117TH CONGRESS
1ST SESSION

S. 1898

To ensure medications are affordable.

IN THE SENATE OF THE UNITED STATES

MAY 27, 2021

Ms. SMITH (for herself, Ms. WARREN, Mr. BLUMENTHAL, Ms. KLOBUCHAR, Mr. MERKLEY, Mr. REED, Ms. BALDWIN, Ms. HASSAN, Mr. BOOKER, Mr. SANDERS, Mr. BROWN, Mrs. GILLIBRAND, Mr. WHITEHOUSE, and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To ensure medications are affordable.

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 ''Affordable Medications Act''.

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

TITLE I—TRANSPARENCY

SEC. 101. DRUG MANUFACTURER REPORTING.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399V–7. DRUG MANUFACTURER REPORTING.

''(a) DEFINITIONS.—In this section:

''(1) INDEPENDENT CHARITY PATIENT ASSISTANCE PROGRAM.—The term 'independent charity patient assistance program' means any organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under

section 501(a) of such Code and which is not a private foundation (as defined in section 509(a) of such Code) that offers patient assistance.

''(2) MANUFACTURER PATIENT ASSISTANCE PROGRAM.—The term 'manufacturer patient assistance program' means an organization, including a private foundation (as so defined), that is sponsored by, or receives funding from, a manufacturer and that offers patient assistance. Such term does not include an independent charity patient assistance program.

''(3) PATIENT ASSISTANCE.—The term 'patient assistance' means assistance provided to offset the cost of drugs for individuals. Such term includes free products, coupons, rebates, copay or discount cards, and other means of providing assistance to individuals related to drug costs, as determined by the Secretary.

''(b) REPORTING ON DOMESTIC SALES.—An applicable manufacturer of an approved drug (including a drug approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act and a biological product licensed under subsection (a) or (k) of section 351 of this Act) shall submit to the Secretary and to Congress an annual report, in such format as the Secretary shall

require, outlining with respect to the previous calendar year (except as provided in subsection (c)(3))—

''(1) with respect to each such drug—

''(A) the total expenditures of the manufacturer on—

''(i) domestic and foreign drug research and development, including an itemized description of—

''(I) basic and preclinical research;

''(II) clinical research, broken out by clinical trial phase;

''(III) development of alternative dosage forms and strengths for the drug molecule or combinations, including the molecule;

''(IV) other drug development activities, such as nonclinical laboratory studies and record and report maintenance;

''(V) pursuing new or expanded indications for such drug through supplemental applications under section 505 of the Federal Food, Drug, and Cosmetic Act;

"(VI) carrying out postmarket requirements related to such drug, including under section 505(o)(3) of such Act;

"(VII) carrying out risk evaluation and mitigation strategies in accordance with section 505–1 of such Act; and

"(VIII) marketing research;

"(ii) cost of goods sold, broken out by source and cost of each component and identifying specific costs that reflect internal transfers within the manufacturer's company;

"(iii) acquisition costs in total and per unit sold, including costs for the purchase of patents and licensing; and

"(iv) marketing and advertising for the promotion of the drug, including a breakdown of amounts aimed at consumers, prescribers, managed care organizations, and others;

"(B) the gross revenue, net revenue, gross profit, and net profit to the manufacturer;

''(C) the total number of units of the prescription drug that were sold in interstate commerce in the most recently completed calendar year;

''(D) pricing information, including—

''(i) wholesale acquisition cost;

''(ii) net average price realized by pharmacy benefit managers for drugs provided to individuals in the United States, after accounting for any rebates or other payments from the manufacturer to the pharmacy benefit manager and from the pharmacy benefit manager to the manufacturer; and

''(iii) the net price of the drug, after accounting for discounts, rebates, or other financial considerations, charged to purchasers in each applicable country of the Organisation for Economic Co-operation and Development;

''(E) information, including the dollar value to the recipient of manufacturer patient assistance programs offered by the manufacturer or a manufacturer patient assistance pro-

gram sponsored by or associated with the manufacturer, per patient, including—

''(i) the specific forms of such patient assistance available, such as coupons, rebates, discount codes, or copayment cards;

''(ii) the total dollar value of each manufacturer patient assistance program and the dollar value of each program to the patient, including the basis used to assign value to the manufacturer patient assistance program;

''(iii) the duration of each type of such patient assistance available; and

''(iv) any requirements, such as income thresholds, for how to qualify for such patient assistance;

''(F) information on usage of patient assistance offered by the manufacturer or a manufacturer patient assistance program sponsored by or associated with the manufacturer, including—

''(i) the number of transactions of each type of patient assistance used;

''(ii) the number of individuals receiving each type of patient assistance;

''(iii) the total value of each type of patient assistance that was used;

''(iv) the average length of time that each individual received each type of patient assistance;

''(v) the number of individuals who were discontinued from receiving each type of patient assistance; and

''(vi) complete documentation of the terms and conditions for an individual agreeing to participate in the program for each type of patient assistance provided;

''(G) any Federal benefits received by the manufacturer, including the amounts and periods of impact for each such benefit, including tax credits, patent applications that benefitted from a Federal grant, patent extensions, exclusivity periods, and other Federal benefits with respect to such drug; and

''(H) the percentage of research and development expenditures on—

''(i) activities conducted by the manufacturer;

''(ii) activities funded by Federal entities; and

''(iii) activities conducted by other entities such as academic institutions or other drug manufacturers;

''(2) executive compensation for the chief executive officer, chief financial officer, and the three other most highly compensated executive officers, including bonuses, paid by such manufacturer, and stock options affiliated with the manufacturer that were offered to or accrued by such officers;

''(3) any additional information the manufacturer chooses to provide related to drug pricing decisions, such as total expenditures on drug research, drug development, and clinical trials on drugs that failed to receive approval by the Food and Drug Administration, a list of drugs and drug prices against which the manufacturer compared the applicable drug, and other relevant information; and

''(4) any other information as the Secretary may require.

''(c) SUBMISSION OF REPORTS.—

''(1) IN GENERAL.—

''(A) SUBMISSION BY DRUG MANUFACTURERS.—Drug manufacturers shall submit the annual reports required under this section sub-

mitted to the Secretary in a usable format, as the Secretary may require.

''(B) COLLATION BY THE SECRETARY.—The Secretary shall collate the reports received as described in subparagraph (A) and submit such collated reports to Congress, together with an analysis of the reports by the Secretary that includes—

''(i) a summary of data from the reports;

''(ii) consideration of factors such as trends on research and development costs, Federal benefits, and manufacturer patient assistance programs; and

''(iii) the relationship between the factors described in clause (ii) and prescription drug prices.

''(C) PUBLIC AVAILABILITY.—The Secretary shall make the reports submitted by manufacturers as described in subparagraph (A) and the collated reports together with the analysis of the Secretary described in subparagraph (B) publicly available, including by posting such reports to the internet website of the Department of Health and Human Services, in

a searchable format. In publicizing such reports, the Secretary may redact such proprietary information as the Secretary determines appropriate.

''(2) SINGLE REPORTS.—A drug manufacturer shall submit all information required under subsection (b) with respect to each applicable drug, in a single, annual report.

''(3) INITIAL REPORT.—

''(A) IN GENERAL.—An applicable drug manufacturer shall submit a report pursuant to this section one year after the date of enactment of the Affordable Medications Act (except as provided in subparagraph (B)) that includes the information required under subsection (b)(1) with respect to each calendar year since the drug for which the report is required was approved under section 505 of the Federal Food, Drug, and Cosmetic Act, licensed under section 351 of this Act, or received an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or section 351(a)(3) of this Act, or the calendar year in which the manufacturer acquired the drug.

''(B) SMALL BUSINESSES.—In the case of an applicable drug manufacturer that has fewer than 500 employees, the initial report described in subparagraph (A) shall be submitted by a date determined by the Secretary, which shall be not earlier than the date described in subparagraph (A) and not later than the date that is 3 years after the date of enactment of the Affordable Medications Act.

''(d) PENALTY FOR NONCOMPLIANCE.—The Secretary shall report to the Office of the Inspector General any manufacturer's failure to submit a complete report as required under this section. Any manufacturer that fails to submit a complete report required under this section shall be subject to a civil penalty of up to $200,000 for each day on which the violation continues. The Secretary shall collect the civil penalties under this subsection, and without further appropriation, shall use such funds to support the programs under sections 409K and 485E, and, at the discretion of the Secretary, research of the National Institutes of Health and other activities authorized under the Affordable Medications Act, including any amendments made by such Act.''.

SEC. 102. DETERMINING THE PUBLIC AND PRIVATE BENEFIT OF COPAYMENT COUPONS AND OTHER PATIENT ASSISTANCE PROGRAMS.

(a) INFORMATION REPORTING BY INDEPENDENT CHARITY PATIENT ASSISTANCE PROGRAMS.—Section 6033(b) of the Internal Revenue Code of 1986 is amended—

(1) in paragraph (15)(B), by striking ''and'' at the end,

(2) by redesignating paragraph (16) as paragraph (17), and

(3) by inserting after paragraph (15) the following new paragraph:

''(16) the total amount of patient assistance (within the meaning of section 399V–7 of the Public Health Service Act) provided to individuals who are prescribed drugs manufactured by any contributor to the organization, and''.

(b) GAO STUDY AND REPORT ON IMPACT OF COPAYMENT COUPONS AND OTHER PATIENT ASSISTANCE PROGRAMS ON PRESCRIPTION DRUG PRICING AND EXPENDITURES.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on the impact of copayment coupons and other patient assistance programs on prescription drug pricing and expendi-

tures. Such study shall include an analysis of the following:

(A) The extent to which copayment coupons and patient assistance programs contribute to inflated prescription drug prices and health insurance premiums, including with respect to—

(i) the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.);

(ii) the Medicare program under title XVIII of such Act (42 U.S.C. 1395 et seq.);

(iii) the TRICARE program under chapter 55 of title 10, United States Code;

(iv) health care under the laws administered by the Secretary of Veterans Affairs;

(v) the commercial health insurance market; and

(vi) the cash pay health market.

(B) The extent to which manufacturers offering copayment coupons and other patient assistance programs or sponsoring manufacturer patient assistance programs report obtaining

tax deductions for offering or sponsoring such assistance (either as business expenses or charitable deductions), including—

(i) the total reported value of the tax deductions claimed by manufacturers for offering or sponsoring patient assistance programs during the 10 years preceding the date of enactment of this Act;

(ii) a description of the methodology manufacturers reported for assigning a value to the tax deduction claimed by manufacturers for offering or sponsoring patient assistance programs; and

(iii) a description of the extent to which the activities of independent charity patient assistance programs, which are sponsored by, or receive funding from, pharmaceutical manufacturers (as determined using tax returns, sales data, and other public disclosures) provide a financial benefit to the manufacturers that sponsor them.

(C) Oversight that is conducted to ensure that independent charity patient assistance programs adhere to guidance from the Office of

the Inspector General of the Department of Health and Human Services on avoiding waste, fraud, and abuse.

(2) DEFINITIONS.—In this subsection, the terms ''patient assistance'', ''independent charity patient assistance program'', and ''manufacturer patient assistance program'' have the meanings given those terms under section 399V–7 of the Public Health Service Act, as added by section 101.

(3) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report describing the findings of the study required under this subsection.

TITLE II—ACCESS AND AFFORDABILITY

SEC. 201. NEGOTIATING FAIR PRICES FOR MEDICARE PRESCRIPTION DRUGS.

(a) NEGOTIATING FAIR PRICES.—

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

''(i) NEGOTIATING FAIR PRICES WITH DRUG MANUFACTURERS.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, in furtherance of the goals of providing quality care and containing costs under this part, the Secretary shall, with respect to applicable covered part D drugs, and may, with respect to other covered part D drugs, negotiate, using the negotiation technique or techniques that the Secretary determines will maximize savings and value to the government for prescription drug plans and MA–PD plans and for plan enrollees (in a manner that may be similar to Federal entities and that may include, but is not limited to, formularies, reference pricing, discounts, rebates, other price concessions, and coverage determinations), with drug manufacturers the prices that may be charged to PDP sponsors and MA organizations for such drugs for part D eligible individuals who are enrolled in a prescription drug plan or in an MA–PD plan. In conducting such negotiations, the Secretary shall consider the drug's current price, initial launch price, prevalence of disease and usage, and approved indications, the number of similarly effective alternative treatments for each approved use of the drug, the budgetary impact of providing coverage under this part for such drug for all individuals who would likely benefit from the

drug, evidence on the drug's effectiveness and safety compared to similar drugs, and the quality and quantity of clinical data and rigor of the applicable process of approval of a drug under section 505 of the Federal Food, Drug, and Cosmetic Act or a biological product under section 351 of the Public Health Service Act.

''(2) USE OF LOWER OF VA OR BIG FOUR PRICE IF NEGOTIATIONS FAIL.—If, after attempting to negotiate for a price with respect to a covered part D drug under paragraph (1) for a period of 1 year, the Secretary is not successful in obtaining an appropriate price for the drug (as determined by the Secretary), the Secretary shall establish the price that may be charged to PDP sponsors and MA organizations for such drug for part D eligible individuals who are enrolled in a prescription drug plan or in an MA–PD plan at an amount equal to the lesser of—

''(A) the price paid by the Secretary of Veterans Affairs to procure the drug under the laws administered by the Secretary of Veterans Affairs; or

''(B) the price paid to procure the drug under section 8126 of title 38, United States Code.

''(3) APPLICABLE COVERED PART D DRUG DEFINED.—For purposes of this subsection, the term 'applicable covered part D drug' means a covered part D drug that the Secretary determines to be appropriate for negotiation under paragraph (1) based on one or more of the following factors as applied to such drug:

''(A) Spending on a per beneficiary basis.

''(B) The proportion of total spending under this title.

''(C) Unit price increases over the preceding 5 years.

''(D) Initial launch price.

''(E) Availability of less expensive, similarly effective alternative treatments.

''(F) Status of the drug as a follow-on to previously approved drugs.

''(G) Any other criteria determined by the Secretary.

''(4) PDP SPONSORS AND MA ORGANIZATION MAY NEGOTIATE LOWER PRICES.—Nothing in this subsection shall be construed as preventing the spon-

sor 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) or the price established under paragraph (2).

''(5) NO EFFECT ON EXISTING APPEALS PROCESS.—Nothing in this subsection shall be construed to affect the appeals procedures under subsections (g) and (h) of section 1860D–4.''.

(2) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date of the enactment of this Act and shall first apply to negotiations and prices for plan years beginning on January 1, 2022.

(b) REQUIREMENT TO INCLUDE A LINK TO THE MEDICARE DRUG SPENDING DASHBOARD ON THE MEDICARE PLAN FINDER.—Beginning not later than January 1, 2022, the Secretary of Health and Human Services shall ensure that the Medicare Plan Finder on the Medicare.gov internet website includes a link to the Medicare Drug Spending Dashboard on the CMS.gov internet website. Such link shall be easily accessible on the Medicare Plan Finder.

(c) REPORTS TO CONGRESS.—

(1) SECRETARY OF HHS.—

(A) IN GENERAL.—Not later than 3 years after the date of the enactment of this Act, and every 6 months thereafter, the Secretary of Health and Human Services shall submit to Congress a report on the following:

(i) The price negotiations conducted by the Secretary under section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)), as amended by subsection (a), including a description of—

(I) how such price negotiations are achieving lower prices for covered part D drugs (as defined in section 1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e))) for Medicare beneficiaries;

(II) how such lower prices are passed through to Medicare beneficiaries;

(III) how such price negotiations are affecting drug prices in the private market; and

(IV) how such price negotiations are affecting the list price of covered part D drugs.

(ii) Data on spending under part D of the Medicare program on covered part D drugs, including data on covered part D drugs with—

(I) spending on a per beneficiary basis that is above the median spending on other drugs in the same class or above the median spending of other drug classes; and

(II) high unit cost increases over the past five years, especially where such increases are greater than the increases for covered part D drugs in general.

(iii) A list of the covered part D drugs with no therapeutic substitute and data on spending under part D of the Medicare program on such drugs.

(iv) Access to covered part D drugs and, where available, compliance rates and health outcomes associated with compliance rates.

(v) Appeals by enrollees with respect to covered part D drugs not included on plan formularies.

(B) PUBLIC AVAILABILITY OF REPORT.—The Secretary of Health and Human Services shall publish on the internet website of the Centers for Medicare & Medicaid Services a copy of each report submitted under subparagraph (A), including the detailed tables, figures, and data published in the report and its appendices.

(2) MEDPAC.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study on the price negotiations conducted by the Secretary under section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)), as amended by subsection (a), including an analysis of—

(i) how such price negotiations are achieving lower prices for covered part D drugs (as defined in section 1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e))) for Medicare beneficiaries;

(ii) who is benefiting from such lower prices, such as Medicare beneficiaries, the Federal Government, States, prescription drug plans and MA–PD plans, or other entities;

(iii) how such price negotiations are a factor affecting drug prices in the private market; and

(iv) how such price negotiations are a factor affecting the list price of covered part D drugs.

(B) REPORT.—Not later than January 1, 2024, the Comptroller General of the United States shall submit to Congress a report on the study conducted under subparagraph (A), together with recommendations for improving such price negotiations.

(d) CMI TESTING OF NEGOTIATING DRUG AND BIOLOGICAL PRICES TO IMPROVE VALUE.—Section 1115A(b)(2) of the Social Security Act (42 U.S.C. 1315a(b)(2)) is amended—

(1) in subparagraph (A), by adding at the end the following new sentence: ''The models selected under this subparagraph shall include at least three of the models described in subparagraph (D), which shall be implemented by not later than 18 months after the date of the enactment of the Affordable Medications Act''; and

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

''(D) MODELS OF NEGOTIATING DRUG AND BIOLOGICAL PRICES TO IMPROVE VALUE.—The models described in this subparagraph are the following models for negotiating drug and biological prices under the applicable titles (including under both parts B and D of title XVIII) in order to improve the value of payments for such drugs and biologicals under such titles:

''(i) Discounting or eliminating patient cost-sharing on high-value drugs and biologicals.

''(ii) Value-based formularies.

''(iii) Indications-based pricing.

''(iv) Reference pricing.

''(v) Risk-sharing agreements based on outcomes.

''(vi) Pricing based on comparative effectiveness research.

''(vii) Episode-based payments for chemotherapy and other conditions determined appropriate by the Secretary.

''(viii) Alternative ways of paying for drugs and biologicals under part B of title XVIII.

''(ix) Other models determined appropriate by the Secretary.''.

SEC. 202. PRESCRIPTION DRUG PRICE SPIKES.

(a) IDENTIFICATION OF PRESCRIPTION DRUG PRICE SPIKES.—

(1) DEFINITIONS.—In this subsection:

(A) APPLICABLE ENTITY.—The term ''applicable entity'' means the holder of an application approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or of a license issued under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) for a drug described in paragraph (5)(A).

(B) AVERAGE MANUFACTURER PRICE.—The term ''average manufacturer price''—

(i) has the same meaning given such term under section 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r–8(k)(1)); or

(ii) with respect to a drug for which there is no average manufacturer price as so defined, such term shall mean the wholesale acquisition cost of the drug.

(C) COMMERCE.—The term ''commerce'' has the meaning given such term in section 4 of the Federal Trade Commission Act (15 U.S.C. 44).

(D) INSPECTOR GENERAL.—The term ''Inspector General'' means the Inspector General of the Department of Health and Human Services.

(E) PRESCRIPTION DRUG.—

(i) IN GENERAL.—The term ''prescription drug'' means any drug (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g))), including a combination product whose primary mode of action is determined under section 503(g) of such Act (21 U.S.C. 353(g)) to be that of a drug, and that—

(I) is subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and

(II) is covered by a Federal health care program (as defined in section 1128B(f) of the Social Security Act (42 U.S.C. 1320a–7b(f))).

(ii) TREATMENT OF REFORMULATED DRUGS.—For purposes of this subsection, a prescription drug with respect to which the Secretary of Health and Human Services has approved any minor reformulation that does not produce a meaningful therapeutic benefit, the drug that was approved prior to any such reformulation and the drug with any such reformulation shall be considered one prescription drug.

(F) PRICE SPIKE.—

(i) IN GENERAL.—The term ''price spike'' means an increase in the average manufacturer price in commerce of a prescription drug for which the price spike percentage is equal to or greater than applicable price increase allowance.

(ii) PRICE SPIKE PERCENTAGE.—The price spike percentage is the percentage (if any) by which—

(I) the average manufacturer price of a prescription drug in commerce for the calendar year; exceeds

(II) the average manufacturer price of such prescription drug in

commerce for the calendar year preceding such year.

(iii) APPLICABLE PRICE INCREASE ALLOWANCE.—The applicable price increase allowance for any calendar year is the percentage (rounded to the nearest one-tenth of 1 percent) by which the C–CPI–U (as defined in section 1(f)(6) of the Internal Revenue Code of 1986) for that year exceeds the C–CPI–U for the preceding calendar year.

(G) PRICE SPIKE REVENUE.—

(i) IN GENERAL.—The price spike revenue for any calendar year is an amount equal to—

(I) the gross price spike revenue; minus

(II) the adjustment amount.

(ii) GROSS PRICE SPIKE REVENUE.—The gross price spike revenue for any calendar year is an amount equal to the product of—

(I) an amount equal to the difference between subclause (I) of sub-

paragraph (F)(ii) and subclause (II) of such subparagraph; and

(II) the total number of units of the prescription drug which were sold in commerce in such calendar year.

(iii) ADJUSTMENT AMOUNT.—The adjustment amount is the amount, if any, of the gross price spike revenue which the Inspector General has determined is due solely to an increase in the cost of the inputs necessary to manufacture the prescription drug subject to the price spike.

(2) SUBMISSION BY PHARMACEUTICAL COMPANIES OF INFORMATION TO INSPECTOR GENERAL.—

(A) IN GENERAL.—For each prescription drug, the applicable entity shall submit to the Inspector General a quarterly report that includes the following:

(i) For each prescription drug of the applicable entity—

(I) the total number of units of the prescription drug which were sold in commerce in the preceding calendar quarter;

(II) the average and median price per unit of such prescription drug in commerce in the preceding calendar quarter, disaggregated by month; and

(III) the gross revenues from sales of such prescription drug in commerce in the preceding calendar quarter.

(ii) Such information related to increased input costs or public health considerations as the applicable entity may wish the Inspector General to consider in making a determination under subclause (II) of paragraph (3)(B)(ii) or an assessment in subclause (III) of such paragraph for the preceding calendar quarter.

(iii) Such information related to any anticipated increased input costs for the subsequent calendar quarter as the applicable entity may wish the Inspector General to consider in making a determination under subclause (II) of paragraph (3)(B)(ii) or an assessment in subclause (III) of such paragraph for such calendar quarter.

(B) PENALTY FOR FAILURE TO SUBMIT.—

(i) IN GENERAL.—An applicable entity described in subparagraph (A) that fails to submit information to the Inspector General regarding a prescription drug, as required by such subparagraph, before the date specified in subparagraph (C) shall be liable for a civil penalty, as determined under clause (ii).

(ii) AMOUNT OF PENALTY.—The amount of the civil penalty shall be equal to the product of—

(I) an amount, as determined appropriate by the Inspector General, which is—

(aa) not less than 0.5 percent of the gross revenues from sales of the prescription drug described in clause (i) for the preceding calendar year, and

(bb) not greater than 1 percent of the gross revenues from sales of such prescription drug for the preceding calendar year, and

(II) the number of days in the period between—

(aa) the applicable date specified in subparagraph (C), and

(bb) the date on which the Inspector General receives the information described in subparagraph (A) from the applicable entity.

(C) SUBMISSION DEADLINE.—An applicable entity shall submit each quarterly report described in subparagraph (A) not later than January 17, April 18, June 15, and September 15 of each calendar year.

(3) ASSESSMENT BY INSPECTOR GENERAL.—

(A) IN GENERAL.—Not later than the last day in February of each year, the Inspector General, in consultation with other relevant Federal agencies (including the Federal Trade Commission), shall—

(i) complete an assessment of the information the Inspector General received pursuant to paragraph (2)(A) with respect

to sales of prescription drugs in the preceding calendar year; and

(ii) in the case of any prescription drug which satisfies the conditions described in subparagraph (A) or (B) of paragraph (4), submit a recommendation to the Secretary of Health and Human Services that such drug be exempted from application of the tax imposed under section 4191 of the Internal Revenue Code of 1986 (as added by subsection (b) of this section) for such year.

(B) ELEMENTS.—The assessment required by subparagraph (A) shall include the following:

(i) Identification of each price spike relating to a prescription drug in the preceding calendar year.

(ii) For each price spike identified under clause (i)—

(I) a determination of the price spike revenue;

(II) a determination regarding the accuracy of the information submitted by the applicable entity regarding increased input costs; and

(III) an assessment of the rationale of the applicable entity for the price spike.

(4) EXEMPTION OF CERTAIN DRUGS.—

(A) IN GENERAL.—The Secretary of Health and Human Services, upon recommendation of the Inspector General pursuant to paragraph (3)(A)(ii), may exempt any prescription drug which has been subject to a price spike during the preceding calendar year from application of the tax imposed under section 4191 of the Internal Revenue Code of 1986 for such year, if the Secretary determines that—

(i) based on information submitted pursuant to paragraph (2)(A)(ii), a for-cause price increase exemption should apply; or

(ii)(I) the prescription drug which has been subject to a price spike has an average manufacturer price of not greater than $10 for a 30-day supply; and

(II) such drug is marketed by not less than three other holders of applications approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 355), where such applications approved under such subsection (j) use as a reference drug the drug so approved under such subsection (c).

(B) CLARIFICATION.—In considering, under subparagraph (A)(i), information submitted pursuant to paragraph (2)(A)(ii), the Secretary—

(i) has the discretion to determine that such information does not warrant a for-cause price increase exemption; and

(ii) shall exclude from such consideration any information submitted by the applicable entity threatening to curtail or limit production of the prescription drug if the Secretary does not grant an exemption from the application of the tax under section 4191 of the Internal Revenue Code of 1986.

(5) INSPECTOR GENERAL REPORT TO INTERNAL REVENUE SERVICE.—

(A) IN GENERAL.—Subject to subparagraph (C), not later than the last day in February of each year, the Inspector General shall transmit to the Internal Revenue Service a re-

port on the findings of the Inspector General with respect to the information the Inspector General received under paragraph (2)(A) with respect to the preceding calendar year and the assessment carried out by the Inspector General under paragraph (3)(A) with respect to such information.

(B) CONTENTS.—The report transmitted under subparagraph (A) shall include the following:

(i) The information received under paragraph (2)(A) with respect to the preceding calendar year.

(ii) The price spikes identified under clause (i) of paragraph (3)(B).

(iii) The price spike revenue determinations made under clause (ii)(I) of such paragraph.

(iv) The determinations and assessments made under subclauses (II) and (III) of clause (ii) of such paragraph.

(C) NOTICE AND OPPORTUNITY FOR HEARING.—

(i) IN GENERAL.—No report shall be transmitted to the Internal Revenue Serv-

ice under subparagraph (A) in regards to a prescription drug unless the Inspector General has provided the applicable entity with—

(I) the assessment of such drug under paragraph (3)(A); and

(II) notice of their right to a hearing in regards to such assessment.

(ii) NOTICE.—The notice required under clause (i) shall be provided to the applicable entity not later than 30 days after completion of the assessment under paragraph (3)(A).

(iii) REQUEST FOR HEARING.—Subject to clause (v), an applicable entity may request a hearing before the Secretary of Health and Human Services not later than 30 days after the date on which the notice under clause (ii) is received.

(iv) COMPLETION OF HEARING.—In the case of an applicable entity which requests a hearing pursuant to clause (iii), the Secretary of Health and Human Services shall, not later than 12 months after

the date on which the assessment under paragraph (3)(A) was completed by the Inspector General—

(I) make a final determination in regards the accuracy of such assessment; and

(II) provide the report described in subparagraph (B) to the Internal Revenue Service.

(v) LIMITATION.—An applicable entity may request a hearing under clause (iii) with respect to a particular prescription drug only once within a 5-year period.

(D) PUBLICATION.—

(i) IN GENERAL.—Not later than the last day in February of each year, subject to clause (ii), the Inspector General shall make the report transmitted under subparagraph (A) available to the public, including on the internet website of the Inspector General.

(ii) PROPRIETARY INFORMATION.—The Inspector General shall ensure that any information made public in accordance

with clause (i) excludes trade secrets and confidential commercial information.

(6) NOTIFICATION.—The Secretary of the Treasury, in conjunction with the Inspector General, shall notify, at such time and in such manner as the Secretary of the Treasury shall provide, each applicable entity in regard to any prescription drug which has been determined to have been subject to a price spike during the preceding calendar year and the amount of the tax imposed on such applicable entity pursuant to section 4191 of the Internal Revenue Code of 1986.

(b) EXCISE TAX ON PRESCRIPTION DRUGS SUBJECT TO PRICE SPIKES.—

(1) IN GENERAL.—Chapter 32 of the Internal Revenue Code of 1986 is amended by inserting after subchapter D the following new subchapter:

"Subchapter E—Prescription Drugs

"Sec. 4191. Prescription drugs subject to price spikes.

"SEC. 4191. PRESCRIPTION DRUGS SUBJECT TO PRICE SPIKES.

"(a) IMPOSITION OF TAX.—

"(1) IN GENERAL.—Subject to paragraph (3), for each taxable prescription drug sold by an applicable entity during the calendar year, there is hereby

imposed on such entity a tax equal to the greater of—

''(A) the annual price spike tax for such prescription drug, or

''(B) subject to paragraph (2), the cumulative price spike tax for such prescription drug.

''(2) LIMITATION.—In the case of a taxable prescription drug for which the applicable period (as determined under subsection (c)(2)(E)(i)) is less than 2 calendar years, the cumulative price spike tax shall not apply.

''(3) EXEMPTION.—For any calendar year in which the Secretary of Health and Human Services has provided an exemption for a taxable prescription drug pursuant to section 202(a)(4) of the Affordable Medications Act, the amount of the tax determined under paragraph (1) for such drug or device for such calendar year shall be reduced to zero.

''(b) ANNUAL PRICE SPIKE TAX.—

''(1) IN GENERAL.—The amount of the annual price spike tax shall be equal to the applicable percentage of the price spike revenue received by the applicable entity on the sale of the taxable prescription drug during the calendar year.

''(2) APPLICABLE PERCENTAGE.—For purposes of paragraph (1), the applicable percentage shall be equal to—

''(A) in the case of a taxable prescription drug which has been subject to a price spike percentage greater than the applicable price increase allowance (as defined in section 202(a)(1)(F)(iii) of the Affordable Medications Act) but less than 15 percent, 50 percent,

''(B) in the case of a taxable prescription drug which has been subject to a price spike percentage equal to or greater than 15 percent but less than 20 percent, 75 percent, and

''(C) in the case of a taxable prescription drug which has been subject to a price spike percentage equal to or greater than 20 percent, 100 percent.

''(c) CUMULATIVE PRICE SPIKE TAX.—

''(1) IN GENERAL.—The amount of the cumulative price spike tax shall be equal to the applicable percentage of the cumulative price spike revenue received by the applicable entity on the sale of the taxable prescription drug during the calendar year.

''(2) APPLICABLE PERCENTAGE.—

"(A) IN GENERAL.—For purposes of paragraph (1), the applicable percentage shall be equal to—

"(i) in the case of a taxable prescription drug which has been subject to a cumulative price spike percentage greater than the cumulative price increase allowance but less than the first multi-year percentage, 50 percent,

"(ii) in the case of a taxable prescription drug which has been subject to a cumulative price spike percentage equal to or greater than the first multi-year percentage but less than the second multi-year percentage, 75 percent, and

"(iii) in the case of a taxable prescription drug which has been subject to a cumulative price spike percentage equal to or greater than the second multi-year percentage, 100 percent.

"(B) CUMULATIVE PRICE SPIKE PERCENTAGE.—The cumulative price spike percentage is the percentage (if any) by which—

"(i) the average manufacturer price of the taxable prescription drug in commerce for the preceding calendar year, exceeds

"(ii) the average manufacturer price of such prescription drug in commerce for the base year.

"(C) CUMULATIVE PRICE INCREASE ALLOWANCE.—For purposes of clause (i) of subparagraph (A), the cumulative price increase allowance for any calendar year is the percentage (rounded to the nearest one-tenth of 1 percent) by which the C–CPI–U (as defined in section 1(f)(6)) for that year exceeds the C–CPI–U for the base year.

"(D) MULTI-YEAR PERCENTAGES.—For purposes of subparagraph (A), the first multi-year percentage and second multi-year percentage shall be determined in accordance with the following table:

"Number of years in applicable period	First multi-year percentage	Second multi-year percentage
2 years	17.5	22.5
3 years	20	25
4 years	22.5	27.5
5 years	25	30.

"(E) APPLICABLE PERIOD AND BASE YEAR.—

"(i) APPLICABLE PERIOD.—The applicable period shall be the lesser of—

"(I) the 5 preceding calendar years,

"(II) all calendar years beginning after the date of enactment of this section, or

"(III) all calendar years in which the taxable prescription drug was sold in commerce.

"(ii) BASE YEAR.—The base year shall be the calendar year immediately preceding the applicable period.

"(3) CUMULATIVE PRICE SPIKE REVENUE.—For purposes of paragraph (1), the cumulative price spike revenue for any taxable prescription drug shall be an amount equal to—

"(A) an amount equal to the product of—

"(i) an amount (not less than zero) equal to—

"(I) the average manufacturer price of such prescription drug in commerce for the preceding calendar year, minus

"(II) the average manufacturer price of such prescription drug in commerce for the base year, and

"(ii) the total number of units of such prescription drug which were sold in commerce in the preceding calendar year, minus

"(B) an amount equal to the sum of the adjustment amounts, if any, determined under section 202(a)(1)(G)(iii) of the Affordable Medications Act for each calendar year during the applicable period.

"(d) DEFINITIONS.—For purposes of this section—

"(1) TAXABLE PRESCRIPTION DRUG.—The term 'taxable prescription drug' means a prescription drug (as defined in section 202(a)(1)(E) of the Affordable Medications Act) which has been identified by the Inspector General of the Department of Health and Human Services, under section 202(a)(3)(B)(i) of such Act, as being subject to a price spike.

"(2) OTHER TERMS.—The terms 'applicable entity', 'average manufacturer price', 'price spike', 'price spike percentage', and 'price spike revenue'

have the same meaning given such terms under section 202(a)(1) of the Affordable Medications Act.''.

(2) CLERICAL AMENDMENT.—The table of subchapters for chapter 32 of such Code is amended by inserting after the item relating to subchapter D the following new item:

''SUBCHAPTER E. PRESCRIPTION DRUGS''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to sales after the date of the enactment of this Act.

(c) REVENUES COLLECTED.—There are authorized to be appropriated to the Secretary of Health and Human Services such sums as are equal to any increase in revenue to the Treasury by reason of the provisions of this section or the amendments made by this section for the purposes of—

(1) funding or conducting research on the economic and policy implications of price patterns of prescription drugs;

(2) increasing amounts available to the National Institutes of Health for research and development of drugs;

(3) reducing prescription drug cost-sharing for patients; or

(4) reducing health insurance premiums.

SEC. 203. IMPORTING AFFORDABLE AND SAFE DRUGS.

(a) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) is amended to read as follows:

"SEC. 804. IMPORTATION OF SAFE AND AFFORDABLE DRUGS BY WHOLESALE DISTRIBUTORS, PHARMACIES, AND INDIVIDUALS.

''(a) IN GENERAL.—Not later than 180 days after the date of enactment of the Affordable Medications Act, the Secretary shall promulgate regulations permitting the importation of qualifying prescription drugs into the United States, in accordance with this section.

''(b) DEFINITIONS.—For purposes of this section:

''(1) CERTIFIED FOREIGN SELLER.—The term 'certified foreign seller' means a licensed foreign pharmacy or foreign wholesale distributor that the Secretary certifies under subsection (d)(1)(B), that pays the fee required under subsection (d)(1)(C), and that is included on the list described in subsection (c).

''(2) FOREIGN WHOLESALE DISTRIBUTOR.—The term 'foreign wholesale distributor' means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager) engaged in wholesale distribution.

''(3) IMPORTER.—The term 'importer' means a dispenser (as defined in section 581(3)) or wholesale distributor registered under section 503(e) who imports prescription drugs into the United States in accordance with this section.

''(4) LICENSED FOREIGN PHARMACY.—The term 'licensed foreign pharmacy' means a pharmacy located in Canada, or subject to subsection (e), another applicable country, that—

''(A) operates in accordance with applicable pharmacy standards set forth by the provincial pharmacy rules and regulations enacted in Canada, or, subject to subsection (e), such applicable rules and regulations of the permitted country in which such seller is located; and

''(B) is licensed to operate and dispense prescription drugs to individuals in Canada, or, subject to subsection (e), the permitted country in which the pharmacy is located.

''(5) QUALIFYING PRESCRIPTION DRUG.—The term 'qualifying prescription drug'—

''(A) means a prescription drug that—

''(i) is approved for use in patients, and marketed, in Canada, or subject to subsection (e), approved for use in pa-

tients, and marketed, in another permitted country;

"(ii) is manufactured in a facility registered under subsection (b)(1) or (i) of section 510 that is in compliance with good manufacturing practices regulations of the Food and Drug Administration;

"(iii) has the same active ingredient or ingredients, route of administration, and strength as a prescription drug approved under chapter V, or, for purposes of subparagraph (B)(iv), is biosimilar to an approved biological product and has the same route of administration and strength as the approved biological product; and

"(iv) is labeled in accordance with—

"(I) the laws of Canada, or another country from which importation is permitted pursuant to subsection (e); and

"(II) the requirements promulgated by the Secretary, which shall include labeling in English;

"(B) with respect to importers only, includes—

''(i) peritoneal dialysis solution;

''(ii) insulin;

''(iii) a drug for which a risk evaluation and mitigation strategy is required under section 505–1;

''(iv) biological products, as defined in section 351 of the Public Health Service Act that are proteins (except any chemically synthesized polypeptides) or analogous products; and

''(v) intravenously infused drugs; and

''(C) does not include—

''(i) a controlled substance (as defined in section 102 of the Controlled Substances Act);

''(ii) an anesthetic drug inhaled during surgery; or

''(iii) a compounded drug.

''(6) VALID PRESCRIPTION.—The term 'valid prescription' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—

''(A) a practitioner who has conducted at least one in-person medical evaluation of the patient; or

''(B) a covering practitioner.

''(c) PUBLICATION OF CERTIFIED FOREIGN SELLERS.—The Secretary shall publish on a dedicated internet website a list of certified foreign sellers, including the internet website address, physical address, and telephone number of each such certified foreign seller.

''(d) ADDITIONAL CRITERIA.—

''(1) CERTIFIED FOREIGN SELLERS.—

''(A) IN GENERAL.—To be a certified foreign seller, such seller shall—

''(i) be certified by the Secretary in accordance with subparagraph (B);

''(ii) pay the registration fee established under subparagraph (C); and

''(iii) sell only qualifying prescription drugs to importers or individuals who import prescription drugs into the United States in accordance with this section.

''(B) CERTIFICATION.—To be a certified foreign seller, the Secretary shall certify that such seller—

''(i) is a foreign wholesale distributor or licensed foreign pharmacy operating an establishment, which may include an online foreign pharmacy, that is located in Can-

ada, or, subject to subsection (e), another permitted country;

''(ii) is engaged in the distribution or dispensing of a prescription drug that is imported or offered for importation into the United States;

''(iii) has been in existence for a period of at least 5 years preceding the date of such certification and has a purpose other than to participate in the program established under this section;

''(iv) in the case of a certified foreign seller that is a licensed foreign pharmacy, agrees to dispense a qualifying prescription drug to an individual in the United States only after receiving a valid prescription, as described in paragraph (2)(C);

''(v) has processes established by the seller, or participates in another established process, to certify that the physical premises and data reporting procedures and licenses are in compliance with all applicable laws and regulations of Canada, or, subject to subsection (e), the permitted country in which the seller is located, and

has implemented policies designed to monitor ongoing compliance with such laws and regulations;

''(vi) conducts or commits to participate in ongoing and comprehensive quality assurance programs and implements such quality assurance measures, including blind testing, to ensure the veracity and reliability of the findings of the quality assurance program;

''(vii) agrees that, pursuant to subsection (g), laboratories approved by the Secretary may be authorized to conduct product testing to determine the chemical authenticity of sample pharmaceutical products;

''(viii) agrees to notify the Secretary, importers, and individuals of product recalls in Canada, or pursuant to subsection (e), the permitted country in which the seller is located, and agrees to cease, or refrain from, exporting such product;

''(ix) has established, or will establish or participate in, a process for resolving grievances, as defined by the Secretary,

and will be held accountable for violations of established guidelines and rules;

''(x) except as otherwise permitted under this section, does not sell products that the seller could not otherwise legally sell in Canada, or, subject to subsection (e), the permitted country in which such seller is located to customers in the United States; and

''(xi) meets any other criteria established by the Secretary.

''(C) CERTIFICATION FEE.—Not later than 30 days before the start of each fiscal year, the Secretary shall establish a fee to be collected from foreign sellers for such fiscal year that are certified under subparagraph (B), in an amount that is sufficient, and not more than necessary, to pay the costs of administering the program under this section, and enforcing this section pursuant to section 303(h), for that fiscal year.

''(D) RECERTIFICATION.—A certification under subparagraph (B) shall be in effect for a period of 2 years, or until there is a material change in the circumstances under which the foreign seller meets the requirements under

such subparagraph, whichever occurs earlier. A foreign seller may reapply for certification under such subparagraph (B), in accordance with a process established by the Secretary.

''(2) INDIVIDUALS.—An individual may import a qualifying prescription drug described in subsection (b) from Canada or another country pursuant to subsection (e) if such drug—

''(A) is dispensed, including through an online pharmacy, by a certified foreign seller that is a licensed foreign pharmacy;

''(B) is purchased for personal use by the individual, not for resale, in quantities that do not exceed a 90-day supply; and

''(C) is filled only after providing to the licensed foreign pharmacy a valid prescription issued by a health care practitioner licensed to practice in a State in the United States.

''(e) IMPORTATION FROM OTHER COUNTRIES.—Beginning on the date that is 2 years after the date on which final regulations are promulgated to carry out this section, if, based on a review of the evidence obtained after such effective date, including the reports submitted under section 203(d) of the Affordable Medications Act, that importation of qualifying prescription drugs from Canada under

this section resulted in cost savings for consumers in the United States and increased access to safe medication, the Secretary shall have the authority to permit importation of qualifying prescription drugs by importers and individuals from, in addition to Canada, any country that—

''(1) is a member of the Organisation for Economic Co-operation and Development; and

''(2) has statutory or regulatory standards for the approval and sale of prescription drugs that are comparable to the standards in the United States and that—

''(A) authorizes the approval of drugs only if a drug has been determined to be safe and effective by experts employed by or acting on behalf of a governmental entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs;

''(B) requires that any determination of safety and effectiveness described in subparagraph (A) be made on the basis of adequate and well-controlled investigations, including clinical investigations, as appropriate, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs;

''(C) requires the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of drugs in the country to be adequate to preserve the identity, quality, purity, and strength of the drugs; and

''(D) requires the reporting of adverse reactions to drugs and establish procedures to recall, and withdraw approval of, drugs found not to be safe or effective.

''(f) LABELING.—Any qualifying prescription drug imported that meets the labeling requirements described in subsection (b)(5)(A)(iv) is deemed not misbranded for purposes of section 502.

''(g) DRUG TESTING LABORATORIES.—The Secretary may approve one or more laboratories to conduct random testing of prescription drugs sold by certified foreign sellers to assess the chemical authenticity of such drugs.

''(h) UNFAIR AND DISCRIMINATORY ACTS AND PRACTICES.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing agreement or other agreement)—

''(1) to discriminate by charging a higher price for a prescription drug sold to a certified foreign seller that sells such drug to an importer in accord-

ance with this section than the price that is charged, inclusive of rebates or other incentives to the country from which the drug is exported, to another person that is in the same country and that does not import such a drug into the United States in accordance with this section;

''(2) except with respect to a prescription drug on the drug shortage list under section 506E, discriminate by denying, restricting, or delaying supplies of a prescription drug to a certified foreign seller, on account of such seller's status as a certified foreign seller, that sells such drug to an importer in accordance with this section, or by publicly, privately, or otherwise refusing to do business with such a certified foreign seller on account of such seller's status as a certified foreign seller;

''(3) cause there to be a difference (including a difference in active ingredient, route of administration, bioequivalence, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and the drug for distribution in Canada or another permitted country, subject to subsection (e), for the

purpose of avoiding sales by certified foreign sellers; or

''(4) except with respect to a prescription drug on the drug shortage list under section 506E, engage in any other action to restrict, prohibit, or delay the importation of a prescription drug under this section.

''(i) INFORMATION AND RECORDS.—

''(1) BIANNUAL REPORTS.—Each importer shall submit biannual reports to the Secretary which shall contain, for each qualifying prescription drug imported into the United States—

''(A) the unique facility identifier of the manufacturer of the drug, described in section 510;

''(B) the transaction information described in section 581(26) (other than the information described in subparagraph (C)); and

''(C) the price paid by the importer for the drug.

''(2) MAINTENANCE OF RECORDS BY SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be appropriate.

''(j) SUSPENSION OF IMPORTATION.—

''(1) PATTERNS OF NONCOMPLIANCE.—The Secretary shall require that importation of a specific qualifying prescription drug or importation by a specific certified foreign seller or importer pursuant to this section be immediately suspended if the Secretary determines that there is a pattern of importation of such specific drug or by such specific seller or importer that involves counterfeit drugs, drugs that have been recalled or withdrawn, or drugs in violation of any requirement of this section, until an investigation is completed and the Secretary determines that importation of such drug or by such seller or importer does not endanger the public health.

''(2) TEMPORARY SUSPENSION.—The Secretary may require that importation of a specific qualifying prescription drug or importation by a specific certified foreign seller or importer pursuant to this section be temporarily suspended if, with respect to such drug, seller, or importer, there is a violation of any requirement of this section or if the Secretary determines that importation of such drug or by such seller or importer might endanger the public health. Such temporary suspension shall apply until the Secretary completes an investigation and determines

that importation of such drug or by such seller or importer does not endanger the public health.

''(k) SUPPLY CHAIN SECURITY.—

''(1) PURCHASE FROM REGISTERED FACILITIES AND CERTIFIED FOREIGN SELLERS.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), certified foreign sellers who sell qualifying prescription drugs for importation into the United States pursuant to this section may purchase such drugs only from manufacturers or entities registered under section 510 or other certified foreign sellers.

''(B) EXCEPTION.—Certified foreign sellers who sell qualifying prescription drugs for importation into the United States pursuant to this section may purchase such drugs from foreign sellers in Canada or another permitted country, even if such foreign seller is not a manufacturer registered under section 510 or a certified foreign seller, if the Secretary enters into a memorandum of understanding or cooperative agreement with Canada, or such other permitted country, to ensure compliance, to the extent appropriate and feasible, with subchapter H of chapter V. The Secretary shall seek to

enter into such a memorandum of understanding or cooperative agreement with Canada and each country from which importation is permitted under subsection (e).

''(2) IMPORTATION TRACING.—Certified foreign sellers shall provide importers with the unique facility identifier associated with the manufacturer registered under section 510 of the qualifying prescription drug and the information under paragraph (25), paragraph (26) (other than subparagraph (C)), and subparagraphs (D), (F), and (G) of paragraph (27) of section 581. Certified foreign sellers shall provide such information to individuals purchasing such drugs, upon request.

''(l) REMS.—In the case of an importer that imports a qualifying prescription drug, where the drug with the same active ingredient or ingredients (or that is biosimilar to an approved biological product), route of administration, and strength that is approved under chapter V or section 351 of the Public Health Service Act is subject to elements to assure safe use under section 505–1, such importer shall be subject to such elements to assure safe use, as applicable and appropriate.

''(m) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation

of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.''.

(b) PENALTIES WITH RESPECT TO ONLINE PHARMACIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(h) In the case of a person operating an internet website, whether in the United States or in another country, that violates section 301(aa) by—

''(1) selling, by means of the internet, with the intent to defraud or mislead or with reckless disregard for safety of the public, an adulterated or counterfeit drug to an individual in the United States; or

''(2) dispenses, by means of the internet, a drug to an individual in the United States who the person knows or has reasonable cause to believe, does not possess a valid prescription for that drug,

such person shall be imprisoned for not more than 10 years or fined not more than $250,000.''.

(c) NO PREEMPTION.—Nothing in this section, including the amendments made by this section, shall be construed to preempt, alter, displace, abridge, or supplant any remedy available under any State or Federal law, in-

cluding common law, that provides a remedy for civil relief.

(d) REPORTS.—

(1) HHS.—Not later than 1 year after the date on which final regulations are promulgated to carry out section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384), as amended by subsection (a), and every 2 years thereafter, the Secretary of Health and Human Services, after consultation with appropriate Federal agencies, shall submit to Congress and make public a report on the importation of drugs into the United States.

(2) GAO REPORT.—Not later than 18 months after the first report is submitted under paragraph (1), the Comptroller General of the United States shall submit to Congress a report containing an analysis of the implementation of the amendments made by this section, including a review of drug safety and cost-savings and expenses, including cost-savings to consumers in the United States and trans-shipment and importation tracing processes, resulting from such implementation.

SEC. 204. 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, 2022, 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) 2022 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, 2022, and ending on December 31, 2022, shall not be in-

cluded 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, 2021, in the amount specified in paragraph (3) for any covered part D drug of the manufacturer dispensed after December 31, 2021, 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)(8), 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 dis-

pensed 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 information collected under section 1860D–12(b)(8)(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)(8):

''(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:

"(8) 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, 2022, 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 conces-

sions, 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 average 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:

"(E) REPORTING REQUIREMENT RELATED TO REBATE FOR REBATE ELIGIBLE MEDICARE

DRUG PLAN ENROLLEES.—Section 1860D–12(b)(8).''.

(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. 205. CAP ON PRESCRIPTION DRUG COST-SHARING.

(a) QUALIFIED HEALTH PLANS.—Section 1302(c) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(c)) is amended—

(1) in paragraph (3)(A)(i), by inserting '', including cost-sharing with respect to prescription drugs covered by the plan'' after ''charges''; and

(2) by adding at the end the following:

''(5) PRESCRIPTION DRUG COST-SHARING.—

''(A) 2022.—For plan years beginning in 2022, the cost-sharing incurred under a health plan with respect to prescription drugs covered by the plan shall not exceed $250 per month for each enrolled individual, or $500 for each family.

''(B) 2023 AND LATER.—

''(i) IN GENERAL.—In the case of any plan year beginning in a calendar year after 2022, the limitation under this para-

graph shall be equal to the applicable dollar amount under subparagraph (A) for plan years beginning in 2022, increased by an amount equal to the product of that amount and the medical care component of the consumer price index for all urban consumers (as published by the Bureau of Labor Statistics) for that year.

''(ii) ADJUSTMENT TO AMOUNT.—If the amount of any increase under clause (i) is not a multiple of $5, such increase shall be rounded to the next lowest multiple of $5.''.

(b) GROUP HEALTH PLANS.—Section 2707(b) of the Public Health Service Act (42 U.S.C. 300gg–6(b)) is amended—

(1) by striking ''annual''; and

(2) by striking ''paragraph (1) of section 1302(c)'' and inserting ''paragraphs (1) and (5) of section 1302(c) of the Patient Protection and Affordable Care Act''.

(c) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) shall take effect with respect to plans beginning after December 31, 2021.

SEC. 206. MODIFICATION OF TRADE NEGOTIATING OBJECTIVES RELATING TO INTELLECTUAL PROPERTY RIGHTS TO ENSURE ACCESS TO BIOLOGICAL PRODUCTS.

Section 102(b)(5)(C) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (19 U.S.C. 4201(b)(5)(C)) is amended by striking the period at the end and inserting the following: ", including by ensuring that trade agreements do not require a party to provide biological product exclusivity of more than 7 years.".

TITLE III—INNOVATION

SEC. 301. INNOVATION INCENTIVE FUND FOR NEW AND MORE EFFECTIVE TREATMENTS OF BACTERIAL INFECTIONS.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

"SEC. 409K. INNOVATION INCENTIVE FUND FOR NEW AND MORE EFFECTIVE TREATMENTS OF BACTERIAL INFECTIONS.

"(a) ESTABLISHMENT OF FUND.—There is hereby established in the Treasury of the United States a revolving fund to be known as the 'Antibiotics Innovation Incentive Fund', which shall consist of funds transferred under subsection (b).

''(b) AMOUNTS CREDITED TO THE FUND.—There are hereby authorized to be appropriated, and appropriated, to the Antibiotics Innovation Incentive Fund, for fiscal year 2022, out of any monies in the Treasury not otherwise appropriated, $2,000,000,000. Such funds shall remain available until expended.

''(c) AWARDS.—

''(1) IN GENERAL.—During the 10-year period following the date of enactment of the Affordable Medications Act, the Director of the NIH, in accordance with the criteria under subsection (d) and the goals under subsection (e), shall award—

''(A) up to 3 market entry awards for qualifying products that provide added benefit for patients over existing therapies in the treatment of serious and life-threatening bacterial infections demonstrating in superiority trials; and

''(B) award open source dividend prizes for contributions that significantly advance the field of antibiotic research with openly sourced materials, technology, data, and knowledge.

''(2) AWARD AMOUNT REQUIREMENTS.—No more than 5 percent of the amount available in the

Antibiotics Innovation Incentive shall be dedicated to open source dividend prizes.

''(d) CRITERIA AND STRUCTURE OF PRIZES.—

''(1) ESTABLISHMENT OF CRITERIA.—Not later than 120 days after the date of enactment of the Affordable Medications Act, the Director of NIH shall establish criteria for the selection of recipients and eligibility of persons for market entry rewards and open source dividend prizes under this section and criteria for determining the amounts of such prizes, through notice and comment rulemaking.

''(2) CONSIDERATIONS IN ESTABLISHING CRITERIA FOR QUALIFYING PRODUCTS.—In establishing the criteria for selection of recipients and amounts of market entry rewards and open source dividend prizes under paragraph (1), the Director of NIH, in consultation with other agencies as appropriate, shall consider the following:

''(A) The number of patients in the United States and in other countries who would benefit from the qualifying product that treats a serious or life-threatening bacterial infection, and the number of patients in the United States and in other countries projected to benefit during the upcoming 10-year period.

''(B) Whether the qualifying product treats, or has the potential to treat, a serious or life-threatening bacterial infection for which no other treatment is currently available or for which there is a high threat of resistance to existing treatments.

''(C) The incremental and additional therapeutic benefit to human in the United States and other countries of the qualifying product as compared to other treatments available to treat the bacterial infection, evaluating the incremental therapeutic benefit in comparison to treatments that were not recently developed.

''(D) The transmissibility of the bacterial infection the qualifying product would treat, and barriers to prevention of that infection.

''(E) The extent to which knowledge, data, materials, and technology that are openly sourced have contributed to the successful development of new treatments that provide an added benefit to patients, such as decreasing mortality or irreversible morbidity on patient-centered outcomes, significantly advancing the field of antibiotic research, or improving proc-

esses for manufacturing products used for the treatment.

''(F) Other criteria that the Director of NIH determines to be relevant and useful in ensuring that the prizes provide appropriate incentives.

''(3) CRITERIA FOR OPEN SOURCE DIVIDEND PRIZES.—An open source dividend prize under this section shall reward persons that openly shared on a royalty-free, not-for-profit and non-discriminatory basis, materials, technology, data, and knowledge that contribute in a significant way to the successful development of a qualifying product or significantly advanced the field of antibiotic research.

''(e) GOALS.—With respect to each year for which the Director of NIH awards market entry rewards and open source dividend prizes under subsection (c), the Director of NIH shall establish a framework of goals that a qualifying product or contribution that significantly advances the field of antibiotic research is required to show promise to help meet in order for a person to be eligible to receive a market entry reward or open source dividend prize with respect to such product or such contribution. Such goals may include—

''(1) reduced hospital admissions or readmissions;

''(2) use of diagnostics prior to prescribing of drugs; and

''(3) use of innovative programs for antibiotic stewardship.

''(f) CONDITION ON RECEIPT OF MARKET ENTRY REWARD.—

''(1) IN GENERAL.—Each market entry reward for a qualifying product offered under this section shall be conditioned on the following:

''(A) The recipient shall agree to offer the qualifying product at a reasonable price as described in paragraph (3).

''(B) Subject to applicable patient privacy protections, the recipient shall agree to publicly disclose all pre-clinical and clinical trial data with respect to the qualifying product.

''(C) The recipient shall agree to submit to the Director of NIH, for review and approval by such director, in collaboration with the Commissioner of Food and Drugs and the Director of the Centers for Disease Control and Prevention, all marketing, sales, and other promotional and educational activities associated with the

qualifying product, to ensure that such activities align with, and advance the goals of, resource conserving stewardship, protecting the utility of antibiotics, and encouraging and ensuring the correct use of antibiotics.

''(D) The recipient shall irrevocably waive—

''(i) all periods of exclusivity available to the product under chapter V of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act; and

''(ii) all applicable patent rights under title 35, United States Code.

''(E) Any other conditions the Director of NIH determines appropriate.

''(2) APPLICABILITY.—All conditions described in paragraph (1) shall apply to subsequent owners, licensees, producers, and manufacturers, and assignees of the product or any chemical component of the qualifying product for which the market entry reward was awarded.

''(3) REASONABLE PRICE.—

''(A) IN GENERAL.—A recipient may satisfy the requirement to offer a qualifying prod-

uct or contribution at a 'reasonable price' for purposes of paragraph (1)(A) by—

''(i)(I) providing open licensing of all necessary rights to patents, manufacturing processes, rights in data, and other intellectual property rights needed to make and sell the product to manufacturers of the generic version of such product; or

''(II) selling such product at a price that is no more than twice the price of antibiotic drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act with similar manufacturing costs; and

''(ii) selling such product at a price that is not higher than the median price charged, at the time of such sale, in the applicable 7 countries, as determined under in subparagraph (B).

''(B) CRITERIA.—For purposes of subparagraph (A)(ii), the Director of NIH shall identify, on an annual basis, the countries that have a per capita income that is not less than half the per capita income of the United States, select the 7 of such countries that have the larg-

est gross domestic product, and determine the median price charged for each qualifying product for which an award has been granted under subsection (c).

''(g) ENFORCEMENT.—If the market entry reward recipient, or subsequent owner, licensee, or assignee of the qualifying product, does not fulfill the conditions described subsection (f)(1), the Secretary, in collaboration with the Attorney General, shall take all necessary action to clawback the market entry reward.

''(h) TRANSPARENCY.—With respect to each market entry reward or open source dividend prize awarded under this section, the Director of NIH shall make public—

''(1) the methodology used and criteria analyzed in determining the market entry reward or open source dividend prize recipient; and

''(2) a complete analysis of the recipient's fulfillment of award conditions under subsection (e)(1).

''(i) QUALIFYING PRODUCT.—For purposes of this section, the term 'qualifying product' means a drug (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act) subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act.

''(j) STUDY.—

''(1) IN GENERAL.—The Director of NIH shall seek to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to conduct a study to examine—

''(A) the use of innovation inducement reward funds and push financing mechanisms as ways to stimulate investments in biomedical research and development that de-links costs from product prices;

''(B) models of different possible means of de-linking research and development costs from drug prices, including the progressive replacement of the monopoly on new products with a combination of expanded research subsidies and new incentives from innovation inducement funds to stimulate the development of drugs, including drugs to treat bacterial infections, rare diseases, HIV/AIDS, and cancer;

''(C) the size of market entry rewards, open source dividends and other innovation inducement prizes that would be necessary to achieve innovation objectives and the relative cost effectiveness of incentives delinked from the prices of products and services in stimu-

lating innovation, compared to time-limited monopolies; and

''(D) methods of progressively implementing policies that delink research and development funding from prices of products and services, including to the progressive reduction in the effective term of exclusive rights, accompanied by a progressive introduction and expansion of market entry rewards.

''(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated, and there are appropriated, $3,000,000 for fiscal year 2022. Such funds shall remain available until expended.''.

SEC. 302. PUBLIC FUNDING FOR CLINICAL TRIALS.

(a) IN GENERAL.—Part E of title IV of the Public Health Service Act (42 U.S.C. 287 et seq.) is amended by adding at the end the following:

''Subpart 6—Center for Clinical Research

''SEC. 485E. CENTER FOR CLINICAL RESEARCH.

''(a) IN GENERAL.—There is established within the National Institutes of Health the Center for Clinical Research, for the purpose of conducting clinical trials on drugs, as described in subsection (b), with the intention of obtaining approval of such drug under section 505 of

the Federal Food, Drug, and Cosmetic Act or section 351 of this Act. The Director of NIH shall appoint a Director of the Center for Clinical Research referred to in this section as the 'Director') not later than 90 days after the date of enactment of the Affordable Medications Act.

''(b) CLINICAL TRIALS.—

''(1) IN GENERAL.—Each year, beginning not later than 1 year after the date of enactment of the Affordable Medications Act, the Director shall select at least 2 molecules, compounds, drugs, or biological products and conduct clinical trials on such molecules, compounds, drugs, or biological products, or enter into contracts with other entities to conduct such clinical trials.

''(2) SELECTION OF DRUGS.—

''(A) CRITERIA.—The Director shall establish criteria, which shall be made public, for acquiring the patent rights for, and selecting, drugs under paragraph (1) to ensure that the drugs selected for clinical trials through the Center—

''(i) have the potential to address an existing or emerging need, including drugs that can be repurposed to treat a new con-

dition in the case of a national emergency; and

''(ii) are not solely drugs that private sector researchers with access to all available information on such drugs chose not to develop.

''(B) PROCESS.—The Director shall secure all patent rights to each drug selected under paragraph (1), as applicable, and perform the clinical trials at NIH or subcontract with another entity to conduct the clinical trials.

''(c) TREATMENT OF APPROVED DRUGS.—If a drug for which clinical trials have been conducted by the Center for Clinical Research is approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act, the Director shall—

''(1) execute non-exclusive licenses to allow drug manufacturers to manufacture and sell the drug; or

''(2) in collaboration with other Federal agencies as appropriate, enter into purchasing contracts.

''(d) PUBLIC INFORMATION.—

''(1) RESEARCH DATA AND FINDINGS.—Subject to applicable patient privacy protections, the Secretary shall—

''(A)(i) submit all completed studies (and terminated studies, if terminated for safety or ethical reasons) for publication in a peer-reviewed publication within 180 days of completion or termination; and

''(ii) if a study submitted as described in clause (i) is not selected for publication, publicly disclose all de-identified primary clinical data not later than 180 days after the Secretary's final decision not to pursue further submissions for publication; and

''(B) publicly disclose all de-identified primary clinical data upon publication of a study as described in subparagraph (A)(i).

''(2) FINANCIAL INFORMATION.—The Director shall make public all costs to the Federal Government associated with carrying out clinical trials by the Center for Clinical Research and with subcontract agreements under this section, in a manner that identifies the cost associated with each trial.

''(e) DEFINITION.—In this section, the term 'drug' has the meaning given such term in section 201(g) of the Federal Food, Drug, and Cosmetic Act.

''(f) APPROPRIATIONS.—For the purpose of carrying out this section, in addition to any other funds available for such purpose, there are authorized to be appropriated, and there are appropriated, $1,000,000,000 for each of fiscal years 2022 through 2032, to remain available until expended.''.

(b) CLERICAL AMENDMENT.—Section 401(b) of the Public Health Service Act (42 U.S.C. 281(b)) is amended—

(1) by redesignating paragraph (25) as paragraph (26); and

(2) by inserting after paragraph (24) the following:

''(25) The Center for Clinical Research.''.

SEC. 303. REWARDING INNOVATIVE DRUG DEVELOPMENT.

(a) DRUG EXCLUSIVITY.—

(1) NEW CHEMICAL ENTITY EXCLUSIVITY.—

(A) IN GENERAL.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(i) in subparagraph (B)—

(I) in clause (i), by inserting ''except that such approval may not be made effective before the date that is 5 years after the date on which the drug to which the application refers was approved under subsection (c)'' before the period; and

(II) in clause (ii), by inserting ''except that such approval may not be made effective before the date that is 5 years after the date on which the drug to which the application refers was approved under subsection (c)'' before the period; and

(ii) in subparagraph (F)(ii)—

(I) by striking ''expiration of five years'' and inserting ''expiration of 3 years'';

(II) by striking '', except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement

described in subclause (IV) of paragraph (2)(A)(vii)''; and

(III) by striking ''seven and one-half years'' and inserting ''6 and one-half years''.

(B) CONFORMING AMENDMENTS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended—

(i) in subsection (v)(2)(A)(i)(II) of section 505, by inserting ''the 3-year exclusivity period referred to'' before ''under clause (ii) of subsection (j)(5)(F)'';

(ii) in subsections (b)(1)(A)(i)(I) and (c)(1)(A)(i)(I) of section 505A—

(I) by striking ''five years'' each place such term appears and inserting ''3 years'';

(II) by striking ''seven and one-half years'' each place such term appears and inserting ''6 and one-half years''; and

(III) by striking ''eight years'' each place such term appears and inserting ''7 years''; and

(iii) in section 505E, by striking ''the 4- and 5-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F)'' and inserting ''the 4- and 5-year periods described in subsection (c)(3)(E)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (ii), (iii), and (iv) of subsection (j)(5)(F)''.

(2) NEW CLINICAL INVESTIGATION EXCLUSIVITY.—Section 505(c)(3)(E)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E)(iv)) is amended by inserting '', and the supplement shows a significant clinical benefit over existing therapies manufactured by the applicant in the 5-year period preceding the submission of the application,'' before ''the Secretary''.

(3) BIOLOGICAL PRODUCT EXCLUSIVITY.—

(A) IN GENERAL.—Section 351(k)(7)(A) of the Public Health Service Act (42 U.S.C. 262(k)(7)(A)) is amended by striking ''12 years'' and inserting ''7 years''.

(B) CONFORMING AMENDMENTS.—Paragraphs (2)(A) and (3)(A) of section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)) is amended by striking ''12 years'' each place it appears and inserting ''7 years''.

(b) APPLICABILITY.—The amendments made by subsection (a) apply only with respect to a drug or biological product for which the listed drug (as described in section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7))) or reference product (as such term is used in section 351 of the Public Health Service Act (42 U.S.C. 262)) is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act or licensed under section 351(a) of the Public Health Service Act, as applicable, on or after the date of enactment of this Act.

(c) GAO STUDY.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study and submit to Congress a report that includes—

(1)(A) the number of requests for designation as a drug for a rare disease or condition under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) the Food and Drug Administration receives each year in the previous 10-year period;

(B) the number of such requests granted, denied, and pending;

(C) the names of all drugs receiving such designation during such period, including the date of approval and indication for which market exclusivity was granted; and

(D) any drugs for which such designation has been revoked or amended during such period;

(2) for each drug so designated as a drug for a rare disease or condition in the previous 10-year period, the total annual expenditures for such drugs under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) and the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), the number of Medicare and Medicaid beneficiaries who used each such drug each year during such time period, and any changes in price per unit during such time period; and

(3) for a sample of drugs (selected by the Comptroller General) so designated in the previous 10-year period, to the extent feasible—

(A) gross revenues of the manufacturers with respect to each such drug, and manufac-

turer spending for marketing and patient assistance programs;

(B) the average price per drug and how those prices changed over time for the selected drugs based on industry drug pricing benchmarks; and

(C) the indications that were the basis of such designation and other approved indications for the drugs, and the indications for which each drug has most commonly been used, including non-approved indications for which the drug may be recommended by external organizations such as physician or patient organizations.

SEC. 304. IMPROVING PROGRAM INTEGRITY.

(a) IN GENERAL.—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. 569E. 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 commits a violation described in subsection (c)(1) with respect to such drug.

''(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), enforced by a Federal or State governmental entity 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) Section 3729 of title 31, United States Code.

''(C) Section 286 or 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.—

"(1) IN GENERAL.—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—

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

"(B)(i) a settlement agreement described in subsection (c)(1)(C) is approved by a court order that is or becomes final and nonappealable; or

"(ii) 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.

"(2) CIVIL PENALTY.—A person who fails to report a violation as required under paragraph (1) shall be subject to a civil penalty in the amount of $200,000 for each day the failure to report continues, beginning with the day after the date on which such report is due as described in paragraph (1).".

(b) FTC.—There are authorized to be appropriated to the Federal Trade Commission such sums as may be necessary for the purpose of carrying out activities related to addressing criminal activity and anticompetitive practices by pharmaceutical companies.

TITLE IV—CHOICE AND COMPETITION

SEC. 401. UNLAWFUL COMPENSATION FOR DELAY.

(a) IN GENERAL.—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 AND BIOSIMILARS.

''(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 or biological product.

''(2) PRESUMPTION AND VIOLATION.—

''(A) IN GENERAL.—Subject to subparagraph (B), in such a proceeding, an agreement shall be presumed to have anticompetitive effects and shall be a violation of this section if—

''(i) an ANDA filer or a biosimilar biological product application filer receives anything of value, including an exclusive license; and

''(ii) the ANDA filer or biosimilar biological product application filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product or biosimilar biological product, as applicable, for any period of time.

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

''(i) the value described in subparagraph (A)(i) is compensation solely for other goods or services that the ANDA filer or biosimilar biological product application filer has promised to provide; or

''(ii) the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

''(b) LIMITATIONS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall not presume—

''(1) that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity; or

''(2) that the agreement's provision for entry of the ANDA product or biosimilar biological product prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is procompetitive.

''(c) 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 or biological product license holder to the ANDA filer or biosimilar biological product application filer, respectively, as part of the resolution or settlement includes only one or more of the following:

''(1) The right to market the ANDA product or biosimilar biological 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 ANDA product or biosimilar biological product.

''(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 or biosimilar biological product infringes a United States patent.

''(d) ENFORCEMENT.—

''(1) ENFORCEMENT.—A violation of this section shall be treated as a violation of section 5.

''(2) JUDICIAL REVIEW.—

''(A) IN GENERAL.—Any party that is subject to a final order of the Commission, issued in an administrative adjudicative proceeding under the authority of subsection (a)(1), may, within 30 days of the issuance of such order, petition for review of such order in—

''(i) the United States Court of Appeals for the District of Columbia Circuit;

''(ii) the United States Court of Appeals for the circuit in which the ultimate parent entity, as defined in section 801.1(a)(3) of title 16, Code of Federal Regulations, or any successor thereto, of the NDA holder or biological product license holder is incorporated as of the date that the NDA or biological product license application, as applicable, is filed with the Commissioner of Food and Drugs; or

"(iii) the United States Court of Appeals for the circuit in which the ultimate parent entity of the ANDA filer or biosimilar biological product application filer is incorporated as of the date that the ANDA or biosimilar biological product application is filed with the Commissioner of Food and Drugs.

"(B) TREATMENT OF FINDINGS.—In a proceeding for judicial review of a final order of the Commission, the findings of the Commission as to the facts, if supported by evidence, shall be conclusive.

"(e) ANTITRUST LAWS.—Nothing in this section shall modify, impair, limit, or supersede the applicability of the antitrust laws as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), and of section 5 of this Act to the extent that section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit, or supersede the right of an ANDA filer or biosimilar biological product application filer to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition.

"(f) PENALTIES.—

''(1) FORFEITURE.—Each party that violates or assists in the violation of this section shall forfeit and pay to the United States a civil penalty sufficient to deter violations of this section, but in no event greater than 3 times the value received by the party that is reasonably attributable to the violation of this section. If no such value has been received by the NDA holder or biological product license holder, the penalty to the NDA holder or biological product license holder shall be sufficient to deter violations, but in no event greater than 3 times the value given to the ANDA filer or biosimilar biological product application filer reasonably attributable to the violation of this section. Such penalty shall accrue to the United States and may be recovered in a civil action brought by the Commission, in its own name by any of its attorneys designated by it for such purpose, in a district court of the United States against any party that violates this section. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

''(2) CEASE AND DESIST.—

''(A) IN GENERAL.—If the Commission has issued a cease and desist order with respect to

a party in an administrative adjudicative proceeding under the authority of subsection (a)(1), an action brought pursuant to paragraph (1) may be commenced against such party at any time before the expiration of 1 year after such order becomes final pursuant to section 5(g).

''(B) EXCEPTION.—In an action under subparagraph (A), the findings of the Commission as to the material facts in the administrative adjudicative proceeding with respect to the violation of this section by a party shall be conclusive unless—

''(i) the terms of such cease and desist order expressly provide that the Commission's findings shall not be conclusive; or

''(ii) the order became final by reason of section 5(g)(1), in which case such finding shall be conclusive if supported by evidence.

''(3) CIVIL PENALTY.—In determining the amount of the civil penalty described in this section, the court shall take into account—

"(A) the nature, circumstances, extent, and gravity of the violation;

"(B) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the NDA holder or biological product license holder, compensation received by the ANDA filer or biosimilar biological product application filer, and the amount of commerce affected; and

"(C) other matters that justice requires.

"(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

"(g) 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 Food and Drug Administration 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) BIOLOGICAL PRODUCT.—The term 'biological product' has the meaning given such term in section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)).

''(7) BIOLOGICAL PRODUCT LICENSE APPLICATION.—The term 'biological product license application' means an application under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

''(8) BIOLOGICAL PRODUCT LICENSE HOLDER.—The term 'biological product license holder' means—

''(A) the holder of an approved biological product license application for a biological product;

''(B) a person owning or controlling enforcement of any patents that claim the biological product that is the subject of such approved application; 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) BIOSIMILAR BIOLOGICAL PRODUCT.—The term 'biosimilar biological product' means the product to be manufactured under the biosimilar biologi-

cal product application that is the subject of the patent infringement claim.

''(10) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION.—The term 'biosimilar biological product application' means an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) for licensure of a biological product as biosimilar to, or interchangeable with, a reference product.

''(11) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FILER.—The term 'biosimilar biological product application filer' means a party that owns or controls a biosimilar biological product application filed with the Food and Drug Administration or has the exclusive rights under such application to distribute the biosimilar biological product.

''(12) 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).

''(13) 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)).

''(14) 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.

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

"(16) 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.

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

''(18) 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), or on the licensing of biological product applications under section 351(k)(7) (12-year exclusivity) or paragraph (2) or (3) of section 351(m) (pediatric exclusivity) of the Public Health Service Act (42 U.S.C. 262) or under section 527 of the Federal Food, Drug, and Cosmetic Act (orphan drug exclusivity).''.

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

SEC. 402. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS REGARDING FIRST APPLICANT STATUS.

(a) AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) IN GENERAL.—Section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)) is amended—

(A) in clause (iv)(II)—

(i) by striking item (bb); and

(ii) by redesignating items (cc) and (dd) as items (bb) and (cc), respectively; and

(B) by adding at the end the following:

''(vi) FIRST APPLICANT DEFINED.—As used in this subsection, the term 'first applicant' means an applicant—

''(I)(aa) that, on the first day on which a substantially complete application containing a

certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug; and

''(bb) that has not entered into a disqualifying agreement described under clause (viii)(II); or

''(II)(aa) for the drug that is not described in subclause (I) and that, with respect to the applicant and drug, each requirement described in clause (viii) is satisfied; and

''(bb) that has not entered into a disqualifying agreement described under clause (vii)(II).

''(vii) REQUIREMENT.—The requirements described in this clause are the following:

''(I) The applicant described in clause (v)(II) submitted and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) or a statement described in paragraph (2)(A)(viii) for each unexpired patent for which a first applicant described in clause (v)(I) had submitted a certification described in paragraph

(2)(A)(vii)(IV) on the first day on which a substantially complete application containing such a certification was submitted.

''(II) With regard to each such unexpired patent for which the applicant described in clause (v)(II) submitted a certification described in paragraph (2)(A)(vii)(IV), no action for patent infringement was brought against such applicant within the 45-day period specified in paragraph (5)(B)(iii); or if an action was brought within such time period, such an action was withdrawn or dismissed by a court (including a district court) without a decision that the patent was valid and infringed; or if an action was brought within such time period and was not withdrawn or so dismissed, such applicant has obtained the decision of a court (including a district court) that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity, and including a settlement order or consent decree signed and entered by the court stating that the patent is invalid or not infringed).

"(III) If an applicant described in clause (v)(I) has begun commercial marketing of such drug, the applicant described in clause (v)(II) does not begin commercial marketing of such drug until the date that is 30 days after the date on which the applicant described in clause (v)(I) began such commercial marketing.".

(2) CONFORMING AMENDMENT.—Section 505(j)(5)(D)(i)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(IV)) is amended by striking "The first applicant" and inserting "The first applicant, as defined in subparagraph (B)(vi)(I),".

(b) APPLICABILITY.—The amendments made by subsection (a) shall apply only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) to which the amendments made by section 1102(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) apply.

SEC. 403. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS REGARDING AGREEMENTS TO DEFER COMMERCIAL MARKETING.

(a) AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) LIMITATIONS ON AGREEMENTS TO DEFER COMMERCIAL MARKETING DATE.—Section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)), as amended by section 402, is further amended by adding at the end the following:

''(viii) AGREEMENT BY FIRST APPLICANT TO DEFER COMMERCIAL MARKETING; LIMITATION ON ACCELERATION OF DEFERRED COMMERCIAL MARKETING DATE.—

''(I) AGREEMENT TO DEFER APPROVAL OR COMMERCIAL MARKETING DATE.—An agreement described in this subclause is an agreement between a first applicant and the holder of the application for the listed drug or an owner of one or more of the patents as to which any applicant submitted a certification qualifying such applicant for the 180-day exclusivity period whereby that applicant agrees, directly or indirectly, (aa) not to seek an approval of its application that is made effective on the earliest possible date under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, (bb) not to begin the commercial marketing of its drug on the earliest possible

date after receiving an approval of its application that is made effective under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or (cc) to both items (aa) and (bb).

''(II) AGREEMENT THAT DISQUALIFIES APPLICANT FROM FIRST APPLICANT STATUS.—An agreement described in this subclause is an agreement between an applicant and the holder of the application for the listed drug or an owner of one or more of the patents as to which any applicant submitted a certification qualifying such applicant for the 180-day exclusivity period whereby that applicant agrees, directly or indirectly, not to seek an approval of its application or not to begin the commercial marketing of its drug until a date that is after the expiration of the 180-day exclusivity period awarded to another applicant with respect to such drug (without regard to whether such 180-day exclusivity period is awarded before or after the date of the agreement).

''(ix) LIMITATION ON ACCELERATION.—If an agreement described in clause (viii)(I) includes more than 1 possible date when an applicant may seek an

approval of its application or begin the commercial marketing of its drug—

"(I) the applicant may seek an approval of its application or begin such commercial marketing on the date that is the earlier of—

"(aa) the latest date set forth in the agreement on which that applicant can receive an approval that is made effective under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or begin the commercial marketing of such drug, without regard to any other provision of such agreement pursuant to which the commercial marketing could begin on an earlier date; or

"(bb) 180 days after another first applicant begins commercial marketing of such drug; and

"(II) the latest date set forth in the agreement on which that applicant can receive an approval that is made effective under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or begin the commercial marketing of such drug, without regard to any other provision of such agreement pursu-

ant to which commercial marketing could begin on an earlier date, shall be the date used to determine whether an applicant is disqualified from first applicant status pursuant to clause (viii)(II).''.

(2) NOTIFICATION OF FDA.—Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended by adding at the end the following:

''(14)(A) The holder of an abbreviated application under this subsection shall submit to the Secretary a notification that includes—

''(i)(I) the text of any agreement entered into by such holder described under paragraph (5)(B)(viii)(I); or

''(II) if such an agreement has not been reduced to text, a written detailed description of such agreement that is sufficient to disclose all the terms and conditions of the agreement; and

''(ii) the text, or a written detailed description in the event of an agreement that has not been reduced to text, of any other agreements that are contingent upon, provide a contingent condition for, or are otherwise related to an agreement described in clause (i).

''(B) The notification described under subparagraph (A) shall be submitted not later than 10 business days after execution of the agreement described in subparagraph (A)(i). Such notification is in addition to any notification required under section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

''(C) Any information or documentary material filed with the Secretary pursuant to this paragraph shall be exempt from disclosure under section 552 of title 5, United States Code, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this paragraph is intended to prevent disclosure to either body of the Congress or to any duly authorized committee or subcommittee of the Congress.''.

(3) PROHIBITED ACTS.—Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is amended by striking ''505 (i) or (k)'' and inserting ''505(i), 505(j)(11), 505(k)''.

(b) INFRINGEMENT OF PATENT.—Section 271(e) of title 35, United States Code, is amended by adding at the end the following:

''(7) The exclusive remedy under this section for an infringement of a patent for which the Secretary of Health

and Human Services has published information pursuant to subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act shall be an action brought under this subsection within the 45-day period described in subsection (j)(5)(B)(iii) or (c)(3)(C) of section 505 of the Federal Food, Drug, and Cosmetic Act.''.

(c) APPLICABILITY.—

(1) LIMITATIONS ON ACCELERATION OF DEFERRED COMMERCIAL MARKETING DATE.—The amendment made by subsection (a)(1) shall apply only with respect to—

(A) an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) to which the amendments made by section 1102(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) apply; and

(B) an agreement described under section 505(j)(5)(B)(viii)(I) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)(1)) executed after the date of enactment of this Act.

(2) NOTIFICATION OF FDA.—The amendments made by paragraphs (2) and (3) of subsection (a)

shall apply only with respect to an agreement described under section 505(j)(5)(B)(viii)(I) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)(1)) executed after the date of enactment of this Act.

SEC. 404. INCREASING DRUG COMPETITION AND PREVENTING DRUG SHORTAGES.

Section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

''(E)(i) The Commissioner shall—

''(I) not later than 9 months after the date of enactment of the Affordable Medications Act, publish a complete, up-to-date list on the internet website of the Food and Drug Administration of all drugs, including authorized generics, together with, with respect to the drug, as applicable—

''(aa) the drug trade name;

''(bb) the established name;

''(cc) each active pharmaceutical ingredient facility (as defined in section 744B(a)(4)(a)(ii));

''(dd) each generic drug facility;

''(ee) each contract manufacturing organization facility (as defined in section 744A(5));

''(ff) the date any authorized generic drug entered the market;

''(gg) the marketing status; and

''(hh) any other information the Secretary may require to mitigate or prevent drug shortages;

''(II) designate each drug on the list that is a sole-source generic drug;

''(III) designate each drug on the list that is an essential medicine, as identified by the World Health Organization, or another entity designated by the Secretary that meets evidence-based standards as required by the Secretary; and

''(IV) maintain a confidential list of the identity and address of each facility described in subclause (I), and publicly report on the website only the city and State or country of each such facility.

''(ii) The Commissioner may choose not to make information collected under clause (i) publicly available if the Secretary determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of drug products to patients).

''(iii) The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid

Services and the Federal Trade Commission, when the Commissioner first publishes the information under clause (i) that the information has been published and will be updated regularly.

''(iv) In this subparagraph, the term 'sole-source' means, with respect to a drug, there is not more than one approved drug on the list of drugs under subparagraph (A), not including drugs on the discontinued section of such list.''.

SEC. 405. DISALLOWANCE OF DEDUCTION FOR ADVERTISING FOR PRESCRIPTION DRUGS.

(a) IN GENERAL.—Part IX of subchapter B of chapter 1 of subtitle A of the Internal Revenue Code of 1986 (relating to items not deductible) is amended by adding at the end the following new section:

''SEC. 280I. DISALLOWANCE OF DEDUCTION FOR DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS.

''(a) IN GENERAL.—No deduction shall be allowed under this chapter for expenses relating to direct-to-consumer advertising of prescription drugs for any taxable year.

''(b) DIRECT-TO-CONSUMER ADVERTISING.—For purposes of this section, the term 'direct-to-consumer advertising' means any dissemination, by or on behalf of a

sponsor of a prescription drug product (as such term is defined in section 735(3) of the Federal Food, Drug, and Cosmetic Act), of an advertisement which—

"(1) is in regard to such prescription drug product, and

"(2) primarily targeted to the general public, including through—

"(A) publication in journals, magazines, other periodicals, and newspapers,

"(B) broadcasting through media such as radio, television, telephone communication systems, direct mail, and billboards,

"(C) dissemination on the internet (including social media), and

"(D) manufacturer patient assistance programs, as defined in section 399V–7 of the Public Health Service Act.".

(b) CONFORMING AMENDMENT.—The table of sections for such part IX of the Internal Revenue Code of 1986 is amended by adding after the item relating to section 280H the following new item:

"Sec. 280I. Disallowance of deduction for direct-to-consumer advertising of prescription drugs.".

(c) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) shall apply to amounts paid or in-

curred after the date of the enactment of this Act, in taxable years ending after such date.

(d) OVERSIGHT OF PRESCRIPTION DRUGS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary''), acting through the Commissioner of Food and Drugs and in coordination with other Federal agencies, shall conduct oversight of the risks and benefits of drugs that are on the market and how such risks are presented in drug advertisements for the purpose of correcting false or misleading information published in direct-to-consumer advertisements and to disseminate corrective information to health care providers and the general public regarding the risks and benefits of a drug on an quarterly basis.

(2) PREREVIEW OF TELEVISION ADVERTISEMENTS.—The Secretary, acting through the Commissioner of Food and Drugs and in consultation with relevant stakeholders, shall issue new, or update current, guidance issued under section 503C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353c). In carrying out this paragraph, the Secretary shall focus on drugs that present the greatest risk to consumers, drugs that represent the

greatest proportion of total spending in Federal programs, drugs with high unit price increases over the preceding year, drugs with high launch prices, or any other priority drugs identified by the Secretary.

(3) FUNDING.—There is authorized to be appropriated to the Secretary an amount equal to the increase in revenue resulting from the enactment of section 280I of the Internal Revenue Code of 1986, as added by subsection (a).

SEC. 406. DRUG MANUFACTURER DUTY TO DISCLOSE DRUG PRICES TO PRACTITIONERS.

(a) DUTY TO DISCLOSE.—Whenever a drug manufacturer, including any representative of the manufacturer, communicates with a health care practitioner about a drug manufactured by the drug manufacturer, including through promotional, educational, or marketing communications, meetings or paid events, and the provision of goods, gifts, and samples, the drug manufacturer shall disclose to the practitioner the wholesale acquisition cost (as defined in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B))) for a 30-day supply of the drug, which may include a brief qualitative explanation of reduced cost availability for certain consumers.

(b) ENFORCEMENT BY FEDERAL TRADE COMMISSION.—

(1) UNFAIR OR DECEPTIVE ACTS OR PRACTICES.—A violation of subsection (a) by a person with respect to whom the Commission is empowered under section 5(a)(2) of the Federal Trade Commission Act (15 U.S.C. 45(a)(2)) shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

(2) POWERS OF FEDERAL TRADE COMMISSION.—

(A) IN GENERAL.—The Federal Trade Commission shall enforce this section in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this Act.

(B) PRIVILEGES AND IMMUNITIES.—Any person who violates this section shall be subject to the penalties and entitled to the privileges and immunities provided in the Federal Trade Commission Act (15 U.S.C. 41 et seq.).

(c) RULEMAKING.—The Federal Trade Commission shall promulgate in accordance with section 553 of title 5, United States Code, such rules as may be necessary to carry out this section.

(d) SAVINGS PROVISION.—Nothing in this section shall be construed to limit, impair, or supersede the operation of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) or any other provision of Federal law.

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