I

114TH CONGRESS
1ST SESSION

H. R. 3513

To ensure greater affordability of prescription drugs.

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Prescription Drug Affordability Act of 2015''.

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

TITLE I—DRUGS UNDER THE MEDICARE PROGRAM

SEC. 101. NEGOTIATION OF LOWER COVERED PART D DRUG PRICES ON BEHALF OF MEDICARE BENEFICIARIES.

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

''(i) NEGOTIATION OF LOWER DRUG PRICES.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and other price concessions) that may be charged to PDP sponsors and MA organiza-

tions for covered part D drugs for part D eligible individuals who are enrolled under a prescription drug plan or under an MA–PD plan.

''(2) NO CHANGE IN RULES FOR FORMULARIES.—

''(A) IN GENERAL.—Nothing in paragraph (1) shall be construed to authorize the Secretary to establish or require a particular formulary.

''(B) CONSTRUCTION.—Subparagraph (A) shall not be construed as affecting the Secretary's authority to ensure appropriate and adequate access to covered part D drugs under prescription drug plans and under MA–PD plans, including compliance of such plans with formulary requirements under section 1860D–4(b)(3).

''(3) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the sponsor of a prescription drug plan, or an organization offering an MA–PD plan, from obtaining a discount or reduction of the price for a covered part D drug below the price negotiated under paragraph (1).''.

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

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

SEC. 102. ACCELERATION OF THE CLOSING OF THE MEDICARE PART D DONUT HOLE.

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

(1) in each of subclauses (II) and (III) of subparagraph (C)(ii), by striking ''2020'' and inserting ''2017''; and

(2) in subparagraph (D)(ii)—

(A) in subclause (II), by inserting ''and'' at the end; and

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

''(III) 2017 is 100 percent.''.

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

TITLE II—PRESCRIPTION DRUG IMPORTATION

SEC. 201. PRESCRIPTION DRUG IMPORTATION.

(a) IMPORTATION BY PHARMACISTS AND WHOLESALERS.—Section 804(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(b)) is amended by striking ''The Secretary,'' and inserting ''The Secretary, not later than January 1, 2016,''.

(b) IMPORTATION BY INDIVIDUALS.—

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

(A) in subsection (f), by striking ''within Canada'';

(B) in subsection (j)—

(i) in paragraph (1), in the matter preceding subparagraph (A), by inserting ''from countries other than Canada'' after ''devices''; and

(ii) in paragraph (3)—

(I) in the heading, by striking ''FROM CANADA'' and inserting ''FROM COUNTRIES OTHER THAN CANADA''; and

(II) in subparagraph (C), by striking ''from Canada,''; and

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

''(l) IMPORTATION OF PRESCRIPTION DRUGS FROM CANADA.—Individuals may import from Canada any prescription drug that meets the requirements of subparagraphs (A) through (F) of subsection (j)(3).''.

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

(3) EFFECTIVE DATE.—The amendments made by paragraph (1) shall take effect on the effective date of the final regulations promulgated in accordance with paragraph (2).

(c) FDASIA AMENDMENT.—Subsection (c) of section 708 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 126 Stat. 1068) is amended by striking ''The amendment made by'' and all that follows through the period at the end and inserting ''The amendment made by subsection (a) and the regulations promulgated under subsection (b) shall apply begin-

ning on the effective date of the regulations promulgated under section 804(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(b)) and the amendments made by section 201(b) of the Prescription Drug Affordability Act of 2015.''.

SEC. 202. SENSE OF THE HOUSE OF REPRESENTATIVES REGARDING TRADE AGREEMENTS.

It is the sense of the House of Representatives that the United States Trade Representative should not negotiate trade agreements that would raise the prices of prescription drugs in the United States, extend the periods of market exclusivity otherwise available for prescription drugs, or remove flexibility in Federal or State law regarding pricing of prescription drugs.

TITLE III—MEDICARE AND MEDICAID REBATES

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

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

(1) in subsection (e)(1), in the matter preceding subparagraph (A), by inserting ''and subsection (f)'' after ''this subsection''; and

(2) by adding at the end the following new subsection:

''(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR REBATE ELIGIBLE INDIVIDUALS.—

''(1) REQUIREMENT.—

''(A) IN GENERAL.—For plan years beginning on or after January 1, 2017, in this part, the term 'covered part D drug' does not include any drug or biological product that is manufactured by a manufacturer that has not entered into and have in effect a rebate agreement described in paragraph (2).

''(B) 2016 PLAN YEAR REQUIREMENT.—Any drug or biological product manufactured by a manufacturer that declines to enter into a rebate agreement described in paragraph (2) for the period beginning on January 1, 2016, and ending on December 31, 2016, shall not be included as a 'covered part D drug' for the subsequent plan year.

''(2) REBATE AGREEMENT.—A rebate agreement under this subsection shall require the manufacturer to provide to the Secretary a rebate for each rebate period (as defined in paragraph (6)(B)) ending after December 31, 2015, in the amount

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

''(3) REBATE FOR REBATE ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—

''(A) IN GENERAL.—The amount of the rebate specified under this paragraph for a manufacturer for a rebate period, with respect to each dosage form and strength of any covered part D drug provided by such manufacturer and dispensed to a rebate eligible individual, shall be equal to the product of—

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

''(ii) the amount (if any) by which—

''(I) the Medicaid rebate amount (as defined in subparagraph (B)) for such form, strength, and period, exceeds

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

"(B) MEDICAID REBATE AMOUNT.—For purposes of this paragraph, the term 'Medicaid rebate amount' means, with respect to each dosage form and strength of a covered part D drug provided by the manufacturer for a rebate period—

"(i) in the case of a single source drug or an innovator multiple source drug, the amount specified in paragraph (1)(A)(ii)(II) or (2)(C) of section 1927(c) plus the amount, if any, specified in subparagraph (A)(ii) of paragraph (2) of such section, for such form, strength, and period; or

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

"(C) AVERAGE MEDICARE DRUG PROGRAM REBATE ELIGIBLE REBATE AMOUNT.—For purposes of this subsection, the term 'average Medicare drug program rebate eligible rebate amount' means, with respect to each dosage form and strength of a covered part D drug provided by a manufacturer for a rebate period,

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

"(i) the product, for each such sponsor or organization, of—

"(I) the sum of all rebates, discounts, or other price concessions (not taking into account any rebate provided under paragraph (2) or any discounts under the program under section 1860D–14A) for such dosage form and strength of the drug dispensed, calculated on a per-unit basis, but only to the extent that any such rebate, discount, or other price concession applies equally to drugs dispensed to rebate eligible Medicare drug plan enrollees and drugs dispensed to PDP and MA–PD enrollees who are not rebate eligible individuals; and

"(II) the number of the units of such dosage and strength of the drug dispensed during the rebate period to rebate eligible individuals enrolled in

the prescription drug plans administered by the PDP sponsor or the MA–PD plans administered by the MA organization; divided by

"(ii) the total number of units of such dosage and strength of the drug dispensed during the rebate period to rebate eligible individuals enrolled in all prescription drug plans administered by PDP sponsors and all MA–PD plans administered by MA organizations.

"(D) USE OF ESTIMATES.—The Secretary may establish a methodology for estimating the average Medicare drug program rebate eligible rebate amounts for each rebate period based on bid and utilization information under this part and may use these estimates as the basis for determining the rebates under this section. If the Secretary elects to estimate the average Medicare drug program rebate eligible rebate amounts, the Secretary shall establish a reconciliation process for adjusting manufacturer rebate payments not later than 3 months after the date that manufacturers receive the infor-

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

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

''(5) OTHER TERMS AND CONDITIONS.—The Secretary shall establish other terms and conditions of the rebate agreement under this subsection, including terms and conditions related to compliance, that are consistent with this subsection.

''(6) DEFINITIONS.—In this subsection and section 1860D–12(b)(7):

''(A) REBATE ELIGIBLE INDIVIDUAL.—The term 'rebate eligible individual' means—

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

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

''(iii) any part D eligible individual not described in clause (i) or (ii) who is determined for purposes of the State plan

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

''(B) REBATE PERIOD.—The term 'rebate period' has the meaning given such term in section 1927(k)(8).''.

(b) REPORTING REQUIREMENT FOR THE DETERMINATION AND PAYMENT OF REBATES BY MANUFACTURERS RELATED TO REBATE FOR REBATE ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—

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

''(7) REPORTING REQUIREMENT FOR THE DETERMINATION AND PAYMENT OF REBATES BY MANUFACTURERS RELATED TO REBATE FOR REBATE ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—

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

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

''(i) information (by National Drug Code number) on the total number of units of each dosage, form, and strength of each drug of such manufacturer dispensed to rebate eligible Medicare drug plan enrollees under any prescription drug plan operated by the PDP sponsor during the rebate period;

''(ii) information on the price discounts, price concessions, and rebates for such drugs for such form, strength, and period;

''(iii) information on the extent to which such price discounts, price concessions, and rebates apply equally to rebate eligible Medicare drug plan enrollees and PDP enrollees who are not rebate eligible Medicare drug plan enrollees; and

''(iv) any additional information that the Secretary determines is necessary to enable the Secretary to calculate the aver-

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

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

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

''(D) CONFIDENTIALITY OF INFORMATION.—The provisions of subparagraph (D) of section 1927(b)(3), relating to confidentiality of information, shall apply to information reported by PDP sponsors under this paragraph in the same manner that such provisions apply to information disclosed by manufacturers or wholesalers under such section, except—

''(i) that any reference to 'this section' in clause (i) of such subparagraph

shall be treated as being a reference to this section;

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

''(iii) clause (iv) of such subparagraph shall not apply.

''(E) OVERSIGHT.—Information reported under this paragraph may be used by the Inspector General of the Department of Health and Human Services for the statutorily authorized purposes of audit, investigation, and evaluations.

''(F) PENALTIES FOR FAILURE TO PROVIDE TIMELY INFORMATION AND PROVISION OF FALSE INFORMATION.—In the case of a PDP sponsor—

''(i) that fails to provide information required under subparagraph (B) on a timely basis, the sponsor is subject to a civil money penalty in the amount of $10,000 for each day in which such information has not been provided; or

"(ii) that knowingly (as defined in section 1128A(i)) provides false information under such subparagraph, the sponsor is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information.

Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).".

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

"(D) REPORTING REQUIREMENT RELATED TO REBATE FOR REBATE ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—Section 1860D–12(b)(7).".

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

''(6) REBATE FOR REBATE ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—Amounts paid under a rebate agreement under section 1860D–2(f) shall be deposited into the Account.''.

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

(1) EXCLUSION FROM BEST PRICE DETERMINATION.—Section 1927(c)(1)(C)(ii)(I) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is amended by inserting ''and amounts paid under a rebate agreement under section 1860D–2(f)'' after ''this section''.

(2) EXCLUSION FROM AVERAGE MANUFACTURER PRICE DETERMINATION.—Section 1927(k)(1)(B)(i) of the Social Security Act (42 U.S.C. 1396r–8(k)(1)(B)(i)) is amended—

(A) in subclause (IV), by striking ''and'' after the semicolon;

(B) in subclause (V), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(VI) amounts paid under a rebate agreement under section 1860D–2(f).''.

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

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

(1) in subparagraph (A), by striking ''The amount'' and inserting ''Except as provided in subparagraph (C), the amount''; and

(2) by adding at the end the following new subparagraph:

''(C) ADDITIONAL REBATE.—

''(i) IN GENERAL.—The amount of the rebate specified in this paragraph for a rebate period, with respect to each dosage form and strength of a covered outpatient drug other than a single source drug or an innovator multiple source drug, shall be increased in the manner that the rebate for a dosage form and strength of a single source drug or an innovator multiple source drug is increased under subparagraphs (A) and (D) of paragraph (2), except as provided in clause (ii).

''(ii) SPECIAL RULES FOR APPLICATION OF PROVISION.—In applying subparagraphs (A) and (D) of paragraph (2) under clause (i)—

''(I) the reference in subparagraph (A)(i) of such paragraph to '1990' shall be deemed a reference to '2014';

''(II) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to 'calendar quarter beginning July 1, 1990' shall be deemed a reference to the 'calendar quarter in which the average manufacturer price for the drug is the lowest during the 12-calendar quarter period ending on September 30, 2014';

''(III) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to 'September 1990' shall be deemed a reference to 'the last month of such calendar quarter';

''(IV) the references in subparagraph (D) of such paragraph to 'paragraph (1)(A)(ii)', 'this paragraph', and 'December 31, 2009' shall be deemed references to 'subparagraph (A)', 'this subparagraph', and 'December 31, 2014', respectively; and

"(V) any reference in such paragraph to a 'single source drug or an innovator multiple source drug' shall be deemed to be a reference to a drug to which clause (i) applies.

"(iii) SPECIAL RULE FOR CERTAIN NONINNOVATOR MULTIPLE SOURCE DRUGS.—In applying paragraph (2)(A)(ii)(II) under clause (i) with respect to a covered outpatient drug that is first sold as a drug other than a single source drug or an innovator multiple source drug after the date that is 3 years before the date of the enactment of this subparagraph, such paragraph shall be applied—

"(I) by substituting 'the applicable quarter' for 'the calendar quarter beginning July 1, 1990'; and

"(II) by substituting 'the last month in such applicable quarter' for 'September 1990'.

"(iv) APPLICABLE QUARTER DEFINED.—In this subsection, the term 'applicable quarter' means, with respect to a drug described in clause (iii), the fifth full

calendar quarter in which the drug is sold as a drug other than a single source drug or an innovator multiple source drug.''.

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

TITLE IV—PAY-FOR-DELAY BLOCKING

SEC. 401. PRESERVING ACCESS TO AFFORDABLE GENERICS.

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

''SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS.

''(a) IN GENERAL.—

''(1) ENFORCEMENT PROCEEDING.—The Commission may initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product.

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

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

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

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

"(b) EXCLUSIONS.—Nothing in this section shall prohibit a resolution or settlement of a patent infringement claim in which the consideration granted by the NDA holder to the ANDA filer as part of the resolution or settlement includes only one or more of the following:

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

"(A) any patent that is the basis for the patent infringement claim; or

"(B) any patent right or other statutory exclusivity that would prevent the marketing of such drug.

"(2) A payment for reasonable litigation expenses not to exceed $7,500,000.

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

"(c) DEFINITIONS.—In this section:

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

''(2) AGREEMENT RESOLVING OR SETTLING A PATENT INFRINGEMENT CLAIM.—The term 'agreement resolving or settling a patent infringement claim' includes any agreement that is entered into within 30 days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

''(3) ANDA.—The term 'ANDA' means an abbreviated new drug application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) or a new drug application filed under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)).

''(4) ANDA FILER.—The term 'ANDA filer' means a party that owns or controls an ANDA filed with the Commission of Food and Drugs or has the exclusive rights under such ANDA to distribute the ANDA product.

''(5) ANDA PRODUCT.—The term 'ANDA product' means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

''(6) DRUG PRODUCT.—The term 'drug product' has the meaning given such term in section 314.3(b) of title 21, Code of Federal Regulations (or any successor regulation).

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

''(8) NDA HOLDER.—The term 'NDA holder' means—

''(A) the holder of an approved NDA application for a drug product;

''(B) a person owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the 'FDA Orange Book') in connection with the NDA; or

''(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and

(B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

''(9) PARTY.—The term 'party' means any person, partnership, corporation, or other legal entity.

''(10) PATENT INFRINGEMENT.—The term 'patent infringement' means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition, and extensions thereof.

''(11) PATENT INFRINGEMENT CLAIM.—The term 'patent infringement claim' means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product may infringe any patent held by, or exclusively licensed to, the NDA holder of the drug product.

''(12) STATUTORY EXCLUSIVITY.—The term 'statutory exclusivity' means those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year data exclusivity), section 527 (orphan drug exclusivity), or section 505A (pediatric exclusivity) of the

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

TITLE V—FRAUD

SEC. 501. CONDITIONS ON AWARD OF DRUG EXCLUSIVITY.

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

''SEC. 569D. CONDITIONS ON AWARD OF DRUG EXCLUSIVITY.

''(a) TERMINATION OF EXCLUSIVITY.—Notwithstanding any other provision of this Act, any period of exclusivity described in subsection (b) granted to a person or assigned to a person on or after the date of enactment of this section with respect to a drug shall be terminated if the person to which such exclusivity was granted or any person to which such exclusivity is assigned—

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

''(2) fails to report such a violation as required by subsection (e).

''(b) EXCLUSIVITIES AFFECTED.—The periods of exclusivity described in this subsection are those periods of exclusivity granted under any of the following sections:

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

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

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

''(4) Section 505A.

''(5) Section 505E.

''(6) Section 527.

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

''(8) Any other provision of this Act that provides for market exclusivity (or extension of market exclusivity) with respect to a drug.

''(c) VIOLATIONS.—

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

''(A) a criminal conviction of a person described in subsection (a);

''(B) a civil judgment against a person described in subsection (a); or

''(C) a settlement agreement in which a person described in subsection (a) admits to fault.

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

"(A) The provisions of this Act that prohibit—

"(i) the adulteration or misbranding of a drug;

"(ii) the making of false statements to the Secretary or committing fraud; or

"(iii) the illegal marketing of a drug.

"(B) The provisions of subchapter III of chapter 37 of title 31, United States Code (commonly known as the 'False Claims Act').

"(C) Section 287 of title 18, United States Code.

"(D) The Medicare and Medicaid Patient Protection and Program Act of 1987 (commonly known as the 'Antikickback Statute').

"(E) Section 1927 of the Social Security Act.

"(F) A State law against fraud comparable to a law described in subparagraphs (A) through (E).

"(d) DATE OF EXCLUSIVITY TERMINATION.—The date on which the exclusivity shall be terminated as described in subsection (a) is the date on which, as applicable—

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

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

''(B) if there is no court order approving a settlement agreement described in subsection (c)(1)(C), a court order dismissing the applicable case, issued after the settlement agreement, is or becomes final and nonappealable.

''(e) REPORTING OF INFORMATION.—A person described in subsection (a) that commits a violation described in subsection (c)(1) shall report such violation to the Secretary no later than 30 days after the date that—

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

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

''(B) if there is no court order approving a settlement agreement described in subsection (c)(1)(C), a court order dismissing the applicable case, issued

after the settlement agreement, is or becomes final and nonappealable.''.

TITLE VI—TRANSPARENCY

SEC. 601. DRUG MANUFACTURER REPORTING.

(a) REPORTING ON DOMESTIC SALES.—The manufacturer of a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) shall submit to the Secretary of Health and Human Services and to Congress an annual report, which shall be made publicly available, outlining with respect to each such drug, during the previous calendar year—

(1) the total expenditures of the manufacturer on—

(A) drug research and development;

(B) clinical trials;

(C) materials and manufacturing;

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

(E) marketing and advertising for the promotion of the drug to consumers and prescribers;

(2) the total profit to the manufacturer attributable to such drug;

(3) the total amount of financial assistance the manufacturer has provided through patient prescription assistance programs with respect to such drug, if any;

(4) any Federal benefits received by the manufacturer, including tax credits, grants from the National Institutes of Health, and other Federal benefits with respect to such drug; and

(5) any additional information the manufacturer chooses to provide related to drug pricing decisions, such as total expenditures on drug research and development or clinical trials on drugs that failed to receive approval by the Food and Drug Administration.

(b) REPORTING ON FOREIGN SALES.—In the case of a manufacturer of a drug that sells such drug to the Federal Government, including through the health programs of the Department of Veterans Affairs, the Department of Defense, and the Indian Health Service and through the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), or that has entered into an agreement under section 340B of the Public Health Service Act (42 U.S.C. 256b), the manufacturer shall include in the report submitted under subsection (a) information about the price of the drug, and profits from

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

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