8 mulary.

9 “(B) CONSTRUCTION.—Subparagraph (A)
10 shall not be construed as affecting the Sec-
11 retary’s authority to ensure appropriate and
12 adequate access to covered part D drugs under
13 prescription drug plans and under MA–PD
14 plans, including compliance of such plans with
15 formulary requirements under section 1860D–
16 4(b)(3).

17 “(3) CONSTRUCTION.—Nothing in this sub-
18 section shall be construed as preventing the sponsor
19 of a prescription drug plan, or an organization offer-
20 ing an MA–PD plan, from obtaining a discount or
21 reduction of the price for a covered part D drug
22 below the price negotiated under paragraph (1).”.

23 (b) EFFECTIVE DATE.—The amendment made by
24 subsection (a) shall take effect on the date of the enact-

1 ment of this Act and shall first apply to negotiations and
2 prices for plan years beginning on January 1, 2016.

3 **SEC. 102. ACCELERATION OF THE CLOSING OF THE MEDI-**
4 **CARE PART D DONUT HOLE.**

5 (a) REDUCTION IN COINSURANCE.—Section 1860D–
6 2(b)(2) of the Social Security Act (42 U.S.C. 1395w–
7 102(b)(2)) is amended—

8 (1) in each of subclauses (II) and (III) of sub-
9 paragraph (C)(ii), by striking “2020” and inserting
10 “2017”; and

11 (2) in subparagraph (D)(ii)—

12 (A) in subclause (II), by inserting “and”
13 at the end; and

14 (B) by striking clauses (III) through (VI)
15 and inserting the following:

16 “(III) 2017 is 100 percent.”.

17 (b) INCREASE IN MANUFACTURER REBATE.—Section
18 1860D–14A(g)(4)(A) of the Social Security Act (42
19 U.S.C. 1395w–114a(g)(4)(A)) is amended by inserting
20 “(or, for 2017 and subsequent years, 75 percent)” after
21 “50 percent”.

1 **TITLE II—PRESCRIPTION DRUG**
2 **IMPORTATION**

3 **SEC. 201. PRESCRIPTION DRUG IMPORTATION.**

4 (a) IMPORTATION BY PHARMACISTS AND WHOLE-
5 SALERS.—Section 804(b) of the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 384(b)) is amended by striking
7 “The Secretary,” and inserting “The Secretary, not later
8 than January 1, 2016,”.

9 (b) IMPORTATION BY INDIVIDUALS.—

10 (1) IN GENERAL.—Section 804 of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 384) is
12 amended—

13 (A) in subsection (f), by striking “within
14 Canada”;

15 (B) in subsection (j)—

16 (i) in paragraph (1), in the matter
17 preceding subparagraph (A), by inserting
18 “from countries other than Canada” after
19 “devices”; and

20 (ii) in paragraph (3)—

21 (I) in the heading, by striking
22 “FROM CANADA” and inserting “FROM
23 COUNTRIES OTHER THAN CANADA”;
24 and

1 (II) in subparagraph (C), by
2 striking “from Canada,”; and

3 (C) by striking subsection (l) and inserting
4 the following:

5 “(l) IMPORTATION OF PRESCRIPTION DRUGS FROM
6 CANADA.—Individuals may import from Canada any pre-
7 scription drug that meets the requirements of subpara-
8 graphs (A) through (F) of subsection (j)(3).”.

9 (2) REGULATIONS.—Not later than January 1,
10 2016, the Secretary of Health and Human Services
11 shall promulgate regulations with respect to sub-
12 section (l) of section 804 of the Federal Food, Drug,
13 and Cosmetic Act (21 U.S.C. 384) (as amended by
14 paragraph (1)(B)).

15 (3) EFFECTIVE DATE.—The amendments made
16 by paragraph (1) shall take effect on the effective
17 date of the final regulations promulgated in accord-
18 ance with paragraph (2).

19 (c) FDASIA AMENDMENT.—Subsection (c) of sec-
20 tion 708 of the Food and Drug Administration Safety and
21 Innovation Act (Public Law 112–144; 126 Stat. 1068) is
22 amended by striking “The amendment made by” and all
23 that follows through the period at the end and inserting
24 “The amendment made by subsection (a) and the regula-
25 tions promulgated under subsection (b) shall apply begin-

1 ning on the effective date of the regulations promulgated
2 under section 804(b) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 384(b)) and the amendments made
4 by section 201(b) of the Prescription Drug Affordability
5 Act of 2015.”.

6 **SEC. 202. SENSE OF THE SENATE REGARDING TRADE**
7 **AGREEMENTS.**

8 It is the sense of the Senate that the United States
9 Trade Representative should not negotiate trade agree-
10 ments that would raise the prices of prescription drugs
11 in the United States, extend the periods of market exclu-
12 sivity otherwise available for prescription drugs, or remove
13 flexibility in Federal or State law regarding pricing of pre-
14 scription drugs.

15 **TITLE III—MEDICARE AND**
16 **MEDICAID REBATES**

17 **SEC. 301. REQUIRING DRUG MANUFACTURERS TO PROVIDE**
18 **DRUG REBATES FOR DRUGS DISPENSED TO**
19 **LOW-INCOME INDIVIDUALS.**

20 (a) IN GENERAL.—Section 1860D–2 of the Social
21 Security Act (42 U.S.C. 1395w–102) is amended—

22 (1) in subsection (e)(1), in the matter preceding
23 subparagraph (A), by inserting “and subsection (f)”
24 after “this subsection”; and

1 (2) by adding at the end the following new sub-
2 section:

3 “(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR
4 REBATE ELIGIBLE INDIVIDUALS.—

5 “(1) REQUIREMENT.—

6 “(A) IN GENERAL.—For plan years begin-
7 ning on or after January 1, 2017, in this part,
8 the term ‘covered part D drug’ does not include
9 any drug or biological product that is manufac-
10 tured by a manufacturer that has not entered
11 into and have in effect a rebate agreement de-
12 scribed in paragraph (2).

13 “(B) 2016 PLAN YEAR REQUIREMENT.—
14 Any drug or biological product manufactured by
15 a manufacturer that declines to enter into a re-
16 bate agreement described in paragraph (2) for
17 the period beginning on January 1, 2016, and
18 ending on December 31, 2016, shall not be in-
19 cluded as a ‘covered part D drug’ for the subse-
20 quent plan year.

21 “(2) REBATE AGREEMENT.—A rebate agree-
22 ment under this subsection shall require the manu-
23 facturer to provide to the Secretary a rebate for
24 each rebate period (as defined in paragraph (6)(B))
25 ending after December 31, 2015, in the amount

1 specified in paragraph (3) for any covered part D
2 drug of the manufacturer dispensed after December
3 31, 2015, to any rebate eligible individual (as de-
4 fined in paragraph (6)(A)) for which payment was
5 made by a PDP sponsor or MA organization under
6 this part for such period, including payments passed
7 through the low-income and reinsurance subsidies
8 under sections 1860D–14 and 1860D–15(b), respec-
9 tively. Such rebate shall be paid by the manufac-
10 turer to the Secretary not later than 30 days after
11 the date of receipt of the information described in
12 section 1860D–12(b)(7), including as such section is
13 applied under section 1857(f)(3), or 30 days after
14 the receipt of information under subparagraph (D)
15 of paragraph (3), as determined by the Secretary.
16 Insofar as not inconsistent with this subsection, the
17 Secretary shall establish terms and conditions of
18 such agreement relating to compliance, penalties,
19 and program evaluations, investigations, and audits
20 that are similar to the terms and conditions for re-
21 bate agreements under paragraphs (3) and (4) of
22 section 1927(b).

23 “(3) REBATE FOR REBATE ELIGIBLE MEDICARE
24 DRUG PLAN ENROLLEES.—

1 “(B) MEDICAID REBATE AMOUNT.—For
2 purposes of this paragraph, the term ‘Medicaid
3 rebate amount’ means, with respect to each
4 dosage form and strength of a covered part D
5 drug provided by the manufacturer for a rebate
6 period—

7 “(i) in the case of a single source
8 drug or an innovator multiple source drug,
9 the amount specified in paragraph
10 (1)(A)(ii)(II) or (2)(C) of section 1927(c)
11 plus the amount, if any, specified in sub-
12 paragraph (A)(ii) of paragraph (2) of such
13 section, for such form, strength, and pe-
14 riod; or

15 “(ii) in the case of any other covered
16 outpatient drug, the amount specified in
17 paragraph (3)(A)(i) of such section for
18 such form, strength, and period.

19 “(C) AVERAGE MEDICARE DRUG PROGRAM
20 REBATE ELIGIBLE REBATE AMOUNT.—For pur-
21 poses of this subsection, the term ‘average
22 Medicare drug program rebate eligible rebate
23 amount’ means, with respect to each dosage
24 form and strength of a covered part D drug
25 provided by a manufacturer for a rebate period,

1 the sum, for all PDP sponsors under part D
2 and MA organizations administering an MA-
3 PD plan under part C, of—

4 “(i) the product, for each such spon-
5 sor or organization, of—

6 “(I) the sum of all rebates, dis-
7 counts, or other price concessions (not
8 taking into account any rebate pro-
9 vided under paragraph (2) or any dis-
10 counts under the program under sec-
11 tion 1860D-14A) for such dosage
12 form and strength of the drug dis-
13 pensed, calculated on a per-unit basis,
14 but only to the extent that any such
15 rebate, discount, or other price con-
16 cession applies equally to drugs dis-
17 pensed to rebate eligible Medicare
18 drug plan enrollees and drugs dis-
19 pensed to PDP and MA-PD enrollees
20 who are not rebate eligible individuals;
21 and

22 “(II) the number of the units of
23 such dosage and strength of the drug
24 dispensed during the rebate period to
25 rebate eligible individuals enrolled in

1 the prescription drug plans adminis-
2 tered by the PDP sponsor or the MA-
3 PD plans administered by the MA or-
4 ganization; divided by

5 “(ii) the total number of units of such
6 dosage and strength of the drug dispensed
7 during the rebate period to rebate eligible
8 individuals enrolled in all prescription drug
9 plans administered by PDP sponsors and
10 all MA-PD plans administered by MA or-
11 ganizations.

12 “(D) USE OF ESTIMATES.—The Secretary
13 may establish a methodology for estimating the
14 average Medicare drug program rebate eligible
15 rebate amounts for each rebate period based on
16 bid and utilization information under this part
17 and may use these estimates as the basis for
18 determining the rebates under this section. If
19 the Secretary elects to estimate the average
20 Medicare drug program rebate eligible rebate
21 amounts, the Secretary shall establish a rec-
22 onciliation process for adjusting manufacturer
23 rebate payments not later than 3 months after
24 the date that manufacturers receive the infor-

1 under title XIX to be eligible for medical
2 assistance under clause (i), (iii), or (iv) of
3 section 1902(a)(10)(E).

4 “(B) REBATE PERIOD.—The term ‘rebate
5 period’ has the meaning given such term in sec-
6 tion 1927(k)(8).”.

7 (b) REPORTING REQUIREMENT FOR THE DETER-
8 MINATION AND PAYMENT OF REBATES BY MANUFACTUR-
9 ERS RELATED TO REBATE FOR REBATE ELIGIBLE MEDI-
10 CARE DRUG PLAN ENROLLEES.—

11 (1) REQUIREMENTS FOR PDP SPONSORS.—Sec-
12 tion 1860D–12(b) of the Social Security Act (42
13 U.S.C. 1395w–112(b)) is amended by adding at the
14 end the following new paragraph:

15 “(7) REPORTING REQUIREMENT FOR THE DE-
16 TERMINATION AND PAYMENT OF REBATES BY MANU-
17 FACTURERS RELATED TO REBATE FOR REBATE ELI-
18 GIBLE MEDICARE DRUG PLAN ENROLLEES.—

19 “(A) IN GENERAL.—For purposes of the
20 rebate under section 1860D–2(f) for contract
21 years beginning on or after January 1, 2017,
22 each contract entered into with a PDP sponsor
23 under this part with respect to a prescription
24 drug plan shall require that the sponsor comply
25 with subparagraphs (B) and (C).

1 “(B) REPORT FORM AND CONTENTS.—Not
2 later than a date specified by the Secretary, a
3 PDP sponsor of a prescription drug plan under
4 this part shall report to each manufacturer—

5 “(i) information (by National Drug
6 Code number) on the total number of units
7 of each dosage, form, and strength of each
8 drug of such manufacturer dispensed to re-
9 bate eligible Medicare drug plan enrollees
10 under any prescription drug plan operated
11 by the PDP sponsor during the rebate pe-
12 riod;

13 “(ii) information on the price dis-
14 counts, price concessions, and rebates for
15 such drugs for such form, strength, and
16 period;

17 “(iii) information on the extent to
18 which such price discounts, price conces-
19 sions, and rebates apply equally to rebate
20 eligible Medicare drug plan enrollees and
21 PDP enrollees who are not rebate eligible
22 Medicare drug plan enrollees; and

23 “(iv) any additional information that
24 the Secretary determines is necessary to
25 enable the Secretary to calculate the aver-

1 shall be treated as being a reference to this
2 section;

3 “(ii) the reference to the Director of
4 the Congressional Budget Office in clause
5 (iii) of such subparagraph shall be treated
6 as including a reference to the Medicare
7 Payment Advisory Commission; and

8 “(iii) clause (iv) of such subparagraph
9 shall not apply.

10 “(E) OVERSIGHT.—Information reported
11 under this paragraph may be used by the In-
12 spector General of the Department of Health
13 and Human Services for the statutorily author-
14 ized purposes of audit, investigation, and eval-
15 uations.

16 “(F) PENALTIES FOR FAILURE TO PRO-
17 VIDE TIMELY INFORMATION AND PROVISION OF
18 FALSE INFORMATION.—In the case of a PDP
19 sponsor—

20 “(i) that fails to provide information
21 required under subparagraph (B) on a
22 timely basis, the sponsor is subject to a
23 civil money penalty in the amount of
24 \$10,000 for each day in which such infor-
25 mation has not been provided; or

1 “(ii) that knowingly (as defined in
2 section 1128A(i)) provides false informa-
3 tion under such subparagraph, the sponsor
4 is subject to a civil money penalty in an
5 amount not to exceed \$100,000 for each
6 item of false information.

7 Such civil money penalties are in addition to
8 other penalties as may be prescribed by law.
9 The provisions of section 1128A (other than
10 subsections (a) and (b)) shall apply to a civil
11 money penalty under this subparagraph in the
12 same manner as such provisions apply to a pen-
13 alty or proceeding under section 1128A(a).”.

14 (2) APPLICATION TO MA ORGANIZATIONS.—Sec-
15 tion 1857(f)(3) of the Social Security Act (42
16 U.S.C. 1395w–27(f)(3)) is amended by adding at
17 the end the following:

18 “(D) REPORTING REQUIREMENT RELATED
19 TO REBATE FOR REBATE ELIGIBLE MEDICARE
20 DRUG PLAN ENROLLEES.—Section 1860D–
21 12(b)(7).”.

22 (c) DEPOSIT OF REBATES INTO MEDICARE PRE-
23 SCRIPTION DRUG ACCOUNT.—Section 1860D–16(c) of the
24 Social Security Act (42 U.S.C. 1395w–116(c)) is amended
25 by adding at the end the following new paragraph:

1 “(6) REBATE FOR REBATE ELIGIBLE MEDICARE
2 DRUG PLAN ENROLLEES.—Amounts paid under a re-
3 bate agreement under section 1860D–2(f) shall be
4 deposited into the Account.”.

5 (d) EXCLUSION FROM DETERMINATION OF BEST
6 PRICE AND AVERAGE MANUFACTURER PRICE UNDER
7 MEDICAID.—

8 (1) EXCLUSION FROM BEST PRICE DETERMINA-
9 TION.—Section 1927(c)(1)(C)(ii)(I) of the Social Se-
10 curity Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is
11 amended by inserting “and amounts paid under a
12 rebate agreement under section 1860D–2(f)” after
13 “this section”.

14 (2) EXCLUSION FROM AVERAGE MANUFAC-
15 TURER PRICE DETERMINATION.—Section
16 1927(k)(1)(B)(i) of the Social Security Act (42
17 U.S.C. 1396r–8(k)(1)(B)(i)) is amended—

18 (A) in subclause (IV), by striking “and”
19 after the semicolon;

20 (B) in subclause (V), by striking the period
21 at the end and inserting “; and”; and

22 (C) by adding at the end the following:

23 “(VI) amounts paid under a re-
24 bate agreement under section 1860D–
25 2(f).”.

1 **SEC. 302. APPLYING THE MEDICAID ADDITIONAL REBATE**
2 **REQUIREMENT TO GENERIC DRUGS.**

3 (a) IN GENERAL.—Section 1927(c)(3) of the Social
4 Security Act (42 U.S.C. 1396r–8(e)(3)) is amended—

5 (1) in subparagraph (A), by striking “The
6 amount” and inserting “Except as provided in sub-
7 paragraph (C), the amount”; and

8 (2) by adding at the end the following new sub-
9 paragraph:

10 “(C) ADDITIONAL REBATE.—

11 “(i) IN GENERAL.—The amount of
12 the rebate specified in this paragraph for
13 a rebate period, with respect to each dos-
14 age form and strength of a covered out-
15 patient drug other than a single source
16 drug or an innovator multiple source drug,
17 shall be increased in the manner that the
18 rebate for a dosage form and strength of
19 a single source drug or an innovator mul-
20 tiple source drug is increased under sub-
21 paragraphs (A) and (D) of paragraph (2),
22 except as provided in clause (ii).

23 “(ii) SPECIAL RULES FOR APPLICA-
24 TION OF PROVISION.—In applying sub-
25 paragraphs (A) and (D) of paragraph (2)
26 under clause (i)—

1 “(I) the reference in subpara-
2 graph (A)(i) of such paragraph to
3 ‘1990’ shall be deemed a reference to
4 ‘2014’;

5 “(II) subject to clause (iii), the
6 reference in subparagraph (A)(ii) of
7 such paragraph to ‘calendar quarter
8 beginning July 1, 1990’ shall be
9 deemed a reference to the ‘calendar
10 quarter in which the average manu-
11 facturer price for the drug is the low-
12 est during the 12-calendar quarter pe-
13 riod ending on September 30, 2014’;
14 and

15 “(III) subject to clause (iii), the
16 reference in subparagraph (A)(ii) of
17 such paragraph to ‘September 1990’
18 shall be deemed a reference to ‘the
19 last month of such calendar quarter’;

20 “(IV) the references in subpara-
21 graph (D) of such paragraph to ‘para-
22 graph (1)(A)(ii)’, ‘this paragraph’,
23 and ‘December 31, 2009’ shall be
24 deemed references to ‘subparagraph

1 (A)', 'this subparagraph', and 'De-
2 cember 31, 2014', respectively; and

3 “(V) any reference in such para-
4 graph to a ‘single source drug or an
5 innovator multiple source drug’ shall
6 be deemed to be a reference to a drug
7 to which clause (i) applies.

8 “(iii) SPECIAL RULE FOR CERTAIN
9 NONINNOVATOR MULTIPLE SOURCE
10 DRUGS.—In applying paragraph
11 (2)(A)(ii)(II) under clause (i) with respect
12 to a covered outpatient drug that is first
13 sold as a drug other than a single source
14 drug or an innovator multiple source drug
15 after the date that is 3 years before the
16 date of the enactment of this subpara-
17 graph, such paragraph shall be applied—

18 “(I) by substituting ‘the applica-
19 ble quarter’ for ‘the calendar quarter
20 beginning July 1, 1990’; and

21 “(II) by substituting ‘the last
22 month in such applicable quarter’ for
23 ‘September 1990’.

24 “(iv) APPLICABLE QUARTER DE-
25 FINED.—In this subsection, the term ‘ap-

1 plicable quarter’ means, with respect to a
2 drug described in clause (iii), the fifth full
3 calendar quarter in which the drug is sold
4 as a drug other than a single source drug
5 or an innovator multiple source drug.”.

6 (b) EFFECTIVE DATE.—The amendments made by
7 subsection (a) shall apply to rebate periods beginning after
8 December 31, 2014.

9 **TITLE IV—PAY-FOR-DELAY**
10 **BLOCKING**

11 **SEC. 401. PRESERVING ACCESS TO AFFORDABLE**
12 **GENERICS.**

13 The Federal Trade Commission Act (15 U.S.C. 44
14 et seq.) is amended by inserting after section 26 (15
15 U.S.C. 57e–2) the following:

16 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE**
17 **GENERICS.**

18 “(a) IN GENERAL.—

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

1 “(2) PRESUMPTION AND VIOLATION.—In such
2 a proceeding, an agreement shall be presumed to
3 have anticompetitive effects and be a violation of
4 this section if—

5 “(A) an ANDA filer receives anything of
6 value, including an exclusive license; and

7 “(B) the ANDA filer agrees to limit or
8 forego research, development, manufacturing,
9 marketing, or sales of the ANDA product for
10 any period of time.

11 “(b) EXCLUSIONS.—Nothing in this section shall pro-
12 hibit a resolution or settlement of a patent infringement
13 claim in which the consideration granted by the NDA
14 holder to the ANDA filer as part of the resolution or set-
15 tlement includes only one or more of the following:

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

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

20 “(B) any patent right or other statutory
21 exclusivity that would prevent the marketing of
22 such drug.

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

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

3 “(c) DEFINITIONS.—In this section:

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

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

17 “(3) ANDA.—The term ‘ANDA’ means an ab-
18 breviated new drug application filed under section
19 505(j) of the Federal Food, Drug, and Cosmetic Act
20 (21 U.S.C. 355(j)) or a new drug application filed
21 under section 505(b)(2) of the Federal Food, Drug,
22 and Cosmetic Act (21 U.S.C. 355(b)(2)).

23 “(4) ANDA FILER.—The term ‘ANDA filer’
24 means a party that owns or controls an ANDA filed
25 with the Commission of Food and Drugs or has the

1 exclusive rights under such ANDA to distribute the
2 ANDA product.

3 “(5) ANDA PRODUCT.—The term ‘ANDA
4 product’ means the product to be manufactured
5 under the ANDA that is the subject of the patent
6 infringement claim.

7 “(6) DRUG PRODUCT.—The term ‘drug prod-
8 uct’ has the meaning given such term in section
9 314.3(b) of title 21, Code of Federal Regulations (or
10 any successor regulation).

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

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

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

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

24 “(C) the predecessors, subsidiaries, divi-
25 sions, groups, and affiliates controlled by, con-

1 trolling, or under common control with any of
2 the entities described in subparagraphs (A) and
3 (B) (such control to be presumed by direct or
4 indirect share ownership of 50 percent or great-
5 er), as well as the licensees, licensors, succes-
6 sors, and assigns of each of the entities.

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

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

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

22 “(12) STATUTORY EXCLUSIVITY.—The term
23 ‘statutory exclusivity’ means those prohibitions on
24 the approval of drug applications under clauses (ii)
25 through (iv) of section 505(c)(3)(E) (5- and 3-year

1 data exclusivity), section 527 (orphan drug exclu-
2 sivity), or section 505A (pediatric exclusivity) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 355(c)(3)(E), 360cc, 355a).”.

5 **TITLE V—FRAUD**

6 **SEC. 501. CONDITIONS ON AWARD OF DRUG EXCLUSIVITY.**

7 Subchapter E of chapter V of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is
9 amended by adding at the end the following:

10 **“SEC. 569D. CONDITIONS ON AWARD OF DRUG EXCLU- 11 SIVITY.**

12 “(a) **TERMINATION OF EXCLUSIVITY.**—Notwith-
13 standing any other provision of this Act, any period of
14 exclusivity described in subsection (b) granted to a person
15 or assigned to a person on or after the date of enactment
16 of this section with respect to a drug shall be terminated
17 if the person to which such exclusivity was granted or any
18 person to which such exclusivity is assigned—

19 “(1) commits a violation described in subsection
20 (c)(1) with respect to such drug; or

21 “(2) fails to report such a violation as required
22 by subsection (e).

23 “(b) **EXCLUSIVITIES AFFECTED.**—The periods of ex-
24 clusivity described in this subsection are those periods of
25 exclusivity granted under any of the following sections:

1 “(1) Clause (ii), (iii), or (iv) of section
2 505(c)(3)(E).

3 “(2) Clause (iv) of section 505(j)(5)(B).

4 “(3) Clause (ii), (iii), or (iv) of section
5 505(j)(5)(F).

6 “(4) Section 505A.

7 “(5) Section 505E.

8 “(6) Section 527.

9 “(7) Section 351(k)(7) of the Public Health
10 Service Act.

11 “(8) Any other provision of this Act that pro-
12 vides for market exclusivity (or extension of market
13 exclusivity) with respect to a drug.

14 “(c) VIOLATIONS.—

15 “(1) IN GENERAL.—A violation described in
16 this subsection is a violation of a law described in
17 paragraph (2) that results in—

18 “(A) a criminal conviction of a person de-
19 scribed in subsection (a);

20 “(B) a civil judgment against a person de-
21 scribed in subsection (a); or

22 “(C) a settlement agreement in which a
23 person described in subsection (a) admits to
24 fault.

1 “(2) LAWS DESCRIBED.—The laws described in
2 this paragraph are the following:

3 “(A) The provisions of this Act that pro-
4 hibit—

5 “(i) the adulteration or misbranding
6 of a drug;

7 “(ii) the making of false statements to
8 the Secretary or committing fraud; or

9 “(iii) the illegal marketing of a drug.

10 “(B) The provisions of subchapter III of
11 chapter 37 of title 31, United States Code
12 (commonly known as the ‘False Claims Act’).

13 “(C) Section 287 of title 18, United States
14 Code.

15 “(D) The Medicare and Medicaid Patient
16 Protection and Program Act of 1987 (com-
17 monly known as the ‘Antikickback Statute’).

18 “(E) Section 1927 of the Social Security
19 Act.

20 “(F) A State law against fraud comparable
21 to a law described in subparagraphs (A)
22 through (E).

23 “(d) DATE OF EXCLUSIVITY TERMINATION.—The
24 date on which the exclusivity shall be terminated as de-

1 scribed in subsection (a) is the date on which, as applica-
2 ble—

3 “(1) a final judgment is entered relating to a
4 violation described in subparagraph (A) or (B) of
5 subsection (c)(1); or

6 “(2)(A) a settlement agreement described in
7 subsection (c)(1)(C) is approved by a court order
8 that is or becomes final and nonappealable; or

9 “(B) if there is no court order approving a set-
10 tlement agreement described in subsection (c)(1)(C),
11 a court order dismissing the applicable case, issued
12 after the settlement agreement, is or becomes final
13 and nonappealable.

14 “(e) REPORTING OF INFORMATION.—A person de-
15 scribed in subsection (a) that commits a violation de-
16 scribed in subsection (c)(1) shall report such violation to
17 the Secretary no later than 30 days after the date that—

18 “(1) a final judgment is entered relating to a
19 violation described in subparagraph (A) or (B) of
20 subsection (c)(1); or

21 “(2)(A) a settlement agreement described in
22 subsection (c)(1)(C) is approved by a court order
23 that is or becomes final and nonappealable; or

24 “(B) if there is no court order approving a set-
25 tlement agreement described in subsection (c)(1)(C),

1 a court order dismissing the applicable case, issued
2 after the settlement agreement, is or becomes final
3 and nonappealable.”.

4 **TITLE VI—TRANSPARENCY**

5 **SEC. 601. DRUG MANUFACTURER REPORTING.**

6 (a) REPORTING ON DOMESTIC SALES.—The manu-
7 facturer of a drug approved under section 505 of the Fed-
8 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355) or
9 section 351 of the Public Health Service Act (42 U.S.C.
10 262) shall submit to the Secretary of Health and Human
11 Services and to Congress an annual report, which shall
12 be made publicly available, outlining with respect to each
13 such drug, during the previous calendar year—

14 (1) the total expenditures of the manufacturer
15 on—

16 (A) drug research and development;

17 (B) clinical trials;

18 (C) materials and manufacturing;

19 (D) acquisition costs, including costs for
20 the purchase of patents and licensing; and

21 (E) marketing and advertising for the pro-
22 motion of the drug to consumers and pre-
23 scribers;

24 (2) the total profit to the manufacturer attrib-
25 utable to such drug;

1 (3) total amount of financial assistance the
2 manufacturer has provided through patient prescrip-
3 tion assistance programs with respect to such drug,
4 if any;

5 (4) any Federal benefits received by the manu-
6 facturer, including tax credits, grants from the Na-
7 tional Institutes of Health, and other Federal bene-
8 fits with respect to such drug; and

9 (5) any additional information the manufac-
10 turer chooses to provide related to drug pricing deci-
11 sions, such as total expenditures on drug research
12 and development or clinical trials on drugs that
13 failed to receive approval by the Food and Drug Ad-
14 ministration.

15 (b) REPORTING ON FOREIGN SALES.—In the case of
16 a manufacturer of a drug that sells such drug to the Fed-
17 eral Government, including through the health programs
18 of the Department of Veterans Affairs, the Department
19 of Defense, and the Indian Health Service and through
20 the Medicare program under title XVIII of the Social Se-
21 curity Act (42 U.S.C. 1395 et seq.), or that has entered
22 into an agreement under section 340B of the Public
23 Health Service Act (42 U.S.C. 256b), the manufacturer
24 shall include in the report submitted under subsection (a)
25 information about the price of the drug, and profits from

- 1 and volume of sales of the drug, in each foreign country
- 2 in which the drug is sold, as applicable.