

114TH CONGRESS  
1ST SESSION

# H. R. 3513

To ensure greater affordability of prescription drugs.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 16, 2015

Mr. CUMMINGS (for himself, Mr. ELLISON, Ms. NORTON, and Mr. SARBANES) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## 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 House of Representatives 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-

1 tions for covered part D drugs for part D eligible in-  
2 dividuals who are enrolled under a prescription drug  
3 plan or under an MA–PD plan.

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

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

10 “(B) CONSTRUCTION.—Subparagraph (A)  
11 shall not be construed as affecting the Sec-  
12 retary’s authority to ensure appropriate and  
13 adequate access to covered part D drugs under  
14 prescription drug plans and under MA–PD  
15 plans, including compliance of such plans with  
16 formulary requirements under section 1860D–  
17 4(b)(3).

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

24 (b) EFFECTIVE DATE.—The amendment made by  
25 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 (e) 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 HOUSE OF REPRESENTATIVES RE-**  
7 **GARDING TRADE AGREEMENTS.**

8 It is the sense of the House of Representatives that  
9 the United States Trade Representative should not nego-  
10 tiate trade agreements that would raise the prices of pre-  
11 scription drugs in the United States, extend the periods  
12 of market exclusivity otherwise available for prescription  
13 drugs, or remove flexibility in Federal or State law regard-  
14 ing pricing of prescription 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           “(A) IN GENERAL.—The amount of the re-  
2           bate specified under this paragraph for a manu-  
3           facturer for a rebate period, with respect to  
4           each dosage form and strength of any covered  
5           part D drug provided by such manufacturer  
6           and dispensed to a rebate eligible individual,  
7           shall be equal to the product of—

8                   “(i) the total number of units of such  
9                   dosage form and strength of the drug so  
10                  provided and dispensed for which payment  
11                  was made by a PDP sponsor or an MA or-  
12                  ganization under this part for the rebate  
13                  period, including payments passed through  
14                  the low-income and reinsurance subsidies  
15                  under sections 1860D–14 and 1860D–  
16                  15(b), respectively; and

17                   “(ii) the amount (if any) by which—

18                           “(I) the Medicaid rebate amount  
19                           (as defined in subparagraph (B)) for  
20                           such form, strength, and period, ex-  
21                           ceeds

22                           “(II) the average Medicare drug  
23                           program rebate eligible rebate amount  
24                           (as defined in subparagraph (C)) for  
25                           such form, strength, and period.

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           mation collected under section 1860D–  
2           12(b)(7)(B).

3           “(4) LENGTH OF AGREEMENT.—The provisions  
4           of paragraph (4) of section 1927(b) (other than  
5           clauses (iv) and (v) of subparagraph (B)) shall apply  
6           to rebate agreements under this subsection in the  
7           same manner as such paragraph applies to a rebate  
8           agreement under such section.

9           “(5) OTHER TERMS AND CONDITIONS.—The  
10          Secretary shall establish other terms and conditions  
11          of the rebate agreement under this subsection, in-  
12          cluding terms and conditions related to compliance,  
13          that are consistent with this subsection.

14          “(6) DEFINITIONS.—In this subsection and sec-  
15          tion 1860D–12(b)(7):

16                 “(A) REBATE ELIGIBLE INDIVIDUAL.—The  
17                 term ‘rebate eligible individual’ means—

18                         “(i) a subsidy eligible individual (as  
19                         defined in section 1860D–14(a)(3)(A));

20                         “(ii) a Medicaid beneficiary treated as  
21                         a subsidy eligible individual under clause  
22                         (v) of section 1860D–14(a)(3)(B); and

23                         “(iii) any part D eligible individual  
24                         not described in clause (i) or (ii) who is de-  
25                         termined for purposes of the State plan

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           age Medicare drug program rebate eligible  
2           rebate amount (as defined in paragraph  
3           (3)(C) of such section), and to determine  
4           the amount of the rebate required under  
5           this section, for such form, strength, and  
6           period.

7           Such report shall be in a form consistent with  
8           a standard reporting format established by the  
9           Secretary.

10           “(C) SUBMISSION TO SECRETARY.—Each  
11           PDP sponsor shall promptly transmit a copy of  
12           the information reported under subparagraph  
13           (B) to the Secretary for the purpose of audit  
14           oversight and evaluation.

15           “(D) CONFIDENTIALITY OF INFORMA-  
16           TION.—The provisions of subparagraph (D) of  
17           section 1927(b)(3), relating to confidentiality of  
18           information, shall apply to information reported  
19           by PDP sponsors under this paragraph in the  
20           same manner that such provisions apply to in-  
21           formation disclosed by manufacturers or whole-  
22           salers under such section, except—

23                   “(i) that any reference to ‘this sec-  
24                   tion’ in clause (i) of such subparagraph

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

19           “(IV) the references in subpara-  
20 graph (D) of such paragraph to ‘para-  
21 graph (1)(A)(ii)’, ‘this paragraph’,  
22 and ‘December 31, 2009’ shall be  
23 deemed references to ‘subparagraph  
24 (A)’, ‘this subparagraph’, and ‘De-  
25 cember 31, 2014’, respectively; and

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

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

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

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

22                   “(iv) APPLICABLE QUARTER DE-  
23                   FINED.—In this subsection, the term ‘ap-  
24                   plicable quarter’ means, with respect to a  
25                   drug described in clause (iii), the fifth full

1 calendar quarter in which the drug is sold  
2 as a drug other than a single source drug  
3 or an innovator multiple source drug.”.

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

## 7 **TITLE IV—PAY-FOR-DELAY** 8 **BLOCKING**

### 9 **SEC. 401. PRESERVING ACCESS TO AFFORDABLE** 10 **GENERICS.**

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

### 14 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE** 15 **GENERICS.**

16 “(a) IN GENERAL.—

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

23 “(2) PRESUMPTION AND VIOLATION.—In such  
24 a proceeding, an agreement shall be presumed to



1 have anticompetitive effects and be a violation of  
2 this section if—

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

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

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

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

16 “(A) any patent that is the basis for the  
17 patent infringement claim; or

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

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

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

25 “(c) DEFINITIONS.—In this section:

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

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

14           “(3) ANDA.—The term ‘ANDA’ means an ab-  
15 breviated new drug application filed under section  
16 505(j) of the Federal Food, Drug, and Cosmetic Act  
17 (21 U.S.C. 355(j)) or a new drug application filed  
18 under section 505(b)(2) of the Federal Food, Drug,  
19 and Cosmetic Act (21 U.S.C. 355(b)(2)).

20           “(4) ANDA FILER.—The term ‘ANDA filer’  
21 means a party that owns or controls an ANDA filed  
22 with the Commission of Food and Drugs or has the  
23 exclusive rights under such ANDA to distribute the  
24 ANDA product.

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

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

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

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

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

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

22           “(C) the predecessors, subsidiaries, divi-  
23 sions, groups, and affiliates controlled by, con-  
24 trolling, or under common control with any of  
25 the entities described in subparagraphs (A) and

1 (B) (such control to be presumed by direct or  
2 indirect share ownership of 50 percent or great-  
3 er), as well as the licensees, licensors, succes-  
4 sors, and assigns of each of the entities.

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

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

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

20 “(12) STATUTORY EXCLUSIVITY.—The term  
21 ‘statutory exclusivity’ means those prohibitions on  
22 the approval of drug applications under clauses (ii)  
23 through (iv) of section 505(c)(3)(E) (5- and 3-year  
24 data exclusivity), section 527 (orphan drug exclu-  
25 sivity), or section 505A (pediatric exclusivity) of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
2 355(c)(3)(E), 360cc, 355a).”.

## 3 **TITLE V—FRAUD**

### 4 **SEC. 501. CONDITIONS ON AWARD OF DRUG EXCLUSIVITY.**

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

### 8 **“SEC. 569D. CONDITIONS ON AWARD OF DRUG EXCLU- 9 SIVITY.**

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

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

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

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

24 “(1) Clause (ii), (iii), or (iv) of section  
25 505(c)(3)(E).

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

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

4 “(4) Section 505A.

5 “(5) Section 505E.

6 “(6) Section 527.

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

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

12 “(c) VIOLATIONS.—

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

16 “(A) a criminal conviction of a person de-  
17 scribed in subsection (a);

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

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

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

1           “(A) The provisions of this Act that pro-  
2           hibit—

3                   “(i) the adulteration or misbranding  
4                   of a drug;

5                   “(ii) the making of false statements to  
6                   the Secretary or committing fraud; or

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

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

11           “(C) Section 287 of title 18, United States  
12           Code.

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

16           “(E) Section 1927 of the Social Security  
17           Act.

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

21           “(d) DATE OF EXCLUSIVITY TERMINATION.—The  
22           date on which the exclusivity shall be terminated as de-  
23           scribed in subsection (a) is the date on which, as applica-  
24           ble—

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

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

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

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

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

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

22           “(B) if there is no court order approving a set-  
23 tlement agreement described in subsection (c)(1)(C),  
24 a court order dismissing the applicable case, issued



1 after the settlement agreement, is or becomes final  
2 and nonappealable.”.

### 3 **TITLE VI—TRANSPARENCY**

#### 4 **SEC. 601. DRUG MANUFACTURER REPORTING.**

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

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

15 (A) drug research and development;

16 (B) clinical trials;

17 (C) materials and manufacturing;

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

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

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

1           (3) the 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.

○