

116TH CONGRESS
1ST SESSION

S. 1801

To ensure medications are affordable.

IN THE SENATE OF THE UNITED STATES

JUNE 12, 2019

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

A BILL

To ensure medications are affordable.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Affordable Medications Act”.

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

Sec. 1. Short title; table of contents.

TITLE I—TRANSPARENCY

Sec. 101. Drug manufacturer reporting.

Sec. 102. Determining the public and private benefit of copayment coupons and other patient assistance programs.

TITLE II—ACCESS AND AFFORDABILITY

- Sec. 201. Negotiating fair prices for Medicare prescription drugs.
 Sec. 202. Prescription drug price spikes.
 Sec. 203. Importing affordable and safe drugs.
 Sec. 204. Requiring drug manufacturers to provide drug rebates for drugs dispensed to low-income individuals.
 Sec. 205. Cap on prescription drug cost-sharing.
 Sec. 206. Modification of trade negotiating objectives relating to intellectual property rights to ensure access to biological products.

TITLE III—INNOVATION

- Sec. 301. Innovation incentive fund for new and more effective treatments of bacterial infections.
 Sec. 302. Public funding for clinical trials.
 Sec. 303. Rewarding innovative drug development.
 Sec. 304. Improving program integrity.

TITLE IV—CHOICE AND COMPETITION

- Sec. 401. Unlawful compensation for delay.
 Sec. 402. 180-day exclusivity period amendments regarding first applicant status.
 Sec. 403. 180-day exclusivity period amendments regarding agreements to defer commercial marketing.
 Sec. 404. Increasing drug competition and preventing drug shortages.
 Sec. 405. Disallowance of deduction for advertising for prescription drugs.
 Sec. 406. Drug manufacturer duty to disclose drug prices to practitioners.
 Sec. 407. Excluding authorized generic drugs from calculation of average manufacturer price under the Medicaid drug rebate program.

1 **TITLE I—TRANSPARENCY**2 **SEC. 101. DRUG MANUFACTURER REPORTING.**

3 Part P of title III of the Public Health Service Act
 4 (42 U.S.C. 280g et seq.) is amended by adding at the end
 5 the following:

6 **“SEC. 399V-7. DRUG MANUFACTURER REPORTING.**

7 “(a) DEFINITIONS.—In this section:

8 “(1) INDEPENDENT CHARITY PATIENT ASSIST-
 9 ANCE PROGRAM.—The term ‘independent charity pa-
 10 tient assistance program’ means any organization
 11 described in section 501(c)(3) of the Internal Rev-

1 enue Code of 1986 and exempt from taxation under
2 section 501(a) of such Code and which is not a pri-
3 vate foundation (as defined in section 509(a) of such
4 Code) that offers patient assistance.

5 “(2) MANUFACTURER PATIENT ASSISTANCE
6 PROGRAM.—The term ‘manufacturer patient assist-
7 ance program’ means an organization, including a
8 private foundation (as so defined), that is sponsored
9 by, or receives funding from, a manufacturer and
10 that offers patient assistance. Such term does not
11 include an independent charity patient assistance
12 program.

13 “(3) PATIENT ASSISTANCE.—The term ‘patient
14 assistance’ means assistance provided to offset the
15 cost of drugs for individuals. Such term includes free
16 products, coupons, rebates, copay or discount cards,
17 and other means of providing assistance to individ-
18 uals related to drug costs, as determined by the Sec-
19 retary.

20 “(b) REPORTING ON DOMESTIC SALES.—An applica-
21 ble manufacturer of an approved drug (including a drug
22 approved under subsection (e) or (j) of section 505 of the
23 Federal Food, Drug, and Cosmetic Act and a biological
24 product licensed under subsection (a) or (k) of section 351
25 of this Act) shall submit to the Secretary and to Congress

1 an annual report, in such format as the Secretary shall
2 require, outlining with respect to the previous calendar
3 year (except as provided in subsection (c)(3))—

4 “(1) with respect to each such drug—

5 “(A) the total expenditures of the manu-
6 facturer on—

7 “(i) domestic and foreign drug re-
8 search and development, including an
9 itemized description of—

10 “(I) basic and preclinical re-
11 search;

12 “(II) clinical research, broken out
13 by clinical trial phase;

14 “(III) development of alternative
15 dosage forms and strengths for the
16 drug molecule or combinations, in-
17 cluding the molecule;

18 “(IV) other drug development ac-
19 tivities, such as nonclinical laboratory
20 studies and record and report mainte-
21 nance;

22 “(V) pursuing new or expanded
23 indications for such drug through sup-
24 plemental applications under section

1 505 of the Federal Food, Drug, and
2 Cosmetic Act;

3 “(VI) carrying out postmarket
4 requirements related to such drug, in-
5 cluding under section 505(o)(3) of
6 such Act;

7 “(VII) carrying out risk evalua-
8 tion and mitigation strategies in ac-
9 cordance with section 505–1 of such
10 Act; and

11 “(VIII) marketing research;

12 “(ii) cost of goods sold, broken out by
13 source and cost of each component and
14 identifying specific costs that reflect inter-
15 nal transfers within the manufacturer’s
16 company;

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

20 “(iv) marketing and advertising for
21 the promotion of the drug, including a
22 breakdown of amounts aimed at con-
23 sumers, prescribers, managed care organi-
24 zations, and others;

1 “(B) the gross revenue, net revenue, gross
2 profit, and net profit to the manufacturer;

3 “(C) the total number of units of the pre-
4 scription drug that were sold in interstate com-
5 merce in the most recently completed calendar
6 year;

7 “(D) pricing information, including—

8 “(i) wholesale acquisition cost;

9 “(ii) net average price realized by
10 pharmacy benefit managers for drugs pro-
11 vided to individuals in the United States,
12 after accounting for any rebates or other
13 payments from the manufacturer to the
14 pharmacy benefit manager and from the
15 pharmacy benefit manager to the manufac-
16 turer; and

17 “(iii) the net price of the drug, after
18 accounting for discounts, rebates, or other
19 financial considerations, charged to pur-
20 chasers in each applicable country of the
21 Organisation for Economic Co-operation
22 and Development;

23 “(E) information, including the dollar
24 value to the recipient of manufacturer patient
25 assistance programs offered by the manufac-

1 turer or a manufacturer patient assistance pro-
2 gram sponsored by or associated with the man-
3 ufacturer, per patient, including—

4 “(i) the specific forms of such patient
5 assistance available, such as coupons, re-
6 bates, discount codes, or copayment cards;

7 “(ii) the total dollar value of each
8 manufacturer patient assistance program
9 and the dollar value of each program to
10 the patient, including the basis used to as-
11 sign value to the manufacturer patient as-
12 sistance program;

13 “(iii) the duration of each type of
14 such patient assistance available; and

15 “(iv) any requirements, such as in-
16 come thresholds, for how to qualify for
17 such patient assistance;

18 “(F) information on usage of patient as-
19 sistance offered by the manufacturer or a man-
20 ufacturer patient assistance program sponsored
21 by or associated with the manufacturer, includ-
22 ing—

23 “(i) the number of transactions of
24 each type of patient assistance used;

1 “(ii) the number of individuals receiv-
2 ing each type of patient assistance;

3 “(iii) the total value of each type of
4 patient assistance that was used;

5 “(iv) the average length of time that
6 each individual received each type of pa-
7 tient assistance;

8 “(v) the number of individuals who
9 were discontinued from receiving each type
10 of patient assistance; and

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

15 “(G) any Federal benefits received by the
16 manufacturer, including the amounts and peri-
17 ods of impact for each such benefit, including
18 tax credits, patent applications that benefited
19 from a Federal grant, patent extensions, exclu-
20 sivity periods, and other Federal benefits with
21 respect to such drug; and

22 “(H) the percentage of research and devel-
23 opment expenditures on—

24 “(i) activities conducted by the manu-
25 facturer;

1 “(ii) activities funded by Federal enti-
2 ties; and

3 “(iii) activities conducted by other en-
4 tities such as academic institutions or
5 other drug manufacturers;

6 “(2) executive compensation for the chief execu-
7 tive officer, chief financial officer, and the three
8 other most highly compensated executive officers, in-
9 cluding bonuses, paid by such manufacturer, and
10 stock options affiliated with the manufacturer that
11 were offered to or accrued by such officers;

12 “(3) any additional information the manufac-
13 turer chooses to provide related to drug pricing deci-
14 sions, such as total expenditures on drug research,
15 drug development, and clinical trials on drugs that
16 failed to receive approval by the Food and Drug Ad-
17 ministration, a list of drugs and drug prices against
18 which the manufacturer compared the applicable
19 drug, and other relevant information; and

20 “(4) any other information as the Secretary
21 may require.

22 “(c) SUBMISSION OF REPORTS.—

23 “(1) IN GENERAL.—

24 “(A) SUBMISSION BY DRUG MANUFACTUR-
25 ERS.—Drug manufacturers shall submit the an-

1 nual reports required under this section sub-
2 mitted to the Secretary in a usable format, as
3 the Secretary may require.

4 “(B) COLLATION BY THE SECRETARY.—

5 The Secretary shall collate the reports received
6 as described in subparagraph (A) and submit
7 such collated reports to Congress, together with
8 an analysis of the reports by the Secretary that
9 includes—

10 “(i) a summary of data from the re-
11 ports;

12 “(ii) consideration of factors such as
13 trends on research and development costs,
14 Federal benefits, and manufacturer patient
15 assistance programs; and

16 “(iii) the relationship between the fac-
17 tors described in clause (ii) and prescrip-
18 tion drug prices.

19 “(C) PUBLIC AVAILABILITY.—The Sec-
20 retary shall make the reports submitted by
21 manufacturers as described in subparagraph
22 (A) and the collated reports together with the
23 analysis of the Secretary described in subpara-
24 graph (B) publicly available, including by post-
25 ing such reports to the internet website of the

1 Department of Health and Human Services, in
2 a searchable format. In publicizing such re-
3 ports, the Secretary may redact such propri-
4 etary information as the Secretary determines
5 appropriate.

6 “(2) SINGLE REPORTS.—A drug manufacturer
7 shall submit all information required under sub-
8 section (b) with respect to each applicable drug, in
9 a single, annual report.

10 “(3) INITIAL REPORT.—

11 “(A) IN GENERAL.—An applicable drug
12 manufacturer shall submit a report pursuant to
13 this section one year after the date of enact-
14 ment of the Affordable Medications Act (except
15 as provided in subparagraph (B)) that includes
16 the information required under subsection
17 (b)(1) with respect to each calendar year since
18 the drug for which the report is required was
19 approved under section 505 of the Federal
20 Food, Drug, and Cosmetic Act, licensed under
21 section 351 of this Act, or received an exemp-
22 tion under section 505(i) of the Federal Food,
23 Drug, and Cosmetic Act or section 351(a)(3) of
24 this Act, or the calendar year in which the man-
25 ufacturer acquired the drug.

1 “(B) SMALL BUSINESSES.—In the case of
2 an applicable drug manufacturer that has fewer
3 than 500 employees, the initial report described
4 in subparagraph (A) shall be submitted by a
5 date determined by the Secretary, which shall
6 be not earlier than the date described in sub-
7 paragraph (A) and not later than the date that
8 is 3 years after the date of enactment of the Af-
9 fordable Medications Act.

10 “(d) PENALTY FOR NONCOMPLIANCE.—The Sec-
11 retary shall report to the Office of the Inspector General
12 any manufacturer’s failure to submit a complete report as
13 required under this section. Any manufacturer that fails
14 to submit a complete report required under this section
15 shall be subject to a civil penalty of up to \$200,000 for
16 each day on which the violation continues. The Secretary
17 shall collect the civil penalties under this subsection, and
18 without further appropriation, shall use such funds to sup-
19 port the programs under sections 409K and 485E, and,
20 at the discretion of the Secretary, research of the National
21 Institutes of Health and other activities authorized under
22 the Affordable Medications Act, including any amend-
23 ments made by such Act.”.

1 **SEC. 102. DETERMINING THE PUBLIC AND PRIVATE BEN-**
2 **EFIT OF COPAYMENT COUPONS AND OTHER**
3 **PATIENT ASSISTANCE PROGRAMS.**

4 (a) INFORMATION REPORTING BY INDEPENDENT
5 CHARITY PATIENT ASSISTANCE PROGRAMS.—Section
6 6033(b) of the Internal Revenue Code of 1986 is amended
7 by striking the period at the end of paragraph (16) and
8 inserting “, and” and by inserting after paragraph (16)
9 the following new paragraph:

10 “(17) the total amount of patient assistance
11 (within the meaning of section 399V–7 of the Public
12 Health Service Act) provided to individuals who are
13 prescribed drugs manufactured by any contributor to
14 the organization.”.

15 (b) GAO STUDY AND REPORT ON IMPACT OF COPAY-
16 MENT COUPONS AND OTHER PATIENT ASSISTANCE PRO-
17 GRAMS ON PRESCRIPTION DRUG PRICING AND EXPENDI-
18 TURES.—

19 (1) STUDY.—The Comptroller General of the
20 United States shall conduct a study on the impact
21 of copayment coupons and other patient assistance
22 programs on prescription drug pricing and expendi-
23 tures. Such study shall include an analysis of the
24 following:

25 (A) The extent to which copayment cou-
26 pons and patient assistance programs con-

1 tribute to inflated prescription drug prices and
2 health insurance premiums, including with re-
3 spect to—

4 (i) the Medicaid program under title
5 XIX of the Social Security Act (42 U.S.C.
6 1396 et seq.);

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

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

12 (iv) health care under the laws admin-
13 istered by the Secretary of Veterans Af-
14 fairs;

15 (v) the commercial health insurance
16 market; and

17 (vi) the cash pay health market.

18 (B) The extent to which manufacturers of-
19 fering copayment coupons and other patient as-
20 sistance programs or sponsoring manufacturer
21 patient assistance programs report obtaining
22 tax deductions for offering or sponsoring such
23 assistance (either as business expenses or chari-
24 table deductions), including—

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

6 (ii) a description of the methodology
7 manufacturers reported for assigning a
8 value to the tax deduction claimed by man-
9 ufacturers for offering or sponsoring pa-
10 tient assistance programs; and

11 (iii) a description of the extent to
12 which the activities of independent charity
13 patient assistance programs, which are
14 sponsored by, or receive funding from,
15 pharmaceutical manufacturers (as deter-
16 mined using tax returns, sales data, and
17 other public disclosures) provide a financial
18 benefit to the manufacturers that sponsor
19 them.

20 (C) Oversight that is conducted to ensure
21 that independent charity patient assistance pro-
22 grams adhere to guidance from the Office of
23 the Inspector General of the Department of
24 Health and Human Services on avoiding waste,
25 fraud, and abuse.

1 (2) DEFINITIONS.—In this subsection, the
 2 terms “patient assistance”, “independent charity pa-
 3 tient assistance program”, “manufacturer”, and
 4 “manufacturer patient assistance program” have the
 5 meaning given those terms under section 399V–7 of
 6 the Public Health Service Act, as added by section
 7 101.

8 (3) REPORT.—Not later than 2 years after the
 9 date of the enactment of this Act, the Comptroller
 10 General of the United States shall submit to Con-
 11 gress a report describing the findings of the study
 12 required under this subsection.

13 **TITLE II—ACCESS AND** 14 **AFFORDABILITY**

15 **SEC. 201. NEGOTIATING FAIR PRICES FOR MEDICARE PRE-** 16 **SCRIPTION DRUGS.**

17 (a) NEGOTIATING FAIR PRICES.—

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

22 “(i) NEGOTIATING FAIR PRICES WITH DRUG MANU-
 23 FACTURERS.—

24 “(1) IN GENERAL.—Notwithstanding any other
 25 provision of law, in furtherance of the goals of pro-

1 viding quality care and containing costs under this
2 part, the Secretary shall, with respect to applicable
3 covered part D drugs, and may, with respect to
4 other covered part D drugs, negotiate, using the ne-
5 gotiation technique or techniques that the Secretary
6 determines will maximize savings and value to the
7 government for prescription drug plans and MA–PD
8 plans and for plan enrollees (in a manner that may
9 be similar to Federal entities and that may include,
10 but is not limited to, formularies, reference pricing,
11 discounts, rebates, other price concessions, and cov-
12 erage determinations), with drug manufacturers the
13 prices that may be charged to PDP sponsors and
14 MA organizations for such drugs for part D eligible
15 individuals who are enrolled in a prescription drug
16 plan or in an MA–PD plan. In conducting such ne-
17 gotiations, the Secretary shall consider the drug’s
18 current price, initial launch price, prevalence of dis-
19 ease and usage, and approved indications, the num-
20 ber of similarly effective alternative treatments for
21 each approved use of the drug, the budgetary impact
22 of providing coverage under this part for such drug
23 for all individuals who would likely benefit from the
24 drug, evidence on the drug’s effectiveness and safety
25 compared to similar drugs, and the quality and

1 quantity of clinical data and rigor of the applicable
2 process of approval of a drug under section 505 of
3 the Federal Food, Drug, and Cosmetic Act or a bio-
4 logical product under section 351 of the Public
5 Health Service Act.

6 “(2) USE OF LOWER OF VA OR BIG FOUR PRICE
7 IF NEGOTIATIONS FAIL.—If, after attempting to ne-
8 gotiate for a price with respect to a covered part D
9 drug under paragraph (1) for a period of 1 year, the
10 Secretary is not successful in obtaining an appro-
11 priate price for the drug (as determined by the Sec-
12 retary), the Secretary shall establish the price that
13 may be charged to PDP sponsors and MA organiza-
14 tions for such drug for part D eligible individuals
15 who are enrolled in a prescription drug plan or in
16 an MA–PD plan at an amount equal to the lesser
17 of—

18 “(A) the price paid by the Secretary of
19 Veterans Affairs to procure the drug under the
20 laws administered by the Secretary of Veterans
21 Affairs; or

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

1 “(3) APPLICABLE COVERED PART D DRUG DE-
2 FINED.—For purposes of this subsection, the term
3 ‘applicable covered part D drug’ means a covered
4 part D drug that the Secretary determines to be ap-
5 propriate for negotiation under paragraph (1) based
6 on one or more of the following factors as applied
7 to such drug:

8 “(A) Spending on a per beneficiary basis.

9 “(B) The proportion of total spending
10 under this title.

11 “(C) Unit price increases over the pre-
12 ceding 5 years.

13 “(D) Initial launch price.

14 “(E) Availability of less expensive, simi-
15 larly effective alternative treatments.

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

18 “(G) Any other criteria determined by the
19 Secretary.

20 “(4) PDP SPONSORS AND MA ORGANIZATION
21 MAY NEGOTIATE LOWER PRICES.—Nothing in this
22 subsection shall be construed as preventing the spon-
23 sor of a prescription drug plan, or an organization
24 offering an MA–PD plan, from obtaining a discount
25 or reduction of the price for a covered part D drug

1 below the price negotiated under paragraph (1) or
2 the price established under paragraph (2).

3 “(5) NO EFFECT ON EXISTING APPEALS PROC-
4 ESS.—Nothing in this subsection shall be construed
5 to affect the appeals procedures under subsections
6 (g) and (h) of section 1860D–4.”.

7 (2) EFFECTIVE DATE.—The amendments made
8 by this subsection shall take effect on the date of the
9 enactment of this Act and shall first apply to nego-
10 tiations and prices for plan years beginning on Jan-
11 uary 1, 2020.

12 (b) REQUIREMENT TO INCLUDE A LINK TO THE
13 MEDICARE DRUG SPENDING DASHBOARD ON THE MEDI-
14 CARE PLAN FINDER.—Beginning not later than January
15 1, 2020, the Secretary of Health and Human Services
16 shall ensure that the Medicare Plan Finder on the Medi-
17 care.gov internet website includes a link to the Medicare
18 Drug Spending Dashboard on the CMS.gov internet
19 website. Such link shall be easily accessible on the Medi-
20 care Plan Finder.

21 (c) REPORTS TO CONGRESS.—

22 (1) SECRETARY OF HHS.—

23 (A) IN GENERAL.—Not later than 3 years
24 after the date of the enactment of this Act, and
25 every 6 months thereafter, the Secretary of

1 Health and Human Services shall submit to
2 Congress a report on the following:

3 (i) The price negotiations conducted
4 by the Secretary under section 1860D–
5 11(i) of the Social Security Act (42 U.S.C.
6 1395w–111(i)), as amended by subsection
7 (a), including a description of—

8 (I) how such price negotiations
9 are achieving lower prices for covered
10 part D drugs (as defined in section
11 1860D–2(e) of the Social Security Act
12 (42 U.S.C. 1395w–102(e))) for Medi-
13 care beneficiaries;

14 (II) how such lower prices are
15 passed through to Medicare bene-
16 ficiaries;

17 (III) how such price negotiations
18 are affecting drug prices in the pri-
19 vate market; and

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

23 (ii) Data on spending under part D of
24 the Medicare program on covered part D

1 drugs, including data on covered part D
2 drugs with—

3 (I) spending on a per beneficiary
4 basis that is above the median spend-
5 ing on other drugs in the same class
6 or above the median spending of other
7 drug classes; and

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

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

17 (iv) Access to covered part D drugs
18 and, where available, compliance rates and
19 health outcomes associated with compli-
20 ance rates.

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

24 (B) PUBLIC AVAILABILITY OF REPORT.—

25 The Secretary of Health and Human Services

1 shall publish on the internet website of the Cen-
2 ters for Medicare & Medicaid Services a copy of
3 each report submitted under subparagraph (A),
4 including the detailed tables, figures, and data
5 published in the report and its appendices.

6 (2) MEDPAC.—

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

13 (i) how such price negotiations are
14 achieving lower prices for covered part D
15 drugs (as defined in section 1860D–2(e) of
16 the Social Security Act (42 U.S.C. 1395w–
17 102(e))) for Medicare beneficiaries;

18 (ii) who is benefiting from such lower
19 prices, such as Medicare beneficiaries, the
20 Federal Government, States, prescription
21 drug plans and MA–PD plans, or other en-
22 tities;

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

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

4 (B) REPORT.—Not later than January 1,
5 2022, the Comptroller General of the United
6 States shall submit to Congress a report on the
7 study conducted under subparagraph (A), to-
8 gether with recommendations for improving
9 such price negotiations.

10 (d) CMI TESTING OF NEGOTIATING DRUG AND BIO-
11 LOGICAL PRICES TO IMPROVE VALUE.—Section
12 1115A(b)(2) of the Social Security Act (42 U.S.C.
13 1315a(b)(2)) is amended—

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

21 (2) by adding at the end the following new sub-
22 paragraph:

23 “(D) MODELS OF NEGOTIATING DRUG AND
24 BIOLOGICAL PRICES TO IMPROVE VALUE.—The
25 models described in this subparagraph are the

1 following models for negotiating drug and bio-
2 logical prices under the applicable titles (includ-
3 ing under both parts B and D of title XVIII)
4 in order to improve the value of payments for
5 such drugs and biologicals under such titles:

6 “(i) Discounting or eliminating pa-
7 tient cost-sharing on high-value drugs and
8 biologicals.

9 “(ii) Value-based formularies.

10 “(iii) Indications-based pricing.

11 “(iv) Reference pricing.

12 “(v) Risk-sharing agreements based
13 on outcomes.

14 “(vi) Pricing based on comparative ef-
15 fectiveness research.

16 “(vii) Episode-based payments for
17 chemotherapy and other conditions deter-
18 mined appropriate by the Secretary.

19 “(viii) Alternative ways of paying for
20 drugs and biologicals under part B of title
21 XVIII.

22 “(ix) Other models determined appro-
23 priate by the Secretary.”

1 **SEC. 202. PRESCRIPTION DRUG PRICE SPIKES.**

2 (a) IDENTIFICATION OF PRESCRIPTION DRUG PRICE
3 SPIKES.—

4 (1) DEFINITIONS.—In this subsection:

5 (A) APPLICABLE ENTITY.—The term “ap-
6 plicable entity” means the holder of an applica-
7 tion approved under subsection (c) or (j) of sec-
8 tion 505 of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 355) or of a license issued
10 under subsection (a) or (k) of section 351 of
11 the Public Health Service Act (42 U.S.C. 262)
12 for a drug described in paragraph (5)(A).

13 (B) AVERAGE MANUFACTURER PRICE.—
14 The term “average manufacturer price”—

15 (i) has the same meaning given such
16 term under section 1927(k)(1) of the So-
17 cial Security Act (42 U.S.C. 1396r-
18 8(k)(1)); or

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

23 (C) COMMERCE.—The term “commerce”
24 has the meaning given such term in section 4
25 of the Federal Trade Commission Act (15
26 U.S.C. 44).

1 (D) INSPECTOR GENERAL.—The term “In-
2 spector General” means the Inspector General
3 of the Department of Health and Human Serv-
4 ices.

5 (E) PRESCRIPTION DRUG.—

6 (i) IN GENERAL.—The term “pre-
7 scription drug” means any drug (as de-
8 fined in section 201(g) of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C.
10 321(g))), including a combination product
11 whose primary mode of action is deter-
12 mined under section 503(g) of such Act
13 (21 U.S.C. 353(g)) to be that of a drug,
14 and that—

15 (I) is subject to section 503(b)(1)
16 of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 353(b)(1)); and

18 (II) is covered by a Federal
19 health care program (as defined in
20 section 1128B(f) of the Social Secu-
21 rity Act (42 U.S.C. 1320a–7b(f))).

22 (ii) TREATMENT OF REFORMULATED
23 DRUGS.—For purposes of this subsection,
24 a prescription drug with respect to which
25 the Secretary of Health and Human Serv-

1 ices has approved any minor reformulation
2 that does not produce a meaningful thera-
3 peutic benefit, the drug that was approved
4 prior to any such reformulation and the
5 drug with any such reformulation shall be
6 considered one prescription drug.

7 (F) PRICE SPIKE.—

8 (i) IN GENERAL.—The term “price
9 spike” means an increase in the average
10 manufacturer price in commerce of a pre-
11 scription drug for which the price spike
12 percentage is equal to or greater than ap-
13 plicable price increase allowance.

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

17 (I) the average manufacturer
18 price of a prescription drug in com-
19 merce for the calendar year; exceeds

20 (II) the average manufacturer
21 price of such prescription drug in
22 commerce for the calendar year pre-
23 ceding such year.

24 (iii) APPLICABLE PRICE INCREASE AL-
25 LOWANCE.—The applicable price increase

1 allowance for any calendar year is the per-
2 centage (rounded to the nearest one-tenth
3 of 1 percent) by which the C-CPI-U (as
4 defined in section 1(f)(6) of the Internal
5 Revenue Code of 1986) for that year ex-
6 ceeds the C-CPI-U for the preceding cal-
7 endar year.

8 (G) PRICE SPIKE REVENUE.—

9 (i) IN GENERAL.—The price spike rev-
10 enue for any calendar year is an amount
11 equal to—

12 (I) the gross price spike revenue;

13 minus

14 (II) the adjustment amount.

15 (ii) GROSS PRICE SPIKE REVENUE.—

16 The gross price spike revenue for any cal-
17 endar year is an amount equal to the prod-
18 uct of—

19 (I) an amount equal to the dif-

20 ference between subclause (I) of sub-

21 paragraph (F)(ii) and subclause (II)

22 of such subparagraph; and

23 (II) the total number of units of

24 the prescription drug which were sold

25 in commerce in such calendar year.

1 (iii) ADJUSTMENT AMOUNT.—The ad-
2 justment amount is the amount, if any, of
3 the gross price spike revenue which the In-
4 spector General has determined is due sole-
5 ly to an increase in the cost of the inputs
6 necessary to manufacture the prescription
7 drug subject to the price spike.

8 (2) SUBMISSION BY PHARMACEUTICAL COMPA-
9 NIES OF INFORMATION TO INSPECTOR GENERAL.—

10 (A) IN GENERAL.—For each prescription
11 drug, the applicable entity shall submit to the
12 Inspector General a quarterly report that in-
13 cludes the following:

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

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

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

24 (III) the gross revenues from
25 sales of such prescription drug in

1 commerce in the preceding calendar
2 quarter.

3 (ii) Such information related to in-
4 creased input costs or public health consid-
5 erations as the applicable entity may wish
6 the Inspector General to consider in mak-
7 ing a determination under subclause (II) of
8 paragraph (3)(B)(ii) or an assessment in
9 subclause (III) of such paragraph for the
10 preceding calendar quarter.

11 (iii) Such information related to any
12 anticipated increased input costs for the
13 subsequent calendar quarter as the appli-
14 cable entity may wish the Inspector Gen-
15 eral to consider in making a determination
16 under subclause (II) of paragraph
17 (3)(B)(ii) or an assessment in subclause
18 (III) of such paragraph for such calendar
19 quarter.

20 (B) PENALTY FOR FAILURE TO SUBMIT.—

21 (i) IN GENERAL.—An applicable enti-
22 ty described in subparagraph (A) that fails
23 to submit information to the Inspector
24 General regarding a prescription drug, as
25 required by such subparagraph, before the

1 date specified in subparagraph (C) shall be
2 liable for a civil penalty, as determined
3 under clause (ii).

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

7 (I) an amount, as determined ap-
8 propriate by the Inspector General,
9 which is—

10 (aa) not less than 0.5 per-
11 cent of the gross revenues from
12 sales of the prescription drug de-
13 scribed in clause (i) for the pre-
14 ceding calendar year, and

15 (bb) not greater than 1 per-
16 cent of the gross revenues from
17 sales of such prescription drug
18 for the preceding calendar year,
19 and

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

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

1 (bb) the date on which the
2 Inspector General receives the in-
3 formation described in subpara-
4 graph (A) from the applicable en-
5 tity.

6 (C) SUBMISSION DEADLINE.—An applica-
7 ble entity shall submit each quarterly report de-
8 scribed in subparagraph (A) not later than Jan-
9 uary 17, April 18, June 15, and September 15
10 of each calendar year.

11 (3) ASSESSMENT BY INSPECTOR GENERAL.—

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

17 (i) complete an assessment of the in-
18 formation the Inspector General received
19 pursuant to paragraph (2)(A) with respect
20 to sales of prescription drugs in the pre-
21 ceding calendar year; and

22 (ii) in the case of any prescription
23 drug which satisfies the conditions de-
24 scribed in subparagraph (A) or (B) of
25 paragraph (4), submit a recommendation

1 to the Secretary of Health and Human
2 Services that such drug be exempted from
3 application of the tax imposed under sec-
4 tion 4192 of the Internal Revenue Code of
5 1986 (as added by subsection (b) of this
6 section) for such year.

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

9 (i) Identification of each price spike
10 relating to a prescription drug in the pre-
11 ceding calendar year.

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

14 (I) a determination of the price
15 spike revenue;

16 (II) a determination regarding
17 the accuracy of the information sub-
18 mitted by the applicable entity regard-
19 ing increased input costs; and

20 (III) an assessment of the ration-
21 ale of the applicable entity for the
22 price spike.

23 (4) EXEMPTION OF CERTAIN DRUGS.—

24 (A) IN GENERAL.—The Secretary of
25 Health and Human Services, upon rec-

1 ommendation of the Inspector General pursuant
2 to paragraph (3)(A)(ii), may exempt any pre-
3 scription drug which has been subject to a price
4 spike during the preceding calendar year from
5 application of the tax imposed under section
6 4192 of the Internal Revenue Code of 1986 for
7 such year, if the Secretary determines that—

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

12 (ii)(I) the prescription drug which has
13 been subject to a price spike has an aver-
14 age manufacturer price of not greater than
15 \$10 for a 30-day supply; and

16 (II) such drug is marketed by not less
17 than three other holders of applications ap-
18 proved under subsection (c) or (j) of sec-
19 tion 505 of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 355), where such
21 applications approved under such sub-
22 section (j) use as a reference drug the drug
23 so approved under such subsection (c).

24 (B) CLARIFICATION.—In considering,
25 under subparagraph (A)(i), information sub-

1 mitted pursuant to paragraph (2)(A)(ii), the
2 Secretary—

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

6 (ii) shall exclude from such consider-
7 ation any information submitted by the ap-
8 plicable entity threatening to curtail or
9 limit production of the prescription drug if
10 the Secretary does not grant an exemption
11 from the application of the tax under sec-
12 tion 4192 of the Internal Revenue Code of
13 1986.

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

16 (A) IN GENERAL.—Subject to subpara-
17 graph (C), not later than the last day in Feb-
18 ruary of each year, the Inspector General shall
19 transmit to the Internal Revenue Service a re-
20 port on the findings of the Inspector General
21 with respect to the information the Inspector
22 General received under paragraph (2)(A) with
23 respect to the preceding calendar year and the
24 assessment carried out by the Inspector General

1 under paragraph (3)(A) with respect to such in-
2 formation.

3 (B) CONTENTS.—The report transmitted
4 under subparagraph (A) shall include the fol-
5 lowing:

6 (i) The information received under
7 paragraph (2)(A) with respect to the pre-
8 ceding calendar year.

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

11 (iii) The price spike revenue deter-
12 minations made under clause (ii)(I) of
13 such paragraph.

14 (iv) The determinations and assess-
15 ments made under subclauses (II) and
16 (III) of clause (ii) of such paragraph.

17 (C) NOTICE AND OPPORTUNITY FOR HEAR-
18 ING.—

19 (i) IN GENERAL.—No report shall be
20 transmitted to the Internal Revenue Serv-
21 ice under subparagraph (A) in regards to
22 a prescription drug unless the Inspector
23 General has provided the applicable entity
24 with—

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

3 (II) notice of their right to a
4 hearing in regards to such assess-
5 ment.

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

11 (iii) REQUEST FOR HEARING.—Sub-
12 ject to clause (v), an applicable entity may
13 request a hearing before the Secretary of
14 Health and Human Services not later than
15 30 days after the date on which the notice
16 under clause (ii) is received.

17 (iv) COMPLETION OF HEARING.—In
18 the case of an applicable entity which re-
19 quests a hearing pursuant to clause (iii),
20 the Secretary of Health and Human Serv-
21 ices shall, not later than 12 months after
22 the date on which the assessment under
23 paragraph (3)(A) was completed by the In-
24 spector General—

1 (I) make a final determination in
2 regards the accuracy of such assess-
3 ment; and

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

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

11 (D) PUBLICATION.—

12 (i) IN GENERAL.—Not later than the
13 last day in February of each year, subject
14 to clause (ii), the Inspector General shall
15 make the report transmitted under sub-
16 paragraph (A) available to the public, in-
17 cluding on the internet website of the In-
18 spector General.

19 (ii) PROPRIETARY INFORMATION.—
20 The Inspector General shall ensure that
21 any information made public in accordance
22 with clause (i) excludes trade secrets and
23 confidential commercial information.

24 (6) NOTIFICATION.—The Secretary of the
25 Treasury, in conjunction with the Inspector General,

1 shall notify, at such time and in such manner as the
2 Secretary of the Treasury shall provide, each appli-
3 cable entity in regard to any prescription drug which
4 has been determined to have been subject to a price
5 spike during the preceding calendar year and the
6 amount of the tax imposed on such applicable entity
7 pursuant to section 4192 of the Internal Revenue
8 Code of 1986.

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

11 (1) IN GENERAL.—Subchapter E of chapter 32
12 of the Internal Revenue Code of 1986 is amended by
13 adding at the end the following new section:

14 **“SEC. 4192. PRESCRIPTION DRUGS SUBJECT TO PRICE**
15 **SPIKES.**

16 “(a) IMPOSITION OF TAX.—

17 “(1) IN GENERAL.—Subject to paragraph (3),
18 for each taxable prescription drug sold by an appli-
19 cable entity during the calendar year, there is hereby
20 imposed on such entity a tax equal to the greater
21 of—

22 “(A) the annual price spike tax for such
23 prescription drug, or

24 “(B) subject to paragraph (2), the cumu-
25 lative price spike tax for such prescription drug.

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

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

13 “(b) ANNUAL PRICE SPIKE TAX.—

14 “(1) IN GENERAL.—The amount of the annual
15 price spike tax shall be equal to the applicable per-
16 centage of the price spike revenue received by the
17 applicable entity on the sale of the taxable prescrip-
18 tion drug during the calendar year.

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

22 “(A) in the case of a taxable prescription
23 drug which has been subject to a price spike
24 percentage greater than the applicable price in-
25 crease allowance (as defined in section

1 202(a)(1)(F)(iii) of the Affordable Medications
2 Act) but less than 15 percent, 50 percent,

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

7 “(C) in the case of a taxable prescription
8 drug which has been subject to a price spike
9 percentage equal to or greater than 20 percent,
10 100 percent.

11 “(c) CUMULATIVE PRICE SPIKE TAX.—

12 “(1) IN GENERAL.—The amount of the cumu-
13 lative price spike tax shall be equal to the applicable
14 percentage of the cumulative price spike revenue re-
15 ceived by the applicable entity on the sale of the tax-
16 able prescription drug during the calendar year.

17 “(2) APPLICABLE PERCENTAGE.—

18 “(A) IN GENERAL.—For purposes of para-
19 graph (1), the applicable percentage shall be
20 equal to—

21 “(i) in the case of a taxable prescrip-
22 tion drug which has been subject to a cu-
23 mulative price spike percentage greater
24 than the cumulative price increase allow-

1 ance but less than the first multi-year per-
2 centage, 50 percent,

3 “(ii) in the case of a taxable prescrip-
4 tion drug which has been subject to a cu-
5 mulative price spike percentage equal to or
6 greater than the first multi-year percent-
7 age but less than the second multi-year
8 percentage, 75 percent, and

9 “(iii) in the case of a taxable prescrip-
10 tion drug which has been subject to a cu-
11 mulative price spike percentage equal to or
12 greater than the second multi-year percent-
13 age, 100 percent.

14 “(B) CUMULATIVE PRICE SPIKE PERCENT-
15 AGE.—The cumulative price spike percentage is
16 the percentage (if any) by which—

17 “(i) the average manufacturer price of
18 the taxable prescription drug in commerce
19 for the preceding calendar year, exceeds

20 “(ii) the average manufacturer price
21 of such prescription drug in commerce for
22 the base year.

23 “(C) CUMULATIVE PRICE INCREASE AL-
24 LOWANCE.—For purposes of clause (i) of sub-
25 paragraph (A), the cumulative price increase al-

1 lowance for any calendar year is the percentage
 2 (rounded to the nearest one-tenth of 1 percent)
 3 by which the C–CPI–U (as defined in section
 4 1(f)(6)) for that year exceeds the C–CPI–U for
 5 the base year.

6 “(D) MULTI-YEAR PERCENTAGES.—For
 7 purposes of subparagraph (A), the first multi-
 8 year percentage and second multi-year percent-
 9 age shall be determined in accordance with the
 10 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.

11 “(E) APPLICABLE PERIOD AND BASE
 12 YEAR.—

13 “(i) APPLICABLE PERIOD.—The appli-
 14 cable period shall be the lesser of—

15 “(I) the 5 preceding calendar
 16 years,

17 “(II) all calendar years beginning
 18 after the date of enactment of this
 19 section, or

1 “(III) all calendar years in which
2 the taxable prescription drug was sold
3 in commerce.

4 “(ii) BASE YEAR.—The base year
5 shall be the calendar year immediately pre-
6 ceding the applicable period.

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

11 “(A) an amount equal to the product of—

12 “(i) an amount (not less than zero)
13 equal to—

14 “(I) the average manufacturer
15 price of such prescription drug in
16 commerce for the preceding calendar
17 year, minus

18 “(II) the average manufacturer
19 price of such prescription drug in
20 commerce for the base year, and

21 “(ii) the total number of units of such
22 prescription drug which were sold in com-
23 merce in the preceding calendar year,
24 minus

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

6 “(d) DEFINITIONS.—For purposes of this section—

7 “(1) TAXABLE PRESCRIPTION DRUG.—The
8 term ‘taxable prescription drug’ means a prescrip-
9 tion drug (as defined in section 202(a)(1)(E) of the
10 Affordable Medications Act) which has been identi-
11 fied by the Inspector General of the Department of
12 Health and Human Services, under section
13 202(a)(3)(B)(i) of such Act, as being subject to a
14 price spike.

15 “(2) OTHER TERMS.—The terms ‘applicable en-
16 tity’, ‘average manufacturer price’, ‘price spike’,
17 ‘price spike percentage’, and ‘price spike revenue’
18 have the same meaning given such terms under sec-
19 tion 202(a)(1) of the Affordable Medications Act.”.

20 (2) CLERICAL AMENDMENTS.—

21 (A) The heading of subchapter E of chap-
22 ter 32 of the Internal Revenue Code of 1986 is
23 amended by striking “**Medical Devices**”
24 and inserting “**Certain Medical Devices**
25 **and Prescription Drugs**”.

1 (B) The table of subchapters for chapter
2 32 of such Code is amended by striking the
3 item relating to subchapter E and inserting the
4 following new item:

“SUBCHAPTER E. CERTAIN MEDICAL DEVICES AND PRESCRIPTION DRUGS”.

5 (3) The table of sections for subchapter E of
6 chapter 32 of such Code is amended by adding at
7 the end the following new item:

“Sec. 4192. Prescription drugs subject to price spikes.”.

8 (4) EFFECTIVE DATE.—The amendments made
9 by this section shall apply to sales after the date of
10 the enactment of this Act.

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

17 (1) funding or conducting research on the eco-
18 nomic and policy implications of price patterns of
19 prescription drugs;

20 (2) increasing amounts available to the Na-
21 tional Institutes of Health for research and develop-
22 ment of drugs;

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

1 (4) reducing health insurance premiums.

2 **SEC. 203. IMPORTING AFFORDABLE AND SAFE DRUGS.**

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

6 **“SEC. 804. IMPORTATION OF SAFE AND AFFORDABLE**
7 **DRUGS BY WHOLESALE DISTRIBUTORS,**
8 **PHARMACIES, AND INDIVIDUALS.**

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

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

15 “(1) CERTIFIED FOREIGN SELLER.—The term
16 ‘certified foreign seller’ means a licensed foreign
17 pharmacy or foreign wholesale distributor that the
18 Secretary certifies under subsection (d)(1)(B), that
19 pays the fee required under subsection (d)(1)(C),
20 and that is included on the list described in sub-
21 section (c).

22 “(2) FOREIGN WHOLESALE DISTRIBUTOR.—
23 The term ‘foreign wholesale distributor’ means a
24 person (other than a manufacturer, a manufactur-
25 er’s co-licensed partner, a third-party logistics pro-

1 vider, or a repackager) engaged in wholesale dis-
2 tribution.

3 “(3) IMPORTER.—The term ‘importer’ means a
4 dispenser (as defined in section 581(3)) or wholesale
5 distributor registered under section 503(e) who im-
6 ports prescription drugs into the United States in
7 accordance with this section.

8 “(4) LICENSED FOREIGN PHARMACY.—The
9 term ‘licensed foreign pharmacy’ means a pharmacy
10 located in Canada, or subject to subsection (e), an-
11 other applicable country, that—

12 “(A) operates in accordance with applica-
13 ble pharmacy standards set forth by the provin-
14 cial pharmacy rules and regulations enacted in
15 Canada, or, subject to subsection (e), such ap-
16 plicable rules and regulations of the permitted
17 country in which such seller is located; and

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

22 “(5) QUALIFYING PRESCRIPTION DRUG.—The
23 term ‘qualifying prescription drug’—

24 “(A) means a prescription drug that—

1 “(i) is approved for use in patients,
2 and marketed, in Canada, or subject to
3 subsection (e), approved for use in pa-
4 tients, and marketed, in another permitted
5 country;

6 “(ii) is manufactured in a facility reg-
7 istered under subsection (b)(1) or (i) of
8 section 510 that is in compliance with good
9 manufacturing practices regulations of the
10 Food and Drug Administration;

11 “(iii) has the same active ingredient
12 or ingredients, route of administration, and
13 strength as a prescription drug approved
14 under chapter V, or, for purposes of sub-
15 paragraph (B)(iv), is biosimilar to an ap-
16 proved biological product and has the same
17 route of administration and strength as the
18 approved biological product; and

19 “(iv) is labeled in accordance with—

20 “(I) the laws of Canada, or an-
21 other country from which importation
22 is permitted pursuant to subsection
23 (e); and

1 “(II) the requirements promul-
2 gated by the Secretary, which shall in-
3 clude labeling in English;

4 “(B) with respect to importers only, in-
5 cludes—

6 “(i) peritoneal dialysis solution;

7 “(ii) insulin;

8 “(iii) a drug for which a risk evalua-
9 tion and mitigation strategy is required
10 under section 505–1;

11 “(iv) biological products, as defined in
12 section 351 of the Public Health Service
13 Act that are proteins (except any chemi-
14 cally synthesized polypeptides) or analo-
15 gous products; and

16 “(v) intravenously infused drugs; and

17 “(C) does not include—

18 “(i) a controlled substance (as defined
19 in section 102 of the Controlled Sub-
20 stances Act);

21 “(ii) an anesthetic drug inhaled dur-
22 ing surgery; or

23 “(iii) a compounded drug.

24 “(6) VALID PRESCRIPTION.—The term ‘valid
25 prescription’ means a prescription that is issued for

1 a legitimate medical purpose in the usual course of
2 professional practice by—

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

6 “(B) a covering practitioner.

7 “(c) PUBLICATION OF CERTIFIED FOREIGN SELL-
8 ERS.—The Secretary shall publish on a dedicated internet
9 website a list of certified foreign sellers, including the
10 internet website address, physical address, and telephone
11 number of each such certified foreign seller.

12 “(d) ADDITIONAL CRITERIA.—

13 “(1) CERTIFIED FOREIGN SELLERS.—

14 “(A) IN GENERAL.—To be a certified for-
15 eign seller, such seller shall—

16 “(i) be certified by the Secretary in
17 accordance with subparagraph (B);

18 “(ii) pay the registration fee estab-
19 lished under subparagraph (C); and

20 “(iii) sell only qualifying prescription
21 drugs to importers or individuals who im-
22 port prescription drugs into the United
23 States in accordance with this section.

1 “(B) CERTIFICATION.—To be a certified
2 foreign seller, the Secretary shall certify that
3 such seller—

4 “(i) is a foreign wholesale distributor
5 or licensed foreign pharmacy operating an
6 establishment, which may include an online
7 foreign pharmacy, that is located in Can-
8 ada, or, subject to subsection (e), another
9 permitted country;

10 “(ii) is engaged in the distribution or
11 dispensing of a prescription drug that is
12 imported or offered for importation into
13 the United States;

14 “(iii) has been in existence for a pe-
15 riod of at least 5 years preceding the date
16 of such certification and has a purpose
17 other than to participate in the program
18 established under this section;

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

1 “(v) has processes established by the
2 seller, or participates in another estab-
3 lished process, to certify that the physical
4 premises and data reporting procedures
5 and licenses are in compliance with all ap-
6 plicable laws and regulations of Canada,
7 or, subject to subsection (e), the permitted
8 country in which the seller is located, and
9 has implemented policies designed to mon-
10 itor ongoing compliance with such laws
11 and regulations;

12 “(vi) conducts or commits to partici-
13 pate in ongoing and comprehensive quality
14 assurance programs and implements such
15 quality assurance measures, including
16 blind testing, to ensure the veracity and re-
17 liability of the findings of the quality as-
18 surance program;

19 “(vii) agrees that, pursuant to sub-
20 section (g), laboratories approved by the
21 Secretary may be authorized to conduct
22 product testing to determine the chemical
23 authenticity of sample pharmaceutical
24 products;

1 “(viii) agrees to notify the Secretary,
2 importers, and individuals of product re-
3 calls in Canada, or pursuant to subsection
4 (e), the permitted country in which the
5 seller is located, and agrees to cease, or re-
6 frain from, exporting such product;

7 “(ix) has established, or will establish
8 or participate in, a process for resolving
9 grievances, as defined by the Secretary,
10 and will be held accountable for violations
11 of established guidelines and rules;

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

19 “(xi) meets any other criteria estab-
20 lished by the Secretary.

21 “(C) CERTIFICATION FEE.—Not later than
22 30 days before the start of each fiscal year, the
23 Secretary shall establish a fee to be collected
24 from foreign sellers for such fiscal year that are
25 certified under subparagraph (B), in an amount

1 that is sufficient, and not more than necessary,
2 to pay the costs of administering the program
3 under this section, and enforcing this section
4 pursuant to section 303(h), for that fiscal year.

5 “(D) RECERTIFICATION.—A certification
6 under subparagraph (B) shall be in effect for a
7 period of 2 years, or until there is a material
8 change in the circumstances under which the
9 foreign seller meets the requirements under
10 such subparagraph, whichever occurs earlier. A
11 foreign seller may reapply for certification
12 under such subparagraph (B), in accordance
13 with a process established by the Secretary.

14 “(2) INDIVIDUALS.—An individual may import
15 a qualifying prescription drug described in sub-
16 section (b) from Canada or another country pursu-
17 ant to subsection (e) if such drug—

18 “(A) is dispensed, including through an
19 online pharmacy, by a certified foreign seller
20 that is a licensed foreign pharmacy;

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

24 “(C) is filled only after providing to the li-
25 censed foreign pharmacy a valid prescription

1 issued by a health care practitioner licensed to
2 practice in a State in the United States.

3 “(e) IMPORTATION FROM OTHER COUNTRIES.—Be-
4 ginning on the date that is 2 years after the date on which
5 final regulations are promulgated to carry out this section,
6 if, based on a review of the evidence obtained after such
7 effective date, including the reports submitted under sec-
8 tion 2(d) of the Affordable Medications Act, that importa-
9 tion of qualifying prescription drugs from Canada under
10 this section resulted in cost savings for consumers in the
11 United States and increased access to safe medication, the
12 Secretary shall have the authority to permit importation
13 of qualifying prescription drugs by importers and individ-
14 uals from, in addition to Canada, any country that—

15 “(1) is a member of the Organisation for Eco-
16 nomic Co-operation and Development; and

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

21 “(A) authorizes the approval of drugs only
22 if a drug has been determined to be safe and
23 effective by experts employed by or acting on
24 behalf of a governmental entity and qualified by

1 scientific training and experience to evaluate
2 the safety and effectiveness of drugs;

3 “(B) requires that any determination of
4 safety and effectiveness described in subpara-
5 graph (A) be made on the basis of adequate
6 and well-controlled investigations, including
7 clinical investigations, as appropriate, con-
8 ducted by experts qualified by scientific training
9 and experience to evaluate the safety and effec-
10 tiveness of drugs;

11 “(C) requires the methods used in, and the
12 facilities and controls used for, the manufac-
13 ture, processing, and packing of drugs in the
14 country to be adequate to preserve the identity,
15 quality, purity, and strength of the drugs; and

16 “(D) requires the reporting of adverse re-
17 actions to drugs and establish procedures to re-
18 call, and withdraw approval of, drugs found not
19 to be safe or effective.

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

24 “(g) DRUG TESTING LABORATORIES.—The Sec-
25 retary may approve one or more laboratories to conduct

1 random testing of prescription drugs sold by certified for-
2 eign sellers to assess the chemical authenticity of such
3 drugs.

4 “(h) UNFAIR AND DISCRIMINATORY ACTS AND PRAC-
5 TICES.—It is unlawful for a manufacturer, directly or indi-
6 rectly (including by being a party to a licensing agreement
7 or other agreement)—

8 “(1) to discriminate by charging a higher price
9 for a prescription drug sold to a certified foreign
10 seller that sells such drug to an importer in accord-
11 ance with this section than the price that is charged,
12 inclusive of rebates or other incentives to the coun-
13 try from which the drug is exported, to another per-
14 son that is in the same country and that does not
15 import such a drug into the United States in accord-
16 ance with this section;

17 “(2) except with respect to a prescription drug
18 on the drug shortage list under section 506E, dis-
19 criminate by denying, restricting, or delaying sup-
20 plies of a prescription drug to a certified foreign sell-
21 er, on account of such seller’s status as a certified
22 foreign seller, that sells such drug to an importer in
23 accordance with this section, or by publicly, pri-
24 vately, or otherwise refusing to do business with

1 such a certified foreign seller on account of such
2 seller's status as a certified foreign seller;

3 “(3) cause there to be a difference (including a
4 difference in active ingredient, route of administra-
5 tion, bioequivalence, strength, formulation, manufac-
6 turing establishment, manufacturing process, or per-
7 son that manufactures the drug) between a prescrip-
8 tion drug for distribution in the United States and
9 the drug for distribution in Canada or another per-
10 mitted country, subject to subsection (e), for the
11 purpose of avoiding sales by certified foreign sellers;
12 or

13 “(4) except with respect to a prescription drug
14 on the drug shortage list under section 506E, en-
15 gage in any other action to restrict, prohibit, or
16 delay the importation of a prescription drug under
17 this section.

18 “(i) INFORMATION AND RECORDS.—

19 “(1) BIENNIAL REPORTS.—Each importer shall
20 submit biennial reports to the Secretary which shall
21 contain, for each qualifying prescription drug im-
22 ported into the United States—

23 “(A) the unique facility identifier of the
24 manufacturer of the drug, described in section
25 510;

1 “(B) the transaction information described
2 in section 581(26) (other than the information
3 described in subparagraph (C)); and

4 “(C) the price paid by the importer for the
5 drug.

6 “(2) MAINTENANCE OF RECORDS BY SEC-
7 RETARY.—The Secretary shall maintain information
8 and documentation submitted under paragraph (1)
9 for such period of time as the Secretary determines
10 to be appropriate.

11 “(j) SUSPENSION OF IMPORTATION.—

12 “(1) PATTERNS OF NONCOMPLIANCE.—The
13 Secretary shall require that importation of a specific
14 qualifying prescription drug or importation by a spe-
15 cific certified foreign seller or importer pursuant to
16 this section be immediately suspended if the Sec-
17 retary determines that there is a pattern of importa-
18 tion of such specific drug or by such specific seller
19 or importer that involves counterfeit drugs, drugs
20 that have been recalled or withdrawn, or drugs in
21 violation of any requirement of this section, until an
22 investigation is completed and the Secretary deter-
23 mines that importation of such drug or by such sell-
24 er or importer does not endanger the public health.

1 “(2) TEMPORARY SUSPENSION.—The Secretary
2 may require that importation of a specific qualifying
3 prescription drug or importation by a specific cer-
4 tified foreign seller or importer pursuant to this sec-
5 tion be temporarily suspended if, with respect to
6 such drug, seller, or importer, there is a violation of
7 any requirement of this section or if the Secretary
8 determines that importation of such drug or by such
9 seller or importer might endanger the public health.
10 Such temporary suspension shall apply until the Sec-
11 retary completes an investigation and determines
12 that importation of such drug or by such seller or
13 importer does not endanger the public health.

14 “(k) SUPPLY CHAIN SECURITY.—

15 “(1) PURCHASE FROM REGISTERED FACILITIES
16 AND CERTIFIED FOREIGN SELLERS.—

17 “(A) IN GENERAL.—Except as provided in
18 subparagraph (B), certified foreign sellers who
19 sell qualifying prescription drugs for importa-
20 tion into the United States pursuant to this
21 section may purchase such drugs only from
22 manufacturers or entities registered under sec-
23 tion 510 or other certified foreign sellers.

24 “(B) EXCEPTION.—Certified foreign sellers
25 who sell qualifying prescription drugs for im-

1 portation into the United States pursuant to
2 this section may purchase such drugs from for-
3 foreign sellers in Canada or another permitted
4 country, even if such foreign seller is not a
5 manufacturer registered under section 510 or a
6 certified foreign seller, if the Secretary enters
7 into a memorandum of understanding or coop-
8 erative agreement with Canada, or such other
9 permitted country, to ensure compliance, to the
10 extent appropriate and feasible, with subchapter
11 H of chapter V. The Secretary shall seek to
12 enter into such a memorandum of under-
13 standing or cooperative agreement with Canada
14 and each country from which importation is
15 permitted under subsection (e).

16 “(2) IMPORTATION TRACING.—Certified foreign
17 sellers shall provide importers with the unique facil-
18 ity identifier associated with the manufacturer reg-
19 istered under section 510 of the qualifying prescrip-
20 tion drug and the information under paragraph
21 (25), paragraph (26) (other than subparagraph (C)),
22 and subparagraphs (D), (F), and (G) of paragraph
23 (27) of section 581. Certified foreign sellers shall
24 provide such information to individuals purchasing
25 such drugs, upon request.

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

10 “(m) CONSTRUCTION.—Nothing in this section limits
11 the authority of the Secretary relating to the importation
12 of prescription drugs, other than with respect to section
13 801(d)(1) as provided in this section.”.

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

18 “(h) In the case of a person operating an internet
19 website, whether in the United States or in another coun-
20 try, that violates section 301(aa) by—

21 “(1) selling, by means of the internet, with the
22 intent to defraud or mislead or with reckless dis-
23 regard for safety of the public, an adulterated or
24 counterfeit drug to an individual in the United
25 States; or

1 “(2) dispenses, by means of the internet, a drug
2 to an individual in the United States who the person
3 knows or has reasonable cause to believe, does not
4 possess a valid prescription for that drug,
5 such person shall be imprisoned for not more than 10
6 years or fined not more than \$250,000.”.

7 (c) NO PREEMPTION.—Nothing in this section, in-
8 cluding the amendments made by this section, shall be
9 construed to preempt, alter, displace, abridge, or supplant
10 any remedy available under any State or Federal law, in-
11 cluding common law, that provides a remedy for civil re-
12 lief.

13 (d) REPORTS.—

14 (1) HHS.—Not later than 1 year after the date
15 on which final regulations are promulgated to carry
16 out section 804 of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 384), as amended by sub-
18 section (a), and every 2 years thereafter, the Sec-
19 retary of Health and Human Services, after con-
20 sultation with appropriate Federal agencies, shall
21 submit to Congress and make public a report on the
22 importation of drugs into the United States.

23 (2) GAO REPORT.—Not later than 18 months
24 after the first report is submitted under paragraph
25 (1), the Comptroller General of the United States

1 shall submit to Congress a report containing an
2 analysis of the implementation of the amendments
3 made by this section, including a review of drug
4 safety and cost-savings and expenses, including cost-
5 savings to consumers in the United States and
6 trans-shipment and importation tracing processes,
7 resulting from such implementation.

8 **SEC. 204. REQUIRING DRUG MANUFACTURERS TO PROVIDE**
9 **DRUG REBATES FOR DRUGS DISPENSED TO**
10 **LOW-INCOME INDIVIDUALS.**

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

13 (1) in subsection (e)(1), in the matter preceding
14 subparagraph (A), by inserting “and subsection (f)”
15 after “this subsection”; and

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

18 “(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR
19 REBATE ELIGIBLE INDIVIDUALS.—

20 “(1) REQUIREMENT.—

21 “(A) IN GENERAL.—For plan years begin-
22 ning on or after January 1, 2020, in this part,
23 the term ‘covered part D drug’ does not include
24 any drug or biological product that is manufac-
25 tured by a manufacturer that has not entered

1 into and have in effect a rebate agreement de-
2 scribed in paragraph (2).

3 “(B) 2020 PLAN YEAR REQUIREMENT.—
4 Any drug or biological product manufactured by
5 a manufacturer that declines to enter into a re-
6 bate agreement described in paragraph (2) for
7 the period beginning on January 1, 2020, and
8 ending on December 31, 2020, shall not be in-
9 cluded as a ‘covered part D drug’ for the subse-
10 quent plan year.

11 “(2) REBATE AGREEMENT.—A rebate agree-
12 ment under this subsection shall require the manu-
13 facturer to provide to the Secretary a rebate for
14 each rebate period (as defined in paragraph (6)(B))
15 ending after December 31, 2019, in the amount
16 specified in paragraph (3) for any covered part D
17 drug of the manufacturer dispensed after December
18 31, 2019, to any rebate eligible individual (as de-
19 fined in paragraph (6)(A)) for which payment was
20 made by a PDP sponsor or MA organization under
21 this part for such period, including payments passed
22 through the low-income and reinsurance subsidies
23 under sections 1860D–14 and 1860D–15(b), respec-
24 tively. Such rebate shall be paid by the manufac-
25 turer to the Secretary not later than 30 days after

1 the date of receipt of the information described in
2 section 1860D–12(b)(8), including as such section is
3 applied under section 1857(f)(3), or 30 days after
4 the receipt of information under subparagraph (D)
5 of paragraph (3), as determined by the Secretary.
6 Insofar as not inconsistent with this subsection, the
7 Secretary shall establish terms and conditions of
8 such agreement relating to compliance, penalties,
9 and program evaluations, investigations, and audits
10 that are similar to the terms and conditions for re-
11 bate agreements under paragraphs (3) and (4) of
12 section 1927(b).

13 “(3) REBATE FOR REBATE ELIGIBLE MEDICARE
14 DRUG PLAN ENROLLEES.—

15 “(A) IN GENERAL.—The amount of the re-
16 bate specified under this paragraph for a manu-
17 facturer for a rebate period, with respect to
18 each dosage form and strength of any covered
19 part D drug provided by such manufacturer
20 and dispensed to a rebate eligible individual,
21 shall be equal to the product of—

22 “(i) the total number of units of such
23 dosage form and strength of the drug so
24 provided and dispensed for which payment
25 was made by a PDP sponsor or an MA or-

1 ganization under this part for the rebate
2 period, including payments passed through
3 the low-income and reinsurance subsidies
4 under sections 1860D–14 and 1860D–
5 15(b), respectively; and

6 “(ii) the amount (if any) by which—

7 “(I) the Medicaid rebate amount
8 (as defined in subparagraph (B)) for
9 such form, strength, and period; ex-
10 ceeds

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

15 “(B) MEDICAID REBATE AMOUNT.—For
16 purposes of this paragraph, the term ‘Medicaid
17 rebate amount’ means, with respect to each
18 dosage form and strength of a covered part D
19 drug provided by the manufacturer for a rebate
20 period—

21 “(i) in the case of a single source
22 drug or an innovator multiple source drug,
23 the amount specified in paragraph
24 (1)(A)(ii)(II) or (2)(C) of section 1927(c)
25 plus the amount, if any, specified in sub-

1 paragraph (A)(ii) of paragraph (2) of such
2 section, for such form, strength, and pe-
3 riod; or

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

8 “(C) AVERAGE MEDICARE DRUG PROGRAM
9 REBATE ELIGIBLE REBATE AMOUNT.—For pur-
10 poses of this subsection, the term ‘average
11 Medicare drug program rebate eligible rebate
12 amount’ means, with respect to each dosage
13 form and strength of a covered part D drug
14 provided by a manufacturer for a rebate period,
15 the sum, for all PDP sponsors under part D
16 and MA organizations administering an MA-
17 PD plan under part C, of—

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

20 “(I) the sum of all rebates, dis-
21 counts, or other price concessions (not
22 taking into account any rebate pro-
23 vided under paragraph (2) or any dis-
24 counts under the program under sec-
25 tion 1860D–14A) for such dosage

1 form and strength of the drug dis-
2 pensed, calculated on a per-unit basis,
3 but only to the extent that any such
4 rebate, discount, or other price con-
5 cession applies equally to drugs dis-
6 pensed to rebate eligible Medicare
7 drug plan enrollees and drugs dis-
8 pensed to PDP and MA–PD enrollees
9 who are not rebate eligible individuals;
10 and

11 “(II) the number of the units of
12 such dosage and strength of the drug
13 dispensed during the rebate period to
14 rebate eligible individuals enrolled in
15 the prescription drug plans adminis-
16 tered by the PDP sponsor or the MA–
17 PD plans administered by the MA or-
18 ganization; divided by

19 “(ii) the total number of units of such
20 dosage and strength of the drug dispensed
21 during the rebate period to rebate eligible
22 individuals enrolled in all prescription drug
23 plans administered by PDP sponsors and
24 all MA–PD plans administered by MA or-
25 ganizations.

1 “(D) USE OF ESTIMATES.—The Secretary
2 may establish a methodology for estimating the
3 average Medicare drug program rebate eligible
4 rebate amounts for each rebate period based on
5 bid and utilization information under this part
6 and may use these estimates as the basis for
7 determining the rebates under this section. If
8 the Secretary elects to estimate the average
9 Medicare drug program rebate eligible rebate
10 amounts, the Secretary shall establish a rec-
11 onciliation process for adjusting manufacturer
12 rebate payments not later than 3 months after
13 the date that manufacturers receive the infor-
14 mation collected under section 1860D–
15 12(b)(8)(B).

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

22 “(5) OTHER TERMS AND CONDITIONS.—The
23 Secretary shall establish other terms and conditions
24 of the rebate agreement under this subsection, in-

1 including terms and conditions related to compliance,
 2 that are consistent with this subsection.

3 “(6) DEFINITIONS.—In this subsection and sec-
 4 tion 1860D–12(b)(8):

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

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

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

12 “(iii) any part D eligible individual
 13 not described in clause (i) or (ii) who is de-
 14 termined for purposes of the State plan
 15 under title XIX to be eligible for medical
 16 assistance under clause (i), (iii), or (iv) of
 17 section 1902(a)(10)(E).

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

21 (b) REPORTING REQUIREMENT FOR THE DETER-
 22 MINATION AND PAYMENT OF REBATES BY MANUFACTUR-
 23 ERS RELATED TO REBATE FOR REBATE ELIGIBLE MEDI-
 24 CARE DRUG PLAN ENROLLEES.—

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

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

9 “(A) IN GENERAL.—For purposes of the
10 rebate under section 1860D–2(f) for contract
11 years beginning on or after January 1, 2020,
12 each contract entered into with a PDP sponsor
13 under this part with respect to a prescription
14 drug plan shall require that the sponsor comply
15 with subparagraphs (B) and (C).

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

20 “(i) information (by National Drug
21 Code number) on the total number of units
22 of each dosage, form, and strength of each
23 drug of such manufacturer dispensed to re-
24 bate eligible Medicare drug plan enrollees
25 under any prescription drug plan operated

1 by the PDP sponsor during the rebate pe-
2 riod;

3 “(ii) information on the price dis-
4 counts, price concessions, and rebates for
5 such drugs for such form, strength, and
6 period;

7 “(iii) information on the extent to
8 which such price discounts, price conces-
9 sions, and rebates apply equally to rebate
10 eligible Medicare drug plan enrollees and
11 PDP enrollees who are not rebate eligible
12 Medicare drug plan enrollees; and

13 “(iv) any additional information that
14 the Secretary determines is necessary to
15 enable the Secretary to calculate the aver-
16 age Medicare drug program rebate eligible
17 rebate amount (as defined in paragraph
18 (3)(C) of such section), and to determine
19 the amount of the rebate required under
20 this section, for such form, strength, and
21 period.

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

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

6 “(D) CONFIDENTIALITY OF INFORMA-
7 TION.—The provisions of subparagraph (D) of
8 section 1927(b)(3), relating to confidentiality of
9 information, shall apply to information reported
10 by PDP sponsors under this paragraph in the
11 same manner that such provisions apply to in-
12 formation disclosed by manufacturers or whole-
13 salers under such section, except—

14 “(i) that any reference to ‘this sec-
15 tion’ in clause (i) of such subparagraph
16 shall be treated as being a reference to this
17 section;

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

23 “(iii) clause (iv) of such subparagraph
24 shall not apply.

1 “(E) OVERSIGHT.—Information reported
2 under this paragraph may be used by the In-
3 spector General of the Department of Health
4 and Human Services for the statutorily author-
5 ized purposes of audit, investigation, and eval-
6 uations.

7 “(F) PENALTIES FOR FAILURE TO PRO-
8 VIDE TIMELY INFORMATION AND PROVISION OF
9 FALSE INFORMATION.—In the case of a PDP
10 sponsor—

11 “(i) that fails to provide information
12 required under subparagraph (B) on a
13 timely basis, the sponsor is subject to a
14 civil money penalty in the amount of
15 \$10,000 for each day in which such infor-
16 mation has not been provided; or

17 “(ii) that knowingly (as defined in
18 section 1128A(i)) provides false informa-
19 tion under such subparagraph, the sponsor
20 is subject to a civil money penalty in an
21 amount not to exceed \$100,000 for each
22 item of false information.

23 Such civil money penalties are in addition to
24 other penalties as may be prescribed by law.
25 The provisions of section 1128A (other than

1 subsections (a) and (b)) shall apply to a civil
 2 money penalty under this subparagraph in the
 3 same manner as such provisions apply to a pen-
 4 alty or proceeding under section 1128A(a).”.

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

9 “(E) REPORTING REQUIREMENT RELATED
 10 TO REBATE FOR REBATE ELIGIBLE MEDICARE
 11 DRUG PLAN ENROLLEES.—Section 1860D–
 12 12(b)(8).”.

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

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

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

24 (1) EXCLUSION FROM BEST PRICE DETERMINA-
 25 TION.—Section 1927(c)(1)(C)(ii)(I) of the Social Se-

1 security Act (42 U.S.C. 1396r-8(c)(1)(C)(ii)(I)) is
 2 amended by inserting “and amounts paid under a
 3 rebate agreement under section 1860D-2(f)” after
 4 “this section”.

5 (2) EXCLUSION FROM AVERAGE MANUFAC-
 6 Turer PRICE DETERMINATION.—Section
 7 1927(k)(1)(B)(i) of the Social Security Act (42
 8 U.S.C. 1396r-8(k)(1)(B)(i)) is amended—

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

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

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

14 “(VI) amounts paid under a re-
 15 bate agreement under section 1860D-
 16 2(f).”.

17 **SEC. 205. CAP ON PRESCRIPTION DRUG COST-SHARING.**

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

21 (1) in paragraph (3)(A)(i), by inserting “, in-
 22 cluding cost-sharing with respect to prescription
 23 drugs covered by the plan” after “charges”; and

24 (2) by adding at the end the following:

25 “(5) PRESCRIPTION DRUG COST-SHARING.—

1 “(A) 2020.—For plan years beginning in
2 2020, the cost-sharing incurred under a health
3 plan with respect to prescription drugs covered
4 by the plan shall not exceed \$250 per month for
5 each enrolled individual, or \$500 for each fam-
6 ily.

7 “(B) 2021 AND LATER.—

8 “(i) IN GENERAL.—In the case of any
9 plan year beginning in a calendar year
10 after 2020, the limitation under this para-
11 graph shall be equal to the applicable dol-
12 lar amount under subparagraph (A) for
13 plan years beginning in 2020, increased by
14 an amount equal to the product of that
15 amount and the medical care component of
16 the consumer price index for all urban con-
17 sumers (as published by the Bureau of
18 Labor Statistics) for that year.

19 “(ii) ADJUSTMENT TO AMOUNT.—If
20 the amount of any increase under clause
21 (i) is not a multiple of \$5, such increase
22 shall be rounded to the next lowest mul-
23 tiple of \$5.”.

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

4 (1) by striking “annual”; and

5 (2) by striking “paragraph (1) of section
6 1302(c)” and inserting “paragraphs (1) and (5) of
7 section 1302(c) of the Patient Protection and Af-
8 fordable Care Act”.

9 (c) EFFECTIVE DATE.—The amendments made by
10 subsections (a) and (b) shall take effect with respect to
11 plans beginning after December 31, 2019.

12 **SEC. 206. MODIFICATION OF TRADE NEGOTIATING OBJEC-**
13 **TIVES RELATING TO INTELLECTUAL PROP-**
14 **ERTY RIGHTS TO ENSURE ACCESS TO BIO-**
15 **LOGICAL PRODUCTS.**

16 Section 102(b)(5)(C) of the Bipartisan Congressional
17 Trade Priorities and Accountability Act of 2015 (19
18 U.S.C. 4201(b)(5)(C)) is amended by striking the end pe-
19 riod and inserting the following: “, including by ensuring
20 that trade agreements do not require a party to provide
21 biological product exclusivity of more than 7 years.”.

1 **TITLE III—INNOVATION**

2 **SEC. 301. INNOVATION INCENTIVE FUND FOR NEW AND**
3 **MORE EFFECTIVE TREATMENTS OF BAC-**
4 **TERIAL INFECTIONS.**

5 Part B of title IV of the Public Health Service Act
6 (42 U.S.C. 284 et seq.) is amended by adding at the end
7 the following:

8 **“SEC. 409K. INNOVATION INCENTIVE FUND FOR NEW AND**
9 **MORE EFFECTIVE TREATMENTS OF BAC-**
10 **TERIAL INFECTIONS.**

11 “(a) ESTABLISHMENT OF FUND.—There is hereby
12 established in the Treasury of the United States a revolv-
13 ing fund to be known as the ‘Antibiotics Innovation Incen-
14 tive Fund’, which shall consist of funds transferred under
15 subsection (b).

16 “(b) AMOUNTS CREDITED TO THE FUND.—There
17 are hereby authorized to be appropriated, and appro-
18 priated, to the Antibiotics Innovation Incentive Fund, for
19 fiscal year 2020, out of any monies in the Treasury not
20 otherwise appropriated, \$2,000,000,000. Such funds shall
21 remain available until expended.

22 “(c) AWARDS.—

23 “(1) IN GENERAL.—During the 10-year period
24 following the date of enactment of the Affordable
25 Medications Act, the Director of the NIH, in accord-

1 ance with the criteria under subsection (d) and the
2 goals under subsection (e), shall award—

3 “(A) up to 3 market entry awards for
4 qualifying products that provide added benefit
5 for patients over existing therapies in the treat-
6 ment of serious and life-threatening bacterial
7 infections demonstrating in superiority trials;
8 and

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

13 “(2) AWARD AMOUNT REQUIREMENTS.—No
14 more than 5 percent of the amount available in the
15 Antibiotics Innovation Incentive shall be dedicated to
16 open source dividend prizes.

17 “(d) CRITERIA AND STRUCTURE OF PRIZES.—

18 “(1) ESTABLISHMENT OF CRITERIA.—Not later
19 than 120 days after the date of enactment of the Af-
20 fordable Medications Act, the Director of NIH shall
21 establish criteria for the selection of recipients and
22 eligibility of persons for market entry rewards and
23 open source dividend prizes under this section and
24 criteria for determining the amounts of such prizes,
25 through notice and comment rulemaking.

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

8 “(A) The number of patients in the United
9 States and in other countries who would benefit
10 from the qualifying product that treats a seri-
11 ous or life-threatening bacterial infection, and
12 the number of patients in the United States
13 and in other countries projected to benefit dur-
14 ing the upcoming 10-year period.

15 “(B) Whether the qualifying product
16 treats, or has the potential to treat, a serious
17 or life-threatening bacterial infection for which
18 no other treatment is currently available or for
19 which there is a high threat of resistance to ex-
20 isting treatments.

21 “(C) The incremental and additional thera-
22 peutic benefit to human in the United States
23 and other countries of the qualifying product as
24 compared to other treatments available to treat
25 the bacterial infection, evaluating the incre-

1 mental therapeutic benefit in comparison to
2 treatments that were not recently developed.

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

6 “(E) The extent to which knowledge, data,
7 materials, and technology that are openly
8 sourced have contributed to the successful de-
9 velopment of new treatments that provide an
10 added benefit to patients, such as decreasing
11 mortality or irreversible morbidity on patient-
12 centered outcomes, significantly advancing the
13 field of antibiotic research, or improving proc-
14 esses for manufacturing products used for the
15 treatment.

16 “(F) Other criteria that the Director of
17 NIH determines to be relevant and useful in
18 ensuring that the prizes provide appropriate in-
19 centives.

20 “(3) CRITERIA FOR OPEN SOURCE DIVIDEND
21 PRIZES.—An open source dividend prize under this
22 section shall reward persons that openly shared on
23 a royalty-free, not-for-profit and non-discriminatory
24 basis, materials, technology, data, and knowledge
25 that contribute in a significant way to the successful

1 development of a qualifying product or significantly
2 advanced the field of antibiotic research.

3 “(e) GOALS.—With respect to each year for which the
4 Director of NIH awards market entry rewards and open
5 source dividend prizes under subsection (c), the Director
6 of NIH shall establish a framework of goals that a quali-
7 fying product or contribution that significantly advances
8 the field of antibiotic research is required to show promise
9 to help meet in order for a person to be eligible to receive
10 a market entry reward or open source dividend prize with
11 respect to such product or such contribution. Such goals
12 may include—

13 “(1) reduced hospital admissions or readmis-
14 sions;

15 “(2) use of diagnostics prior to prescribing of
16 drugs; and

17 “(3) use of innovative programs for antibiotic
18 stewardship.

19 “(f) CONDITION ON RECEIPT OF MARKET ENTRY
20 REWARD.—

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

1 “(A) The recipient shall agree to offer the
2 qualifying product at a reasonable price as de-
3 scribed in paragraph (3).

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

8 “(C) The recipient shall agree to submit to
9 the Director of NIH, for review and approval
10 by such director, in collaboration with the Com-
11 missioner of Food and Drugs and the Director
12 of the Centers for Disease Control and Preven-
13 tion, all marketing, sales, and other promotional
14 and educational activities associated with the
15 qualifying product, to ensure that such activi-
16 ties align with, and advance the goals of, re-
17 source conserving stewardship, protecting the
18 utility of antibiotics, and encouraging and en-
19 suring the correct use of antibiotics.

20 “(D) The recipient shall irrevocably
21 waive—

22 “(i) all periods of exclusivity available
23 to the product under chapter V of the Fed-
24 eral Food, Drug, and Cosmetic Act or sec-
25 tion 351 of this Act; and

1 “(ii) all applicable patent rights under
2 title 35, United States Code.

3 “(E) Any other conditions the Director of
4 NIH determines appropriate.

5 “(2) APPLICABILITY.—All conditions described
6 in paragraph (1) shall apply to subsequent owners,
7 licensees, producers, and manufacturers, and assign-
8 ees of the product or any chemical component of the
9 qualifying product for which the market entry re-
10 ward was awarded.

11 “(3) REASONABLE PRICE.—

12 “(A) IN GENERAL.—A recipient may sat-
13 isfy the requirement to offer a qualifying prod-
14 uct or contribution at a ‘reasonable price’ for
15 purposes of paragraph (1)(A) by—

16 “(i)(I) providing open licensing of all
17 necessary rights to patents, manufacturing
18 processes, rights in data, and other intel-
19 lectual property rights needed to make and
20 sell the product to manufacturers of the
21 generic version of such product; or

22 “(II) selling such product at a price
23 that is no more than twice the price of an-
24 tibiotic drugs approved under section
25 505(j) of the Federal Food, Drug, and

1 Cosmetic Act with similar manufacturing
2 costs; and

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

8 “(B) CRITERIA.—For purposes of subpara-
9 graph (A)(ii), the Director of NIH shall iden-
10 tify, on an annual basis, the countries that have
11 a per capita income that is not less than half
12 the per capita income of the United States, se-
13 lect the 7 of such countries that have the larg-
14 est gross domestic product, and determine the
15 median price charged for each qualifying prod-
16 uct for which an award has been granted under
17 subsection (c).

18 “(g) ENFORCEMENT.—If the market entry reward re-
19 cipient, or subsequent owner, licensee, or assignee of the
20 qualifying product, does not fulfill the conditions described
21 subsection (f)(1), the Secretary, in collaboration with the
22 Attorney General, shall take all necessary action to
23 clawback the market entry reward.

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

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

7 “(2) a complete analysis of the recipient’s ful-
8 fillment of award conditions under subsection (e)(1).

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

14 “(j) STUDY.—

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

19 “(A) the use of innovation inducement re-
20 ward funds and push financing mechanisms as
21 ways to stimulate investments in biomedical re-
22 search and development that de-links costs from
23 product prices;

24 “(B) models of different possible means of
25 de-linking research and development costs from

1 drug prices, including the progressive replace-
2 ment of the monopoly on new products with a
3 combination of expanded research subsidies and
4 new incentives from innovation inducement
5 funds to stimulate the development of drugs, in-
6 cluding drugs to treat bacterial infections, rare
7 diseases, HIV/AIDS, and cancer;

8 “(C) the size of market entry rewards,
9 open source dividends and other innovation in-
10 ducement prizes that would be necessary to
11 achieve innovation objectives and the relative
12 cost effectiveness of incentives delinked from
13 the prices of products and services in stimu-
14 lating innovation, compared to time-limited mo-
15 nopolies; and

16 “(D) methods of progressively imple-
17 menting policies that delink research and devel-
18 opment funding from prices of products and
19 services, including to the progressive reduction
20 in the effective term of exclusive rights, accom-
21 panied by a progressive introduction and expan-
22 sion of market entry rewards.

23 “(2) AUTHORIZATION OF APPROPRIATIONS.—

24 For the purpose of carrying out this subsection,
25 there are authorized to be appropriated, and there

1 are appropriated, \$3,000,000 for fiscal year 2020.
2 Such funds shall remain available until expended.”.

3 **SEC. 302. PUBLIC FUNDING FOR CLINICAL TRIALS.**

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

7 **“Subpart 6—Center for Clinical Research**

8 **“SEC. 485E. CENTER FOR CLINICAL RESEARCH.**

9 “(a) IN GENERAL.—There is established within the
10 National Institutes of Health the Center for Clinical Re-
11 search, for the purpose of conducting clinical trials on
12 drugs, as described in subsection (b), with the intention
13 of obtaining approval of such drug under section 505 of
14 the Federal Food, Drug, and Cosmetic Act or section 351
15 of this Act. The Director of NIH shall appoint a Director
16 of the Center for Clinical Research referred to in this sec-
17 tion as the ‘Director’) not later than 90 days after the
18 date of enactment of the Affordable Medications Act.

19 “(b) CLINICAL TRIALS.—

20 “(1) IN GENERAL.—Each year, beginning not
21 later than 1 year after the date of enactment of the
22 Affordable Medications Act, the Director shall select
23 at least 2 molecules, compounds, drugs, or biological
24 products and conduct clinical trials on such mol-
25 ecules, compounds, drugs, or biological products, or

1 enter into contracts with other entities to conduct
2 such clinical trials.

3 “(2) SELECTION OF DRUGS.—

4 “(A) CRITERIA.—The Director shall estab-
5 lish criteria, which shall be made public, for ac-
6 quiring the patent rights for, and selecting,
7 drugs under paragraph (1) to ensure that the
8 drugs selected for clinical trials through the
9 Center—

10 “(i) have the potential to address an
11 existing or emerging need, including drugs
12 that can be repurposed to treat a new con-
13 dition in the case of a national emergency;
14 and

15 “(ii) are not solely drugs that private
16 sector researchers with access to all avail-
17 able information on such drugs chose not
18 to develop.

19 “(B) PROCESS.—The Director shall secure
20 all patent rights to each drug selected under
21 paragraph (1), as applicable, and perform the
22 clinical trials at NIH or subcontract with an-
23 other entity to conduct the clinical trials.

24 “(c) TREATMENT OF APPROVED DRUGS.—If a drug
25 for which clinical trials have been conducted by the Center

1 for Clinical Research is approved by the Food and Drug
2 Administration under section 505 of the Federal Food,
3 Drug, and Cosmetic Act or section 351 of this Act, the
4 Director shall—

5 “(1) execute non-exclusive licenses to allow
6 drug manufacturers to manufacture and sell the
7 drug; or

8 “(2) in collaboration with other Federal agen-
9 cies as appropriate, enter into purchasing contracts.

10 “(d) PUBLIC INFORMATION.—

11 “(1) RESEARCH DATA AND FINDINGS.—Subject
12 to applicable patient privacy protections, the Sec-
13 retary shall—

14 “(A)(i) submit all completed studies (and
15 terminated studies, if terminated for safety or
16 ethical reasons) for publication in a peer-re-
17 viewed publication within 180 days of comple-
18 tion or termination; and

19 “(ii) if a study submitted as described in
20 clause (i) is not selected for publication, pub-
21 licly disclose all de-identified primary clinical
22 data not later than 180 days after the Sec-
23 retary’s final decision not to pursue further
24 submissions for publication; and

1 “(B) publicly disclose all de-identified pri-
2 mary clinical data upon publication of a study
3 as described in subparagraph (A)(i).

4 “(2) FINANCIAL INFORMATION.—The Director
5 shall make public all costs to the Federal Govern-
6 ment associated with carrying out clinical trials by
7 the Center for Clinical Research and with sub-
8 contract agreements under this section, in a manner
9 that identifies the cost associated with each trial.

10 “(e) DEFINITION.—In this section, the term ‘drug’
11 has the meaning given such term in section 201(g) of the
12 Federal Food, Drug, and Cosmetic Act.

13 “(f) APPROPRIATIONS.—For the purpose of carrying
14 out this section, in addition to any other funds available
15 for such purpose, there are authorized to be appropriated,
16 and there are appropriated, \$1,000,000,000 for each of
17 fiscal years 2020 through 2030, to remain available until
18 expended.”.

19 (b) CLERICAL AMENDMENT.—Section 401(b) of the
20 Public Health Service Act (42 U.S.C. 281(b)) is amend-
21 ed—

22 (1) by redesignating paragraph (25) as para-
23 graph (26); and

24 (2) by inserting after paragraph (24) the fol-
25 lowing:

1 “(25) The Center for Clinical Research.”.

2 **SEC. 303. REWARDING INNOVATIVE DRUG DEVELOPMENT.**

3 (a) DRUG EXCLUSIVITY.—

4 (1) NEW CHEMICAL ENTITY EXCLUSIVITY.—

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

8 (i) in subparagraph (B)—

9 (I) in clause (i), by inserting “ex-
10 cept that such approval may not be
11 made effective before the date that is
12 5 years after the date on which the
13 drug to which the application refers
14 was approved under subsection (c)”
15 before the period; and

16 (II) in clause (ii), by inserting
17 “except that such approval may not
18 be made effective before the date that
19 is 5 years after the date on which the
20 drug to which the application refers
21 was approved under subsection (c)”
22 before the period; and

23 (ii) in subparagraph (F)(ii)—

1 (I) by striking “expiration of five
2 years” and inserting “expiration of 3
3 years”;

4 (II) by striking “, except that
5 such an application may be submitted
6 under this subsection after the expira-
7 tion of four years from the date of the
8 approval of the subsection (b) applica-
9 tion if it contains a certification of
10 patent invalidity or noninfringement
11 described in subclause (IV) of para-
12 graph (2)(A)(vii)”;

13 (III) by striking “seven and one-
14 half years” and inserting “6 and one-
15 half years”.

16 (B) CONFORMING AMENDMENTS.—Chapter
17 V of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 351 et seq.) is amended—

19 (i) in subsection (v)(2)(A)(i)(II) of
20 section 505, by inserting “the 3-year exclu-
21 sivity period referred to” before “under
22 clause (ii) of subsection (j)(5)(F)”;

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

1 (I) by striking “five years” each
2 place such term appears and inserting
3 “3 years”;

4 (II) by striking “seven and one-
5 half years” each place such term ap-
6 pears and inserting “6 and one-half
7 years”; and

8 (III) by striking “eight years”
9 each place such term appears and in-
10 sserting “7 years”; and

11 (iii) in section 505E, by striking “the
12 4- and 5-year periods described in sub-
13 sections (c)(3)(E)(ii) and (j)(5)(F)(ii) of
14 section 505, the 3-year periods described
15 in clauses (iii) and (iv) of subsection
16 (c)(3)(E) and clauses (iii) and (iv) of sub-
17 section (j)(5)(F)” and inserting “the 4-
18 and 5-year periods described in subsection
19 (c)(3)(E)(ii) of section 505, the 3-year pe-
20 riods described in clauses (iii) and (iv) of
21 subsection (c)(3)(E) and clauses (ii), (iii),
22 and (iv) of subsection (j)(5)(F)”.

23 (2) NEW CLINICAL INVESTIGATION EXCLU-
24 SIVITY.—Section 505(c)(3)(E)(iv) of the Federal
25 Food, Drug, and Cosmetic Act (21 U.S.C.

1 355(c)(3)(E)(iv)) is amended by inserting “, and the
2 supplement shows a significant clinical benefit over
3 existing therapies manufactured by the applicant in
4 the 5-year period preceding the submission of the
5 application,” before “the Secretary”.

6 (3) BIOLOGICAL PRODUCT EXCLUSIVITY.—

7 (A) IN GENERAL.—Section 351(k)(7)(A) of
8 the Public Health Service Act (42 U.S.C.
9 262(k)(7)(A)) is amended by striking “12
10 years” and inserting “7 years”.

11 (B) CONFORMING AMENDMENTS.—Para-
12 graphs (2)(A) and (3)(A) of section 351(m) of
13 the Public Health Service Act (42 U.S.C.
14 262(m)) is amended by striking “12 years”
15 each place it appears and inserting “7 years”.

16 (b) APPLICABILITY.—The amendments made by sub-
17 section (a) apply only with respect to a drug or biological
18 product for which the listed drug (as described in section
19 505(j)(7) of the Federal Food, Drug, and Cosmetic Act
20 (21 U.S.C. 355(j)(7))) or reference product (as such term
21 is used in section 351 of the Public Health Service Act
22 (42 U.S.C. 262)) is approved under section 505(c) of the
23 Federal Food, Drug, and Cosmetic Act or licensed under
24 section 351(a) of the Public Health Service Act, as appli-
25 cable, on or after the date of enactment of this Act.

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

5 (1)(A) the number of requests for designation
6 as a drug for a rare disease or condition under sec-
7 tion 526 of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 360bb) the Food and Drug Adminis-
9 tration receives each year in the previous 10-year pe-
10 riod;

11 (B) the number of such requests granted, de-
12 nied, and pending;

13 (C) the names of all drugs receiving such des-
14 ignation during such period, including the date of
15 approval and indication for which market exclusivity
16 was granted; and

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

19 (2) for each drug so designated as a drug for
20 a rare disease or condition in the previous 10-year
21 period, the total annual expenditures for such drugs
22 under the Medicare program under title XVIII of
23 the Social Security Act (42 U.S.C. 1395 et seq.) and
24 the Medicaid program under title XIX of the Social
25 Security Act (42 U.S.C. 1396 et seq.), the number

1 of Medicare and Medicaid beneficiaries who used
2 each such drug each year during such time period,
3 and any changes in price per unit during such time
4 period; and

5 (3) for a sample of drugs (selected by the
6 Comptroller General) so designated in the previous
7 10-year period, to the extent feasible—

8 (A) gross revenues of the manufacturers
9 with respect to each such drug, and manufac-
10 turer spending for marketing and patient as-
11 sistance programs;

12 (B) the average price per drug and how
13 those prices changed over time for the selected
14 drugs based on industry drug pricing bench-
15 marks; and

16 (C) the indications that were the basis of
17 such designation and other approved indications
18 for the drugs, and the indications for which
19 each drug has most commonly been used, in-
20 cluding non-approved indications for which the
21 drug may be recommended by external organi-
22 zations such as physician or patient organiza-
23 tions.

1 **SEC. 304. IMPROVING PROGRAM INTEGRITY.**

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

5 **“SEC. 569E. CONDITIONS ON AWARD OF DRUG EXCLU-**
6 **SIVITY.**

7 “(a) TERMINATION OF EXCLUSIVITY.—Notwith-
8 standing any other provision of this Act, any period of
9 exclusivity described in subsection (b) granted to a person
10 or assigned to a person on or after the date of enactment
11 of this section with respect to a drug shall be terminated
12 if the person to which such exclusivity was granted or any
13 person to which such exclusivity is assigned commits a vio-
14 lation described in subsection (c)(1) with respect to such
15 drug.

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

19 “(1) Clause (ii), (iii), or (iv) of section
20 505(c)(3)(E).

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

22 “(3) Clause (ii), (iii), or (iv) of section
23 505(j)(5)(F).

24 “(4) Section 505A.

25 “(5) Section 505E.

26 “(6) Section 527.

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

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

6 “(c) VIOLATIONS.—

7 “(1) IN GENERAL.—A violation described in
8 this subsection is a violation of a law described in
9 paragraph (2), enforced by a Federal or State gov-
10 ernmental entity that results in—

11 “(A) a criminal conviction of a person de-
12 scribed in subsection (a);

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

15 “(C) a settlement agreement in which a
16 person described in subsection (a) admits to
17 fault.

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

20 “(A) The provisions of this Act that pro-
21 hibit—

22 “(i) the adulteration or misbranding
23 of a drug;

24 “(ii) the making of false statements to
25 the Secretary or committing fraud; or

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

2 “(B) Section 3729 of title 31, United
3 States Code.

4 “(C) Section 286 or 287 of title 18, United
5 States Code.

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

9 “(E) Section 1927 of the Social Security
10 Act.

11 “(F) A State law against fraud comparable
12 to a law described in subparagraphs (A)
13 through (E).

14 “(d) DATE OF EXCLUSIVITY TERMINATION.—The
15 date on which the exclusivity shall be terminated as de-
16 scribed in subsection (a) is the date on which, as applica-
17 ble—

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

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

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

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

4 “(e) REPORTING OF INFORMATION.—

5 “(1) IN GENERAL.—A person described in sub-
6 section (a) that commits a violation described in
7 subsection (c)(1) shall report such violation to the
8 Secretary no later than 30 days after the date
9 that—

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

13 “(B)(i) a settlement agreement described
14 in subsection (c)(1)(C) is approved by a court
15 order that is or becomes final and nonappeal-
16 able; or

17 “(ii) if there is no court order approving a
18 settlement agreement described in subsection
19 (c)(1)(C), a court order dismissing the applica-
20 ble case, issued after the settlement agreement,
21 is or becomes final and nonappealable.

22 “(2) CIVIL PENALTY.—A person who fails to re-
23 port a violation as required under paragraph (1)
24 shall be subject to a civil penalty in the amount of
25 \$200,000 for each day the failure to report con-

1 continues, beginning with the day after the date on
 2 which such report is due as described in paragraph
 3 (1).”.

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

9 **TITLE IV—CHOICE AND**
 10 **COMPETITION**

11 **SEC. 401. UNLAWFUL COMPENSATION FOR DELAY.**

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

15 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS**
 16 **AND BIOSIMILARS.**

17 “(a) IN GENERAL.—

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

24 “(2) PRESUMPTION AND VIOLATION.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (B), in such a proceeding, an agreement
3 shall be presumed to have anticompetitive ef-
4 fects and shall be a violation of this section if—

5 “(i) an ANDA filer or a biosimilar bi-
6 ological product application filer receives
7 anything of value, including an exclusive li-
8 cense; and

9 “(ii) the ANDA filer or biosimilar bio-
10 logical product application filer agrees to
11 limit or forego research, development,
12 manufacturing, marketing, or sales of the
13 ANDA product or biosimilar biological
14 product, as applicable, for any period of
15 time.

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

20 “(i) the value described in subpara-
21 graph (A)(i) is compensation solely for
22 other goods or services that the ANDA
23 filer or biosimilar biological product appli-
24 cation filer has promised to provide; or

1 “(ii) the procompetitive benefits of the
2 agreement outweigh the anticompetitive ef-
3 fects of the agreement.

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

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

10 “(2) that the agreement’s provision for entry of
11 the ANDA product or biosimilar biological product
12 prior to the expiration of the relevant patent or stat-
13 utory exclusivity means that the agreement is pro-
14 competitive.

15 “(c) EXCLUSIONS.—Nothing in this section shall pro-
16 hibit a resolution or settlement of a patent infringement
17 claim in which the consideration granted by the NDA
18 holder or biological product license holder to the ANDA
19 filer or biosimilar biological product application filer, re-
20 spectively, as part of the resolution or settlement includes
21 only one or more of the following:

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

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

3 “(B) any patent right or other statutory
4 exclusivity that would prevent the marketing of
5 such ANDA product or biosimilar biological
6 product.

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

9 “(3) A covenant not to sue on any claim that
10 the ANDA product or biosimilar biological product
11 infringes a United States patent.

12 “(d) ENFORCEMENT.—

13 “(1) ENFORCEMENT.—A violation of this sec-
14 tion shall be treated as a violation of section 5.

15 “(2) JUDICIAL REVIEW.—

16 “(A) IN GENERAL.—Any party that is sub-
17 ject to a final order of the Commission, issued
18 in an administrative adjudicative proceeding
19 under the authority of subsection (a)(1), may,
20 within 30 days of the issuance of such order,
21 petition for review of such order in—

22 “(i) the United States Court of Ap-
23 peals for the District of Columbia Circuit;

24 “(ii) the United States Court of Ap-
25 peals for the circuit in which the ultimate

1 parent entity, as defined in section
2 801.1(a)(3) of title 16, Code of Federal
3 Regulations, or any successor thereto, of
4 the NDA holder or biological product li-
5 cense holder is incorporated as of the date
6 that the NDA or biological product license
7 application, as applicable, is filed with the
8 Commissioner of Food and Drugs; or

9 “(iii) the United States Court of Ap-
10 peals for the circuit in which the ultimate
11 parent entity of the ANDA filer or bio-
12 similar biological product application filer
13 is incorporated as of the date that the
14 ANDA or biosimilar biological product ap-
15 plication is filed with the Commissioner of
16 Food and Drugs.

17 “(B) TREATMENT OF FINDINGS.—In a
18 proceeding for judicial review of a final order of
19 the Commission, the findings of the Commis-
20 sion as to the facts, if supported by evidence,
21 shall be conclusive.

22 “(e) ANTITRUST LAWS.—Nothing in this section
23 shall modify, impair, limit, or supersede the applicability
24 of the antitrust laws as defined in subsection (a) of the
25 first section of the Clayton Act (15 U.S.C. 12(a)), and

1 of section 5 of this Act to the extent that section 5 applies
2 to unfair methods of competition. Nothing in this section
3 shall modify, impair, limit, or supersede the right of an
4 ANDA filer or biosimilar biological product application
5 filer to assert claims or counterclaims against any person,
6 under the antitrust laws or other laws relating to unfair
7 competition.

8 “(f) PENALTIES.—

9 “(1) FORFEITURE.—Each party that violates or
10 assists in the violation of this section shall forfeit
11 and pay to the United States a civil penalty suffi-
12 cient to deter violations of this section, but in no
13 event greater than 3 times the value received by the
14 party that is reasonably attributable to the violation
15 of this section. If no such value has been received by
16 the NDA holder or biological product license holder,
17 the penalty to the NDA holder or biological product
18 license holder shall be sufficient to deter violations,
19 but in no event greater than 3 times the value given
20 to the ANDA filer or biosimilar biological product
21 application filer reasonably attributable to the viola-
22 tion of this section. Such penalty shall accrue to the
23 United States and may be recovered in a civil action
24 brought by the Commission, in its own name by any
25 of its attorneys designated by it for such purpose, in

1 a district court of the United States against any
2 party that violates this section. In such actions, the
3 United States district courts are empowered to grant
4 mandatory injunctions and such other and further
5 equitable relief as they deem appropriate.

6 “(2) CEASE AND DESIST.—

7 “(A) IN GENERAL.—If the Commission has
8 issued a cease and desist order with respect to
9 a party in an administrative adjudicative pro-
10 ceeding under the authority of subsection
11 (a)(1), an action brought pursuant to para-
12 graph (1) may be commenced against such
13 party at any time before the expiration of 1
14 year after such order becomes final pursuant to
15 section 5(g).

16 “(B) EXCEPTION.—In an action under
17 subparagraph (A), the findings of the Commis-
18 sion as to the material facts in the administra-
19 tive adjudicative proceeding with respect to the
20 violation of this section by a party shall be con-
21 clusive unless—

22 “(i) the terms of such cease and de-
23 sist order expressly provide that the Com-
24 mission’s findings shall not be conclusive;
25 or

1 “(ii) the order became final by reason
2 of section 5(g)(1), in which case such find-
3 ing shall be conclusive if supported by evi-
4 dence.

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

8 “(A) the nature, circumstances, extent,
9 and gravity of the violation;

10 “(B) with respect to the violator, the de-
11 gree of culpability, any history of violations, the
12 ability to pay, any effect on the ability to con-
13 tinue doing business, profits earned by the
14 NDA holder or biological product license holder,
15 compensation received by the ANDA filer or
16 biosimilar biological product application filer,
17 and the amount of commerce affected; and

18 “(C) other matters that justice requires.

19 “(4) REMEDIES IN ADDITION.—Remedies pro-
20 vided in this subsection are in addition to, and not
21 in lieu of, any other remedy provided by Federal
22 law. Nothing in this paragraph shall be construed to
23 affect any authority of the Commission under any
24 other provision of law.

25 “(g) DEFINITIONS.—In this section:

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

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

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

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

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

5 “(6) BIOLOGICAL PRODUCT.—The term ‘bio-
6 logical product’ has the meaning given such term in
7 section 351(i)(1) of the Public Health Service Act
8 (42 U.S.C. 262(i)(1)).

9 “(7) BIOLOGICAL PRODUCT LICENSE APPLICA-
10 TION.—The term ‘biological product license applica-
11 tion’ means an application under section 351(a) of
12 the Public Health Service Act (42 U.S.C. 262(a)).

13 “(8) BIOLOGICAL PRODUCT LICENSE HOLD-
14 ER.—The term ‘biological product license holder’
15 means—

16 “(A) the holder of an approved biological
17 product license application for a biological prod-
18 uct;

19 “(B) a person owning or controlling en-
20 forcement of any patents that claim the biologi-
21 cal product that is the subject of such approved
22 application; or

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

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

6 “(9) BIOSIMILAR BIOLOGICAL PRODUCT.—The
7 term ‘biosimilar biological product’ means the prod-
8 uct to be manufactured under the biosimilar biologi-
9 cal product application that is the subject of the pat-
10 ent infringement claim.

11 “(10) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
12 CATION.—The term ‘biosimilar biological product ap-
13 plication’ means an application under section 351(k)
14 of the Public Health Service Act (42 U.S.C. 262(k))
15 for licensure of a biological product as biosimilar to,
16 or interchangeable with, a reference product.

17 “(11) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
18 CATION FILER.—The term ‘biosimilar biological
19 product application filer’ means a party that owns or
20 controls a biosimilar biological product application
21 filed with the Food and Drug Administration or has
22 the exclusive rights under such application to dis-
23 tribute the biosimilar biological product.

24 “(12) DRUG PRODUCT.—The term ‘drug prod-
25 uct’ has the meaning given such term in section

1 314.3(b) of title 21, Code of Federal Regulations (or
2 any successor regulation).

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

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

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

11 “(B) a person owning or controlling en-
12 forcement of the patent listed in the Approved
13 Drug Products With Therapeutic Equivalence
14 Evaluations (commonly known as the ‘FDA Or-
15 ange Book’) in connection with the NDA; or

16 “(C) the predecessors, subsidiaries, divi-
17 sions, groups, and affiliates controlled by, con-
18 trolling, or under common control with any of
19 the entities described in subparagraphs (A) and
20 (B) (such control to be presumed by direct or
21 indirect share ownership of 50 percent or great-
22 er), as well as the licensees, licensors, succes-
23 sors, and assigns of each of the entities.

1 “(15) PARTY.—The term ‘party’ means any
2 person, partnership, corporation, or other legal enti-
3 ty.

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

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

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

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 355(c)(3)(E), 360cc, 355a), or on the licensing of
3 biological product applications under section
4 351(k)(7) (12-year exclusivity) or paragraph (2) or
5 (3) of section 351(m) (pediatric exclusivity) of the
6 Public Health Service Act (42 U.S.C. 262) or under
7 section 527 of the Federal Food, Drug, and Cos-
8 metic Act (orphan drug exclusivity).”.

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

16 **SEC. 402. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS RE-**
17 **GARDING FIRST APPLICANT STATUS.**

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

20 (1) IN GENERAL.—Section 505(j)(5)(B) of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 355(j)(5)(B)) is amended—

23 (A) in clause (iv)(II)—

24 (i) by striking item (bb); and

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

4 (B) by adding at the end the following:

5 “(v) FIRST APPLICANT DEFINED.—As used in
6 this subsection, the term ‘first applicant’ means an
7 applicant—

8 (I)(aa) that, on the first day on which a
9 substantially complete application containing a
10 certification described in paragraph
11 (2)(A)(vii)(IV) is submitted for approval of a
12 drug, submits a substantially complete applica-
13 tion that contains and lawfully maintains a cer-
14 tification described in paragraph (2)(A)(vii)(IV)
15 for the drug; and

16 (bb) that has not entered into a disquali-
17 fying agreement described under clause
18 (vii)(II); or

19 (II)(aa) for the drug that is not described
20 in subclause (I) and that, with respect to the
21 applicant and drug, each requirement described
22 in clause (vi) is satisfied; and

23 (bb) that has not entered into a disquali-
24 fying agreement described under clause
25 (vii)(II).

1 “(vi) REQUIREMENT.—The requirements de-
2 scribed in this clause are the following:

3 “(I) The applicant described in clause
4 (v)(II) submitted and lawfully maintains a cer-
5 tification described in paragraph (2)(A)(vii)(IV)
6 or a statement described in paragraph
7 (2)(A)(viii) for each unexpired patent for which
8 a first applicant described in clause (v)(I) had
9 submitted a certification described in paragraph
10 (2)(A)(vii)(IV) on the first day on which a sub-
11 stantially complete application containing such
12 a certification was submitted.

13 “(II) With regard to each such unexpired
14 patent for which the applicant described in
15 clause (v)(II) submitted a certification de-
16 scribed in paragraph (2)(A)(vii)(IV), no action
17 for patent infringement was brought against
18 such applicant within the 45-day period speci-
19 fied in paragraph (5)(B)(iii); or if an action
20 was brought within such time period, such an
21 action was withdrawn or dismissed by a court
22 (including a district court) without a decision
23 that the patent was valid and infringed; or if an
24 action was brought within such time period and
25 was not withdrawn or so dismissed, such appli-

1 cant has obtained the decision of a court (in-
2 cluding a district court) that the patent is in-
3 valid or not infringed (including any substantive
4 determination that there is no cause of action
5 for patent infringement or invalidity, and in-
6 cluding a settlement order or consent decree
7 signed and entered by the court stating that the
8 patent is invalid or not infringed).

9 “(III) If an applicant described in clause
10 (v)(I) has begun commercial marketing of such
11 drug, the applicant described in clause (v)(II)
12 does not begin commercial marketing of such
13 drug until the date that is 30 days after the
14 date on which the applicant described in clause
15 (v)(I) began such commercial marketing.”.

16 (2) CONFORMING AMENDMENT.—Section
17 505(j)(5)(D)(i)(IV) of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(IV)) is
19 amended by striking “The first applicant” and in-
20 serting “The first applicant, as defined in subpara-
21 graph (B)(v)(I),”.

22 (b) APPLICABILITY.—The amendments made by sub-
23 section (a) shall apply only with respect to an application
24 filed under section 505(j) of the Federal Food, Drug, and
25 Cosmetic Act (21 U.S.C. 355(j)) to which the amendments

1 made by section 1102(a) of the Medicare Prescription
2 Drug, Improvement, and Modernization Act of 2003 (Pub-
3 lic Law 108–173) apply.

4 **SEC. 403. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS RE-**
5 **GARDING AGREEMENTS TO DEFER COMMER-**
6 **CIAL MARKETING.**

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

9 (1) LIMITATIONS ON AGREEMENTS TO DEFER
10 COMMERCIAL MARKETING DATE.—Section
11 505(j)(5)(B) of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 355(j)(5)(B)), as amended by
13 section 402, is further amended by adding at the
14 end the following:

15 “(vii) AGREEMENT BY FIRST APPLICANT TO
16 DEFER COMMERCIAL MARKETING; LIMITATION ON
17 ACCELERATION OF DEFERRED COMMERCIAL MAR-
18 KETING DATE.—

19 “(I) AGREEMENT TO DEFER APPROVAL OR
20 COMMERCIAL MARKETING DATE.—An agree-
21 ment described in this subclause is an agree-
22 ment between a first applicant and the holder
23 of the application for the listed drug or an
24 owner of one or more of the patents as to which
25 any applicant submitted a certification quali-

1 fying such applicant for the 180-day exclusivity
2 period whereby that applicant agrees, directly
3 or indirectly, (aa) not to seek an approval of its
4 application that is made effective on the earliest
5 possible date under this subparagraph, subpara-
6 graph (F) of this paragraph, section 505A, or
7 section 527, (bb) not to begin the commercial
8 marketing of its drug on the earliest possible
9 date after receiving an approval of its applica-
10 tion that is made effective under this subpara-
11 graph, subparagraph (F) of this paragraph, sec-
12 tion 505A, or section 527, or (cc) to both items
13 (aa) and (bb).

14 “(II) AGREEMENT THAT DISQUALIFIES AP-
15 PLICANT FROM FIRST APPLICANT STATUS.—An
16 agreement described in this subclause is an
17 agreement between an applicant and the holder
18 of the application for the listed drug or an
19 owner of one or more of the patents as to which
20 any applicant submitted a certification quali-
21 fying such applicant for the 180-day exclusivity
22 period whereby that applicant agrees, directly
23 or indirectly, not to seek an approval of its ap-
24 plication or not to begin the commercial mar-
25 keting of its drug until a date that is after the

1 expiration of the 180-day exclusivity period
2 awarded to another applicant with respect to
3 such drug (without regard to whether such 180-
4 day exclusivity period is awarded before or after
5 the date of the agreement).

6 “(viii) LIMITATION ON ACCELERATION.—If an
7 agreement described in clause (vii)(I) includes more
8 than 1 possible date when an applicant may seek an
9 approval of its application or begin the commercial
10 marketing of its drug—

11 “(I) the applicant may seek an approval of
12 its application or begin such commercial mar-
13 keting on the date that is the earlier of—

14 “(aa) the latest date set forth in the
15 agreement on which that applicant can re-
16 ceive an approval that is made effective
17 under this subparagraph, subparagraph
18 (F) of this paragraph, section 505A, or
19 section 527, or begin the commercial mar-
20 keting of such drug, without regard to any
21 other provision of such agreement pursu-
22 ant to which the commercial marketing
23 could begin on an earlier date; or

1 “(bb) 180 days after another first ap-
2 plicant begins commercial marketing of
3 such drug; and

4 “(II) the latest date set forth in the agree-
5 ment on which that applicant can receive an ap-
6 proval that is made effective under this sub-
7 paragraph, subparagraph (F) of this paragraph,
8 section 505A, or section 527, or begin the com-
9 mercial marketing of such drug, without regard
10 to any other provision of such agreement pursu-
11 ant to which commercial marketing could begin
12 on an earlier date, shall be the date used to de-
13 termine whether an applicant is disqualified
14 from first applicant status pursuant to clause
15 (vii)(II).”.

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

20 “(14)(A) The holder of an abbreviated application
21 under this subsection shall submit to the Secretary a noti-
22 fication that includes—

23 “(i)(I) the text of any agreement entered into
24 by such holder described under paragraph
25 (5)(B)(vii)(I); or

1 “(II) if such an agreement has not been re-
2 duced to text, a written detailed description of such
3 agreement that is sufficient to disclose all the terms
4 and conditions of the agreement; and

5 “(ii) the text, or a written detailed description
6 in the event of an agreement that has not been re-
7 duced to text, of any other agreements that are con-
8 tingent upon, provide a contingent condition for, or
9 are otherwise related to an agreement described in
10 clause (i).

11 “(B) The notification described under subparagraph
12 (A) shall be submitted not later than 10 business days
13 after execution of the agreement described in subpara-
14 graph (A)(i). Such notification is in addition to any notifi-
15 cation required under section 1112 of the Medicare Pre-
16 scription Drug, Improvement, and Modernization Act of
17 2003.

18 “(C) Any information or documentary material filed
19 with the Secretary pursuant to this paragraph shall be ex-
20 empt from disclosure under section 552 of title 5, United
21 States Code, and no such information or documentary ma-
22 terial may be made public, except as may be relevant to
23 any administrative or judicial action or proceeding. Noth-
24 ing in this paragraph is intended to prevent disclosure to

1 either body of the Congress or to any duly authorized com-
2 mittee or subcommittee of the Congress.”.

3 (3) PROHIBITED ACTS.—Section 301(e) of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 331(e)) is amended by striking “505 (i) or (k)” and
6 inserting “505 (i), (j)(11), or (k)”.

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

10 “(7) The exclusive remedy under this section for an
11 infringement of a patent for which the Secretary of Health
12 and Human Services has published information pursuant
13 to subsection (b)(1) or (c)(2) of section 505 of the Federal
14 Food, Drug, and Cosmetic Act shall be an action brought
15 under this subsection within the 45-day period described
16 in subsection (j)(5)(B)(iii) or (c)(3)(C) of section 505 of
17 the Federal Food, Drug, and Cosmetic Act.”.

18 (c) APPLICABILITY.—

19 (1) LIMITATIONS ON ACCELERATION OF DE-
20 FERRED COMMERCIAL MARKETING DATE.—The
21 amendment made by subsection (a)(1) shall apply
22 only with respect to—

23 (A) an application filed under section
24 505(j) of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 355(j)) to which the

1 amendments made by section 1102(a) of the
2 Medicare Prescription Drug, Improvement, and
3 Modernization Act of 2003 (Public Law 108–
4 173) apply; and

5 (B) an agreement described under section
6 505(j)(5)(B)(vii)(I) of the Federal Food, Drug,
7 and Cosmetic Act (as added by subsection
8 (a)(1)) executed after the date of enactment of
9 this Act.

10 (2) NOTIFICATION OF FDA.—The amendments
11 made by paragraphs (2) and (3) of subsection (a)
12 shall apply only with respect to an agreement de-
13 scribed under section 505(j)(5)(B)(vii)(I) of the
14 Federal Food, Drug, and Cosmetic Act (as added by
15 subsection (a)(1)) executed after the date of enact-
16 ment of this Act.

17 **SEC. 404. INCREASING DRUG COMPETITION AND PRE-**
18 **VENTING DRUG SHORTAGES.**

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

22 “(D)(i) The Commissioner shall—

23 “(I) not later than 9 months after the date of
24 enactment of the Affordable Medications Act, pub-
25 lish a complete, up-to-date list on the internet

1 website of the Food and Drug Administration of all
2 drugs, including authorized generics, together with,
3 with respect to the drug, as applicable—

4 “(aa) the drug trade name;

5 “(bb) the established name;

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

8 “(dd) each generic drug facility;

9 “(ee) each contract manufacturing organi-
10 zation facility (as defined in section 744A(5));

11 “(ff) the date any authorized generic drug
12 entered the market;

13 “(gg) the marketing status; and

14 “(hh) any other information the Secretary
15 may require to mitigate or prevent drug short-
16 ages;

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

19 “(III) designate each drug on the list that is an
20 essential medicine, as identified by the World Health
21 Organization, or another entity designated by the
22 Secretary that meets evidence-based standards as re-
23 quired by the Secretary; and

24 “(IV) maintain a confidential list of the identity
25 and address of each facility described in subclause

1 (I), and publicly report on the website only the city
2 and State or country of each such facility.

3 “(ii) The Commissioner may choose not to make in-
4 formation collected under clause (i) publicly available if
5 the Secretary determines that disclosure of such informa-
6 tion would adversely affect the public health (such as by
7 increasing the possibility of hoarding or other disruption
8 of the availability of drug products to patients).

9 “(iii) The Commissioner shall notify relevant Federal
10 agencies, including the Centers for Medicare & Medicaid
11 Services and the Federal Trade Commission, when the
12 Commissioner first publishes the information under clause
13 (i) that the information has been published and will be
14 updated regularly.

15 “(iv) In this subparagraph, the term ‘sole-source’
16 means, with respect to a drug, there is not more than one
17 approved drug on the list of drugs under subparagraph
18 (A), not including drugs on the discontinued section of
19 such list.”.

20 **SEC. 405. DISALLOWANCE OF DEDUCTION FOR ADVER-**
21 **TISING FOR PRESCRIPTION DRUGS.**

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

1 **“SEC. 280I. DISALLOWANCE OF DEDUCTION FOR DIRECT-**
2 **TO-CONSUMER ADVERTISING OF PRESCRIP-**
3 **TION DRUGS.**

4 “(a) IN GENERAL.—No deduction shall be allowed
5 under this chapter for expenses relating to direct-to-con-
6 sumer advertising of prescription drugs for any taxable
7 year.

8 “(b) DIRECT-TO-CONSUMER ADVERTISING.—For
9 purposes of this section, the term ‘direct-to-consumer ad-
10 vertising’ means any dissemination, by or on behalf of a
11 sponsor of a prescription drug product (as such term is
12 defined in section 735(3) of the Federal Food, Drug, and
13 Cosmetic Act), of an advertisement which—

14 “(1) is in regard to such prescription drug
15 product, and

16 “(2) primarily targeted to the general public,
17 including through—

18 “(A) publication in journals, magazines,
19 other periodicals, and newspapers,

20 “(B) broadcasting through media such as
21 radio, television, telephone communication sys-
22 tems, direct mail, and billboards,

23 “(C) dissemination on the internet (includ-
24 ing social media), and

1 “(D) manufacturer patient assistance pro-
2 grams, as defined in section 399V-7 of the
3 Public Health Service Act.”.

4 (b) CONFORMING AMENDMENT.—The table of sec-
5 tions for such part IX of the Internal Revenue Code of
6 1986 is amended by adding after the item relating to sec-
7 tion 280H the following new item:

 “Sec. 280I. Disallowance of deduction for direct-to-consumer advertising of pre-
 scription drugs.”.

8 (c) EFFECTIVE DATE.—The amendments made by
9 subsections (a) and (b) shall apply to amounts paid or in-
10 curred after the date of the enactment of this Act, in tax-
11 able years ending after such date.

12 (d) OVERSIGHT OF PRESCRIPTION DRUGS.—

13 (1) IN GENERAL.—The Secretary of Health and
14 Human Services (referred to in this subsection as
15 the “Secretary”), acting through the Commissioner
16 of Food and Drugs and in coordination with other
17 Federal agencies, shall conduct oversight of the risks
18 and benefits of drugs that are on the market and
19 how such risks are presented in drug advertisements
20 for the purpose of correcting false or misleading in-
21 formation published in direct-to-consumer advertise-
22 ments and to disseminate corrective information to
23 health care providers and the general public regard-

1 ing the risks and benefits of a drug on an quarterly
2 basis.

3 (2) PREREVIEW OF TELEVISION ADVERTISE-
4 MENTS.—The Secretary, acting through the Com-
5 missioner of Food and Drugs and in consultation
6 with relevant stakeholders, shall issue new, or up-
7 date current, guidance issued under section 503C of
8 the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 353c). In carrying out this paragraph, the
10 Secretary shall focus on drugs that present the
11 greatest risk to consumers, drugs that represent the
12 greatest proportion of total spending in Federal pro-
13 grams, drugs with high unit price increases over the
14 preceding year, drugs with high launch prices, or
15 any other priority drugs identified by the Secretary.

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

21 **SEC. 406. DRUG MANUFACTURER DUTY TO DISCLOSE DRUG**
22 **PRICES TO PRACTITIONERS.**

23 (a) DUTY TO DISCLOSE.—Whenever a drug manu-
24 facturer, including any representative of the manufac-
25 turer, communicates with a health care practitioner about

1 a drug manufactured by the drug manufacturer, including
2 through promotional, educational, or marketing commu-
3 nications, meetings or paid events, and the provision of
4 goods, gifts, and samples, the drug manufacturer shall dis-
5 close to the practitioner the wholesale acquisition cost (as
6 defined in section 1847A(c)(6)(B) of the Social Security
7 Act (42 U.S.C. 1395w-3a(c)(6)(B))) for a 30-day supply
8 of the drug, which may include a brief qualitative expla-
9 nation of reduced cost availability for certain consumers.

10 (b) ENFORCEMENT BY FEDERAL TRADE COMMIS-
11 SION.—

12 (1) UNFAIR OR DECEPTIVE ACTS OR PRAC-
13 TICES.—A violation of subsection (a) by a person
14 with respect to whom the Commission is empowered
15 under section 5(a)(2) of the Federal Trade Commis-
16 sion Act (15 U.S.C. 45(a)(2)) shall be treated as a
17 violation of a rule defining an unfair or deceptive act
18 or practice prescribed under section 18(a)(1)(B) of
19 the Federal Trade Commission Act (15 U.S.C.
20 57a(a)(1)(B)).

21 (2) POWERS OF FEDERAL TRADE COMMIS-
22 SION.—

23 (A) IN GENERAL.—The Federal Trade
24 Commission shall enforce this section in the
25 same manner, by the same means, and with the

1 same jurisdiction, powers, and duties as though
2 all applicable terms and provisions of the Fed-
3 eral Trade Commission Act (15 U.S.C. 41 et
4 seq.) were incorporated into and made a part of
5 this Act.

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

11 (c) RULEMAKING.—The Federal Trade Commission
12 shall promulgate in accordance with section 553 of title
13 5, United States Code, such rules as may be necessary
14 to carry out this section.

15 (d) SAVINGS PROVISION.—Nothing in this section
16 shall be construed to limit, impair, or supersede the oper-
17 ation of the Federal Trade Commission Act (15 U.S.C.
18 41 et seq.) or any other provision of Federal law.

19 **SEC. 407. EXCLUDING AUTHORIZED GENERIC DRUGS FROM**
20 **CALCULATION OF AVERAGE MANUFACTURER**
21 **PRICE UNDER THE MEDICAID DRUG REBATE**
22 **PROGRAM.**

23 (a) IN GENERAL.—Subparagraph (C) of section
24 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r-
25 8(k)(1)) is amended—

1 (1) in the subparagraph heading, by striking
2 “INCLUSION” and inserting “EXCLUSION”;

3 (2) by striking “a new drug application” and
4 inserting “the manufacturer’s new drug applica-
5 tion”; and

6 (3) by striking “inclusive” and inserting “exclu-
7 sive”.

8 (b) **EFFECTIVE DATE.**—The amendments made by
9 this section shall take effect on the first day of the first
10 fiscal quarter that begins after the date of enactment of
11 this Act.

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