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(Original Signature of Member)

115TH CONGRESS
1ST SESSION

H. R. _____

To improve access to affordable prescription drugs.

IN THE HOUSE OF REPRESENTATIVES

Ms. SCHAKOWSKY introduced the following bill; which was referred to the
Committee on _____

A BILL

To improve access to affordable prescription drugs.

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Improving Access To Affordable Prescription Drugs
6 Act”.

7 (b) TABLE OF CONTENTS.—The table of contents for
8 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. Acceleration of the closing of the Medicare Part D coverage gap.
- Sec. 204. Importing affordable and safe drugs.
- Sec. 205. Requiring drug manufacturers to provide drug rebates for drugs dispensed to low-income individuals.
- Sec. 206. Cap on prescription drug cost-sharing.

TITLE III—INNOVATION

- Sec. 301. Prize 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. Preserving access to affordable generics.
- 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 generic drug competition.
- Sec. 405. Disallowance of deduction for advertising for prescription drugs.
- Sec. 406. Product hopping.

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 pre-
10 scription drug benefit managers for drugs
11 provided to individuals in the United
12 States, after accounting for any rebates or
13 other payments from the manufacturer to
14 the pharmacy benefit manager and from
15 the pharmacy benefit manager to the man-
16 ufacturer; 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; and

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 benefitted
19 from a grant from the National Institutes of
20 Health, patent extensions, exclusivity periods,
21 and other Federal benefits with respect to such
22 drug; and

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

1 “(i) activities conducted by the manu-
2 facturer;

3 “(ii) activities funded by Federal enti-
4 ties; and

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

8 “(2) executive compensation for the chief execu-
9 tive officer, chief financial officer, and the 3 other
10 most highly compensated executive officers, includ-
11 ing bonuses, paid by such manufacturer, and stock
12 options affiliated with the manufacturer that were
13 offered to or accrued by such officers;

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

22 “(4) any other information as the Secretary
23 may require.

24 “(c) SUBMISSION OF REPORTS.—

25 “(1) IN GENERAL.—

1 “(A) SUBMISSION BY DRUG MANUFACTUR-
2 ERS.—Drug manufacturers shall submit the an-
3 nual reports required under this section sub-
4 mitted to the Secretary in a usable format, as
5 the Secretary may require.

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

12 “(i) a summary of data from the re-
13 ports;

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

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

21 “(C) PUBLIC AVAILABILITY.—The Sec-
22 retary shall make the reports submitted by
23 manufacturers as described in subparagraph
24 (A) and the collated reports together with the
25 analysis of the Secretary described in subpara-

1 graph (B) publicly available, including by post-
2 ing such reports to the Internet website of the
3 Department of Health and Human Services, in
4 a searchable format.

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

9 “(3) INITIAL REPORT.—

10 “(A) IN GENERAL.—An applicable drug
11 manufacturer shall submit a report pursuant to
12 this section one year after the date of enact-
13 ment of the Improving Access To Affordable
14 Prescription Drugs Act (except as provided in
15 subparagraph (B)) that includes the informa-
16 tion required under subsection (b)(1) with re-
17 spect to each calendar year since the drug for
18 which the report is required was approved
19 under section 505 of the Federal Food, Drug,
20 and Cosmetic Act, licensed under section 351 of
21 this Act, or received an exemption under section
22 505(i) of the Federal Food, Drug, and Cos-
23 metic Act or section 351(a)(3) of this Act, or
24 the calendar year in which the manufacturer ac-
25 quired 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
9 Improving Access To Affordable Prescription
10 Drugs Act.

11 “(d) PENALTY FOR NONCOMPLIANCE.—The Sec-
12 retary shall report to the Office of the Inspector General
13 any manufacturer’s failure to submit a complete report as
14 required under this section. Any manufacturer that fails
15 to submit a complete report required under this section
16 shall be subject to a civil penalty of up to \$200,000 for
17 each day on which the violation continues. The Secretary
18 shall collect the civil penalties under this subsection, and
19 without further appropriation, shall use such funds to sup-
20 port the programs under sections 409K and 485E, and,
21 at the discretion of the Secretary, research of the National
22 Institutes of Health and other activities authorized under
23 the Improving Access To Affordable Prescription Drugs
24 Act, including any amendments 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 obtain tax deduc-
22 tions for offering or sponsoring such assistance
23 (either as business expenses or charitable de-
24 ductions), including—

1 (i) the total value of the tax deduc-
2 tions claimed by manufacturers for offer-
3 ing or sponsoring patient assistance pro-
4 grams during the 10 years preceding the
5 date of enactment of this Act;

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

11 (iii) an analysis of the extent to which
12 the activities of independent charity pa-
13 tient assistance programs, which are spon-
14 sored by, or receive funding from, pharma-
15 ceutical manufacturers, (as determined
16 using tax returns, sales data, and other
17 public disclosures) provide a financial ben-
18 efit to the manufacturers that sponsor
19 them.

20 (C) The extent to which independent char-
21 ity patient assistance programs adhere to guid-
22 ance from the Office of the Inspector General
23 of the Department of Health and Human Serv-
24 ices on avoiding waste, 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, 2019.

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 October
15 1, 2017, 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; and

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
2 Centers for Medicare & Medicaid Services a
3 copy of each report submitted under subpara-
4 graph (A), including the detailed tables, figures,
5 and data published in the report and its appen-
6 dices.

7 (2) MEDPAC.—

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

14 (i) how such price negotiations are
15 achieving lower prices for covered part D
16 drugs (as defined in section 1860D–2(e) of
17 the Social Security Act (42 U.S.C. 1395w–
18 102(e))) for Medicare beneficiaries;

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

1 (iii) how such price negotiations are
2 affecting drug prices in the private market;
3 and

4 (iv) how such price negotiations are
5 affecting the list price of covered part D
6 drugs.

7 (B) REPORT.—Not later than January 1,
8 2021, the Comptroller General of the United
9 States shall submit to Congress a report on the
10 study conducted under subparagraph (A), to-
11 gether with recommendations for improving
12 such price negotiations.

13 (d) CMI TESTING OF NEGOTIATING DRUG AND BIO-
14 LOGICAL PRICES TO IMPROVE VALUE.—Section
15 1115A(b)(2) of the Social Security Act (42 U.S.C.
16 1315a(b)(2)) is amended—

17 (1) in subparagraph (A), by adding at the end
18 the following new sentence: “The models selected
19 under this subparagraph shall include at least 3 of
20 the models described in subparagraph (D), which
21 shall be implemented by not later than 18 months
22 after the date of the enactment of the Improving Ac-
23 cess To Affordable Prescription Drugs Act”; and

24 (2) by adding at the end the following new sub-
25 paragraph:

1 “(D) MODELS OF NEGOTIATING DRUG AND
2 BIOLOGICAL PRICES TO IMPROVE VALUE.—The
3 models described in this subparagraph are the
4 following models for negotiating drug and bio-
5 logical prices under the applicable titles (includ-
6 ing under both parts B and D of title XVIII)
7 in order to improve the value of payments for
8 such drugs and biologicals under such titles:

9 “(i) Discounting or eliminating pa-
10 tient cost-sharing on high-value drugs and
11 biologicals.

12 “(ii) Value-based formularies.

13 “(iii) Indications-based pricing.

14 “(iv) Reference pricing.

15 “(v) Risk-sharing agreements based
16 on outcomes.

17 “(vi) Pricing based on comparative ef-
18 fectiveness research.

19 “(vii) Episode-based payments for
20 chemotherapy and other conditions deter-
21 mined appropriate by the Secretary.

22 “(viii) Alternative ways of paying for
23 drugs and biologicals under part B of title
24 XVIII.

1 “(ix) Other models determined appro-
2 priate by the Secretary.”.

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

4 (a) IDENTIFICATION OF PRESCRIPTION DRUG PRICE
5 SPIKES.—

6 (1) DEFINITIONS.—In this subsection:

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

15 (B) AVERAGE PRICE.—The term “average
16 price” means—

17 (i) the average manufacturer price, as
18 defined in section 1927(k)(1) of the Social
19 Security Act (42 U.S.C. 1396r–8(k)(1)), or

20 (ii) in the case of a drug for which the
21 average manufacturer price is not avail-
22 able, the manufacturer’s average sales
23 price (as defined in section 1847A(c)(1) of
24 the Social Security Act (42 U.S.C. 1395w-
25 3a(c)(1)).

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

5 (D) PRESCRIPTION DRUG.—The term
6 “prescription drug” means any drug subject to
7 section 503(b)(1) of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 353(b)(1)) which
9 is covered by a Federal health care program (as
10 defined in section 1128B(f) of the Social Secu-
11 rity Act (42 U.S.C. 1320a–7b(f))).

12 (E) PRICE SPIKE.—

13 (i) IN GENERAL.—The term “price
14 spike” means an increase in the average
15 price in commerce of a prescription drug
16 for which the price spike percentage is
17 equal to or greater than the applicable
18 price increase allowance.

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

22 (I) the average price of a pre-
23 scription drug in commerce for the
24 most recently completed calendar
25 year; exceeds

1 (II) the average price of such
2 drug in commerce for the calendar
3 year preceding such year.

4 (iii) APPLICABLE PRICE INCREASE AL-
5 LOWANCE.—The applicable price increase
6 allowance for any calendar year is the per-
7 centage (rounded to the nearest one-tenth
8 of 1 percent) by which the medical care
9 component of the consumer price index for
10 all urban consumers (as published by the
11 Bureau of Labor Statistics) for that year
12 exceeds such component for the preceding
13 calendar year.

14 (F) PRICE SPIKE REVENUE.—

15 (i) IN GENERAL.—The price spike rev-
16 enue for any calendar year is an amount
17 equal to—

18 (I) the gross price spike revenue,

19 minus

20 (II) the adjustment amount.

21 (ii) GROSS PRICE SPIKE REVENUE.—

22 The gross price spike revenue for any cal-
23 endar year is an amount equal to the prod-
24 uct of—

1 (I) an amount equal to the dif-
2 ference between subclause (I) of sub-
3 paragraph (E)(ii) and subclause (II)
4 of such subparagraph; and

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

8 (iii) ADJUSTMENT AMOUNT.—The ad-
9 justment amount is the amount, if any, of
10 the gross price spike revenue which the In-
11 spector General has determined is due sole-
12 ly to an increase in the cost of the goods
13 sold (excluding any increase in costs which
14 are related to internal transfers within the
15 applicable entity) which are necessary to
16 manufacture the prescription drug subject
17 to the price spike.

18 (G) INSPECTOR GENERAL.—The term “In-
19 spector General” means the Inspector General
20 of the Department of Health and Human Serv-
21 ices.

22 (2) SUBMISSION BY PHARMACEUTICAL COMPA-
23 NIES OF INFORMATION.—

24 (A) IN GENERAL.—For each prescription
25 drug, the applicable entity shall submit to the

1 Inspector General a quarterly report that in-
2 cludes the following:

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

5 (I) the total number of units of
6 the prescription drug which were sold
7 in commerce in the most recently
8 completed calendar quarter; and

9 (II) the gross revenues from sales
10 of such prescription drug in commerce
11 in the most recently completed cal-
12 endar quarter.

13 (ii) Such information related to in-
14 creased input costs as the applicable entity
15 may wish the Inspector General to consider
16 in making a determination under subclause
17 (II) of paragraph (3)(B)(ii) or an assess-
18 ment in subclause (III) of such paragraph
19 for the most recently completed calendar
20 quarter.

21 (iii) Such information related to any
22 anticipated increased input costs for the
23 subsequent calendar quarter as the appli-
24 cable entity may wish the Inspector Gen-
25 eral to consider in making a determination

1 under subclause (II) of paragraph
2 (3)(B)(ii) or an assessment in subclause
3 (III) of such paragraph for such calendar
4 quarter.

5 (B) PENALTY FOR FAILURE TO SUBMIT.—

6 (i) IN GENERAL.—An applicable enti-
7 ty described in subparagraph (A) that fails
8 to submit information to the Inspector
9 General regarding a prescription drug, as
10 required by such paragraph, before the
11 date specified in subparagraph (C) shall be
12 liable for a civil penalty, as determined
13 under clause (ii).

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

17 (I) an amount, as determined ap-
18 propriate by the Inspector General,
19 which is—

20 (aa) not less than 0.5 per-
21 cent of the gross revenues from
22 sales of the prescription drug de-
23 scribed in clause (i) for the most
24 recently completed calendar year,
25 and

1 (bb) not greater than 1 per-
2 cent of the gross revenues from
3 sales of such drug for the most
4 recently completed calendar year,
5 and

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

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

11 (bb) the date on which the
12 Inspector General receives the in-
13 formation described in subpara-
14 graph (A) from the applicable en-
15 tity.

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

21 (3) ASSESSMENT.—

22 (A) IN GENERAL.—Not later than the last
23 day in February of each year, the Inspector
24 General, in consultation with the Federal Trade
25 Commission, shall complete an assessment of

1 the information the Inspector General received
2 pursuant to paragraph (2)(A) with respect to
3 sales of prescription drugs in the most recently
4 completed calendar year.

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

7 (i) Identification of each price spike
8 relating to a prescription drug in the most
9 recently completed calendar year.

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

12 (I) a determination of the price
13 spike percentage and price spike rev-
14 enue;

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

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

22 (4) REPORT TO INTERNAL REVENUE SERV-
23 ICE.—

24 (A) IN GENERAL.—Not later than the last
25 day in February of each year, the Inspector

1 General shall transmit to the Internal Revenue
2 Service a report on the findings of the Inspector
3 General with respect to the information the In-
4 spector General received under paragraph
5 (2)(A) with respect to the most recently com-
6 pleted calendar year and the assessment carried
7 out by the Inspector General under paragraph
8 (3)(A) with respect to such information.

9 (B) CONTENTS.—The report transmitted
10 under subparagraph (A) shall include the fol-
11 lowing:

12 (i) The information received under
13 paragraph (2)(A) with respect to the most
14 recently completed calendar year.

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

17 (iii) The price spike revenue deter-
18 minations made under clause (ii)(I) of
19 such paragraph.

20 (iv) The average price of the prescrip-
21 tion drug for each month during the most
22 recently completed calendar year.

23 (v) The determinations and assess-
24 ments made under subclauses (II) and
25 (III) of clause (ii) of such paragraph.

1 (C) PUBLICATION.—Not later than the last
2 day in February of each year, the Inspector
3 General shall make the report transmitted
4 under subparagraph (A) available to the public,
5 including on the Internet website of the Inspec-
6 tor General.

7 (5) NOTIFICATION.—The Secretary of the
8 Treasury, in conjunction with the Inspector General,
9 shall notify, at such time and in such manner as the
10 Secretary of the Treasury shall provide, each appli-
11 cable entity in regard to any prescription drug which
12 has been determined to have been subject to a price
13 spike during the most recently completed calendar
14 year and the amount of the tax imposed on such ap-
15 plicable entity pursuant to section 4192 of the Inter-
16 nal Revenue Code of 1986 (as added by subsection
17 (b) of this section).

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

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

23 **“SEC. 4192. PRESCRIPTION DRUGS SUBJECT TO PRICE**
24 **SPIKES.**

25 **“(a) IMPOSITION OF TAX.—**

1 “(1) IN GENERAL.—For each taxable prescrip-
2 tion drug sold by an applicable entity during the cal-
3 endar year, there is hereby imposed on such entity
4 a tax equal to the greater of—

5 “(A) the annual price spike tax for such
6 drug, or

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

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

14 “(b) ANNUAL PRICE SPIKE TAX.—

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

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

23 “(A) in the case of a taxable prescription
24 drug which has been subject to a price spike
25 percentage equal to or greater than the applica-

1 ble price increase allowance (as defined in sec-
2 tion 202(a)(1)(E)(iii) of the Improving Access
3 To Affordable Prescription Drugs Act) but less
4 than 15 percent, 50 percent,

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

9 “(C) in the case of a taxable prescription
10 drug which has been subject to a price spike
11 percentage equal to or greater than 20 percent,
12 100 percent.

13 “(c) CUMULATIVE PRICE SPIKE TAX.—

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

19 “(2) APPLICABLE PERCENTAGE.—

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

23 “(i) in the case of a taxable prescrip-
24 tion drug which has been subject to a cu-
25 mulative price spike percentage equal to or

1 greater than the cumulative price increase
2 allowance but less than the first com-
3 pounded percentage, 50 percent,

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

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

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

18 “(i) the average price of the taxable
19 prescription drug in commerce for the
20 most recently completed calendar year, ex-
21 ceeds

22 “(ii) the average price of such drug in
23 commerce for the base year.

24 “(C) CUMULATIVE PRICE INCREASE AL-
25 LOWANCE.—For purposes of clause (i) of sub-

1 paragraph (A), the cumulative price increase al-
 2 lowance for any calendar year is the percentage
 3 (rounded to the nearest one-tenth of 1 percent)
 4 by which the medical care component of the
 5 consumer price index for all urban consumers
 6 (as published by the Bureau of Labor Statis-
 7 tics) for that year exceeds such component for
 8 the base year.

9 “(D) COMPOUNDED PERCENTAGES.—For
 10 purposes of subparagraph (A), the first com-
 11 pounded percentage and second compounded
 12 percentage shall be determined in accordance
 13 with the following table:

“Number of years in applicable period	First com- pounded percentage	Second com- pounded percentage
2 years	32.35	44.00
3 years	52.09	72.80
4 years	74.90	107.36
5 years	101.14	148.83

14 “(E) APPLICABLE PERIOD AND BASE
 15 YEAR.—

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

18 “(I) the 5 most recently com-
 19 pleted calendar years,

1 “(II) any completed calendar
2 years beginning after March 29, 2017,
3 or

4 “(III) any completed calendar
5 years in which the taxable prescrip-
6 tion drug was sold in commerce.

7 “(ii) BASE YEAR.—The base year
8 shall be the calendar year immediately pre-
9 ceding the applicable period.

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

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

15 “(i) an amount (not less than zero)
16 equal to—

17 “(I) the average price of such
18 drug in commerce for the most re-
19 cently completed calendar year, minus

20 “(II) the average price of such
21 drug in commerce for the base year,
22 and

23 “(ii) the total number of units of such
24 drug which were sold in commerce in the

1 most recently completed calendar year,
2 minus

3 “(B) the adjustment amount, if any, deter-
4 mined under section 202(a)(1)(F)(iii) of the
5 Improving Access To Affordable Prescription
6 Drugs Act for such calendar year.

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

8 “(1) TAXABLE PRESCRIPTION DRUG.—The
9 term ‘taxable prescription drug’ means a prescrip-
10 tion drug (as defined in section 202(a)(1)(D) of the
11 Improving Access To Affordable Prescription Drugs
12 Act) which has been identified by the Inspector Gen-
13 eral of the Department of Health and Human Serv-
14 ices, under section 202(a)(3)(B)(i) of such Act, as
15 being subject to a price spike.

16 “(2) OTHER TERMS.—The terms ‘applicable en-
17 tity’, ‘average price’, ‘price spike’, ‘price spike per-
18 centage’, and ‘price spike revenue’ have the same
19 meaning given such terms under section 202(a)(1)
20 of the Improving Access To Affordable Prescription
21 Drugs Act.”.

22 (2) CLERICAL AMENDMENTS.—

23 (A) The heading of subchapter E of chap-
24 ter 32 of the Internal Revenue Code of 1986 is
25 amended by striking “**Medical Devices**”

1 and inserting “**Certain Medical Devices**
2 **and Prescription Drugs**”.

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

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

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

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

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

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

19 (1) funding or conducting research on the eco-
20 nomic and policy implications of price patterns of
21 prescription drugs, or

22 (2) increasing amounts available to the Na-
23 tional Institutes of Health for research and develop-
24 ment of drugs.

1 **SEC. 203. ACCELERATION OF THE CLOSING OF THE MEDI-**
2 **CARE PART D COVERAGE GAP.**

3 (a) REDUCTION IN COINSURANCE.—Section 1860D–
4 2(b)(2) of the Social Security Act (42 U.S.C. 1395w–
5 102(b)(2)) is amended—

6 (1) in each of subclauses (II) and (III) of sub-
7 paragraph (C)(ii), by striking “2020” and inserting
8 “2018”; and

9 (2) in subparagraph (D)(ii)—

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

12 (B) by striking subclauses (III) through
13 (VI) and inserting the following:

14 “(III) 2018 is 100 percent.”.

15 (b) INCREASE IN MANUFACTURER REBATE.—Section
16 1860D–14A(g)(4)(A) of the Social Security Act (42
17 U.S.C. 1395w–114a(g)(4)(A)) is amended by inserting
18 “(or, for 2018 and subsequent years, 75 percent)” after
19 “50 percent”.

20 **SEC. 204. IMPORTING AFFORDABLE AND SAFE DRUGS.**

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

1 **“SEC. 804. IMPORTATION OF SAFE AND AFFORDABLE**
2 **DRUGS BY WHOLESALE DISTRIBUTORS,**
3 **PHARMACIES, AND INDIVIDUALS.**

4 “(a) IN GENERAL.—Not later than 180 days after
5 the date of enactment of the Improving Access To Afford-
6 able Prescription Drugs Act, the Secretary shall promul-
7 gate regulations permitting the importation of qualifying
8 prescription drugs into the United States, in accordance
9 with this section.

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

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

18 “(2) FOREIGN WHOLESALE DISTRIBUTOR.—
19 The term ‘foreign wholesale distributor’ means a
20 person (other than a manufacturer, a manufactur-
21 er’s co-licensed partner, a third-party logistics pro-
22 vider, or a repackager) engaged in wholesale dis-
23 tribution.

24 “(3) IMPORTER.—The term ‘importer’ means a
25 dispenser (as defined in section 581(3)) or wholesale
26 distributor registered under section 503(e) who im-

1 ports prescription drugs into the United States in
2 accordance with this section.

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

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

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

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

19 “(A) means a prescription drug that—

20 “(i) is approved for use in patients,
21 and marketed, in Canada, or subject to
22 subsection (e), approved for use in pa-
23 tients, and marketed, in another permitted
24 country;

1 “(ii) is manufactured in a facility reg-
2 istered under subsection (b)(1) or (i) of
3 section 510 that is in compliance with good
4 manufacturing practices regulations of the
5 Food and Drug Administration;

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

14 “(iv) is labeled in accordance with—
15 “(I) the laws of Canada, or an-
16 other country from which importation
17 is permitted pursuant to subsection
18 (e); and

19 “(II) the requirements promul-
20 gated by the Secretary, which shall in-
21 clude labeling in English;

22 “(B) with respect to importers only, in-
23 cludes—

24 “(i) peritoneal dialysis solution;

25 “(ii) insulin;

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

4 “(iv) biological products, as defined in
5 section 351 of the Public Health Service
6 Act that are proteins (except any chemi-
7 cally synthesized polypeptides) or analo-
8 gous products; and

9 “(v) intravenously infused drugs; and
10 “(C) does not include—

11 “(i) a controlled substance (as defined
12 in section 102 of the Controlled Sub-
13 stances Act);

14 “(ii) an anesthetic drug inhaled dur-
15 ing surgery; or

16 “(iii) a compounded drug.

17 “(6) VALID PRESCRIPTION.—The term ‘valid
18 prescription’ means a prescription that is issued for
19 a legitimate medical purpose in the usual course of
20 professional practice by—

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

24 “(B) a covering practitioner.

1 “(c) PUBLICATION OF CERTIFIED FOREIGN SELL-
2 ERS.—The Secretary shall publish on a dedicated Internet
3 Web site a list of certified foreign sellers, including the
4 Internet Web site address, physical address, and telephone
5 number of each such certified foreign seller.

6 “(d) ADDITIONAL CRITERIA.—

7 “(1) CERTIFIED FOREIGN SELLERS.—

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

10 “(i) be certified by the Secretary in
11 accordance with subparagraph (B);

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

14 “(iii) sell only qualifying prescription
15 drugs to importers or individuals who im-
16 port prescription drugs into the United
17 States in accordance with this section.

18 “(B) CERTIFICATION.—To be a certified
19 foreign seller, the Secretary shall certify that
20 such seller—

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

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

3 “(ii) is engaged in the distribution or
4 dispensing of a prescription drug that is
5 imported or offered for importation into
6 the United States;

7 “(iii) has been in existence for a pe-
8 riod of at least 5 years preceding the date
9 of such certification and has a purpose
10 other than to participate in the program
11 established under this section;

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

18 “(v) has processes established by the
19 seller, or participates in another estab-
20 lished process, to certify that the physical
21 premises and data reporting procedures
22 and licenses are in compliance with all ap-
23 plicable laws and regulations of Canada,
24 or, subject to subsection (e), the permitted
25 country in which the seller is located, and

1 has implemented policies designed to mon-
2 itor ongoing compliance with such laws
3 and regulations;

4 “(vi) conducts or commits to partici-
5 pate in ongoing and comprehensive quality
6 assurance programs and implements such
7 quality assurance measures, including
8 blind testing, to ensure the veracity and re-
9 liability of the findings of the quality as-
10 surance program;

11 “(vii) agrees that, pursuant to sub-
12 section (g), laboratories approved by the
13 Secretary may be authorized to conduct
14 product testing to determine the chemical
15 authenticity of sample pharmaceutical
16 products;

17 “(viii) agrees to notify the Secretary,
18 importers, and individuals of product re-
19 calls in Canada, or pursuant to subsection
20 (e), the permitted country in which the
21 seller is located, and agrees to cease, or re-
22 frain from, exporting such product;

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

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

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

10 “(xi) meets any other criteria estab-
11 lished by the Secretary.

12 “(C) CERTIFICATION FEE.—Not later than
13 30 days before the start of each fiscal year, the
14 Secretary shall establish a fee to be collected
15 from foreign sellers for such fiscal year that are
16 certified under subparagraph (B), in an amount
17 that is sufficient, and not more than necessary,
18 to pay the costs of administering the program
19 under this section, and enforcing this section
20 pursuant to section 303(h), for that fiscal year.

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

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

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

9 “(A) is dispensed, including through an
10 online pharmacy, by a certified foreign seller
11 that is a licensed foreign pharmacy;

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

15 “(C) is filled only after providing to the li-
16 censed foreign pharmacy a valid prescription
17 issued by a health care practitioner licensed to
18 practice in a State in the United States.

19 “(e) IMPORTATION FROM OTHER COUNTRIES.—Be-
20 ginning on the date that is 2 years after the date on which
21 final regulations are promulgated to carry out this section,
22 if, based on a review of the evidence obtained after such
23 effective date, including the reports submitted under sec-
24 tion 2(d) of the Improving Access To Affordable Prescrip-
25 tion Drugs Act , that importation of qualifying prescrip-

1 tion drugs from Canada under this section resulted in cost
2 savings for consumers in the United States and increased
3 access to safe medication, the Secretary shall have the au-
4 thority to permit importation of qualifying prescription
5 drugs by importers and individuals from, in addition to
6 Canada, any country that—

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

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

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

19 “(B) requires that any determination of
20 safety and effectiveness described in subpara-
21 graph (A) be made on the basis of adequate
22 and well-controlled investigations, including
23 clinical investigations, as appropriate, con-
24 ducted by experts qualified by scientific training

1 and experience to evaluate the safety and effec-
2 tiveness of drugs;

3 “(C) requires the methods used in, and the
4 facilities and controls used for, the manufac-
5 ture, processing, and packing of drugs in the
6 country to be adequate to preserve the identity,
7 quality, purity, and strength of the drugs; and

8 “(D) requires the reporting of adverse re-
9 actions to drugs and establish procedures to re-
10 call, and withdraw approval of, drugs found not
11 to be safe or effective.

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

16 “(g) DRUG TESTING LABORATORIES.—The Sec-
17 retary may approve one or more laboratories to conduct
18 random testing of prescription drugs sold by certified for-
19 eign sellers to assess the chemical authenticity of such
20 drugs.

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

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

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

20 “(3) cause there to be a difference (including a
21 difference in active ingredient, route of administra-
22 tion, bioequivalence, strength, formulation, manufac-
23 turing establishment, manufacturing process, or per-
24 son that manufactures the drug) between a prescrip-
25 tion drug for distribution in the United States and

1 the drug for distribution in Canada or another per-
2 mitted country, subject to subsection (e), for the
3 purpose of avoiding sales by certified foreign sellers;
4 or

5 “(4) except with respect to a prescription drug
6 on the drug shortage list under section 506E, en-
7 gage in any other action to restrict, prohibit, or
8 delay the importation of a prescription drug under
9 this section.

10 “(i) INFORMATION AND RECORDS.—

11 “(1) BIENNIAL REPORTS.—Each importer shall
12 submit biennial reports to the Secretary which shall
13 contain, for each qualifying prescription drug im-
14 ported into the United States—

15 “(A) the unique facility identifier of the
16 manufacturer of the drug, described in section
17 510;

18 “(B) the transaction information described
19 in section 581(26) (other than the information
20 described in subparagraph (C)); and

21 “(C) the price paid by the importer for the
22 drug.

23 “(2) MAINTENANCE OF RECORDS BY SEC-
24 RETARY.—The Secretary shall maintain information
25 and documentation submitted under paragraph (1)

1 for such period of time as the Secretary determines
2 to be appropriate.

3 “(j) SUSPENSION OF IMPORTATION.—

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

17 “(2) TEMPORARY SUSPENSION.—The Secretary
18 may require that importation of a specific qualifying
19 prescription drug or importation by a specific cer-
20 tified foreign seller or importer pursuant to this sec-
21 tion be temporarily suspended if, with respect to
22 such drug, seller, or importer, there is a violation of
23 any requirement of this section or if the Secretary
24 determines that importation of such drug or by such
25 seller or importer might endanger the public health.

1 Such temporary suspension shall apply until the Sec-
2 retary completes an investigation and determines
3 that importation of such drug or by such seller or
4 importer does not endanger the public health.

5 “(k) SUPPLY CHAIN SECURITY.—

6 “(1) PURCHASE FROM REGISTERED FACILITIES
7 AND CERTIFIED FOREIGN SELLERS.—

8 “(A) IN GENERAL.—Except as provided in
9 subparagraph (B), certified foreign sellers who
10 sell qualifying prescription drugs for importa-
11 tion into the United States pursuant to this
12 section may purchase such drugs only from
13 manufacturers or entities registered under sec-
14 tion 510 or other certified foreign sellers.

15 “(B) EXCEPTION.—Certified foreign sellers
16 who sell qualifying prescription drugs for im-
17 portation into the United States pursuant to
18 this section may purchase such drugs from for-
19 eign sellers in Canada or another permitted
20 country, even if such foreign seller is not a
21 manufacturer registered under section 510 or a
22 certified foreign seller, if the Secretary enters
23 into a memorandum of understanding or coop-
24 erative agreement with Canada, or such other
25 permitted country, to ensure compliance, to the

1 extent appropriate and feasible, with subchapter
2 H of chapter V. The Secretary shall seek to
3 enter into such a memorandum of under-
4 standing or cooperative agreement with Canada
5 and each country from which importation is
6 permitted under subsection (e).

7 “(2) IMPORTATION TRACING.—Certified foreign
8 sellers shall provide importers with the unique facil-
9 ity identifier associated with the manufacturer reg-
10 istered under section 510 of the qualifying prescrip-
11 tion drug and the information under paragraph
12 (25), paragraph (26) (other than subparagraph (C)),
13 and subparagraphs (D), (F), and (G) of paragraph
14 (27) of section 581. Certified foreign sellers shall
15 provide such information to individuals purchasing
16 such drugs, upon request.

17 “(1) REMS.—In the case of an importer that imports
18 a qualifying prescription drug, where the drug with the
19 same active ingredient or ingredients (or that is biosimilar
20 to an approved biological product), route of administra-
21 tion, and strength that is approved under chapter V or
22 section 351 of the Public Health Service Act is subject
23 to elements to assure safe use under section 505–1, such
24 importer shall be subject to such elements to assure safe
25 use, as applicable and appropriate.

1 “(m) CONSTRUCTION.—Nothing in this section limits
2 the authority of the Secretary relating to the importation
3 of prescription drugs, other than with respect to section
4 801(d)(1) as provided in this section.”.

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

9 “(h) In the case of person operating an Internet
10 website, whether in the United States or in another coun-
11 try, that violates section 301(aa) by—

12 “(1) selling, by means of the Internet, with the
13 intent to defraud or mislead or with reckless dis-
14 regard for safety of the public, an adulterated or
15 counterfeit drug to an individual in the United
16 States; or

17 “(2) dispenses, by means of the Internet, a
18 drug to an individual in the United States who the
19 person knows or has reasonable cause to believe,
20 does not possess a valid prescription for that drug,
21 such person shall be imprisoned for not more than
22 10 years or fined not more than \$250,000.”.

23 (c) NO PREEMPTION.—Nothing in this section, in-
24 cluding the amendments made by this section, shall be
25 construed to preempt, alter, displace, abridge, or supplant

1 any remedy available under any State or Federal law, in-
2 cluding common law, that provides a remedy for civil re-
3 lief.

4 (d) REPORTS.—

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

14 (2) GAO REPORT.—Not later than 18 months
15 after the date on which final regulations are promul-
16 gated to carry out section 804 of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 384), as amend-
18 ed by subsection (a), the Comptroller General of the
19 United States shall submit to Congress a report con-
20 taining an analysis of the implementation of the
21 amendments made by this section, including a review
22 of drug safety and cost-savings and expenses, includ-
23 ing cost-savings to consumers in the United States
24 and trans-shipment and importation tracing proc-
25 esses, resulting from such implementation.

1 **SEC. 205. REQUIRING DRUG MANUFACTURERS TO PROVIDE**
2 **DRUG REBATES FOR DRUGS DISPENSED TO**
3 **LOW-INCOME INDIVIDUALS.**

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

6 (1) in subsection (e)(1), in the matter preceding
7 subparagraph (A), by inserting “and subsection (f)”
8 after “this subsection”; and

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

11 “(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR
12 REBATE ELIGIBLE INDIVIDUALS.—

13 “(1) REQUIREMENT.—

14 “(A) IN GENERAL.—For plan years begin-
15 ning on or after January 1, 2019, in this part,
16 the term ‘covered part D drug’ does not include
17 any drug or biological product that is manufac-
18 tured by a manufacturer that has not entered
19 into and have in effect a rebate agreement de-
20 scribed in paragraph (2).

21 “(B) 2018 PLAN YEAR REQUIREMENT.—

22 Any drug or biological product manufactured by
23 a manufacturer that declines to enter into a re-
24 bate agreement described in paragraph (2) for
25 the period beginning on January 1, 2018, and
26 ending on December 31, 2018, shall not be in-

1 cluded as a ‘covered part D drug’ for the subse-
2 quent plan year.

3 “(2) REBATE AGREEMENT.—A rebate agree-
4 ment under this subsection shall require the manu-
5 facturer to provide to the Secretary a rebate for
6 each rebate period (as defined in paragraph (6)(B))
7 ending after December 31, 2017, in the amount
8 specified in paragraph (3) for any covered part D
9 drug of the manufacturer dispensed after December
10 31, 2017, to any rebate eligible individual (as de-
11 fined in paragraph (6)(A)) for which payment was
12 made by a PDP sponsor or MA organization under
13 this part for such period, including payments passed
14 through the low-income and reinsurance subsidies
15 under sections 1860D–14 and 1860D–15(b), respec-
16 tively. Such rebate shall be paid by the manufac-
17 turer to the Secretary not later than 30 days after
18 the date of receipt of the information described in
19 section 1860D–12(b)(7), including as such section is
20 applied under section 1857(f)(3), or 30 days after
21 the receipt of information under subparagraph (D)
22 of paragraph (3), as determined by the Secretary.
23 Insofar as not inconsistent with this subsection, the
24 Secretary shall establish terms and conditions of
25 such agreement relating to compliance, penalties,

1 and program evaluations, investigations, and audits
2 that are similar to the terms and conditions for re-
3 bate agreements under paragraphs (3) and (4) of
4 section 1927(b).

5 “(3) REBATE FOR REBATE ELIGIBLE MEDICARE
6 DRUG PLAN ENROLLEES.—

7 “(A) IN GENERAL.—The amount of the re-
8 bate specified under this paragraph for a manu-
9 facturer for a rebate period, with respect to
10 each dosage form and strength of any covered
11 part D drug provided by such manufacturer
12 and dispensed to a rebate eligible individual,
13 shall be equal to the product of—

14 “(i) the total number of units of such
15 dosage form and strength of the drug so
16 provided and dispensed for which payment
17 was made by a PDP sponsor or an MA or-
18 ganization under this part for the rebate
19 period, including payments passed through
20 the low-income and reinsurance subsidies
21 under sections 1860D–14 and 1860D–
22 15(b), respectively; and

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

24 “(I) the Medicaid rebate amount
25 (as defined in subparagraph (B)) for

1 such form, strength, and period, ex-
2 ceeds

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

7 “(B) MEDICAID REBATE AMOUNT.—For
8 purposes of this paragraph, the term ‘Medicaid
9 rebate amount’ means, with respect to each
10 dosage form and strength of a covered part D
11 drug provided by the manufacturer for a rebate
12 period—

13 “(i) in the case of a single source
14 drug or an innovator multiple source drug,
15 the amount specified in paragraph
16 (1)(A)(ii)(II) or (2)(C) of section 1927(c)
17 plus the amount, if any, specified in sub-
18 paragraph (A)(ii) of paragraph (2) of such
19 section, for such form, strength, and pe-
20 riod; or

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

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

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

13 “(I) the sum of all rebates, dis-
14 counts, or other price concessions (not
15 taking into account any rebate pro-
16 vided under paragraph (2) or any dis-
17 counts under the program under sec-
18 tion 1860D–14A) for such dosage
19 form and strength of the drug dis-
20 pensed, calculated on a per-unit basis,
21 but only to the extent that any such
22 rebate, discount, or other price con-
23 cession applies equally to drugs dis-
24 pensed to rebate eligible Medicare
25 drug plan enrollees and drugs dis-

1 pensed to PDP and MA–PD enrollees
2 who are not rebate eligible individuals;
3 and

4 “(II) the number of the units of
5 such dosage and strength of the drug
6 dispensed during the rebate period to
7 rebate eligible individuals enrolled in
8 the prescription drug plans adminis-
9 tered by the PDP sponsor or the MA–
10 PD plans administered by the MA or-
11 ganization; divided by

12 “(ii) the total number of units of such
13 dosage and strength of the drug dispensed
14 during the rebate period to rebate eligible
15 individuals enrolled in all prescription drug
16 plans administered by PDP sponsors and
17 all MA–PD plans administered by MA or-
18 ganizations.

19 “(D) USE OF ESTIMATES.—The Secretary
20 may establish a methodology for estimating the
21 average Medicare drug program rebate eligible
22 rebate amounts for each rebate period based on
23 bid and utilization information under this part
24 and may use these estimates as the basis for
25 determining the rebates under this section. If

1 the Secretary elects to estimate the average
2 Medicare drug program rebate eligible rebate
3 amounts, the Secretary shall establish a rec-
4 onciliation process for adjusting manufacturer
5 rebate payments not later than 3 months after
6 the date that manufacturers receive the infor-
7 mation collected under section 1860D-
8 12(b)(7)(B).

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

15 “(5) OTHER TERMS AND CONDITIONS.—The
16 Secretary shall establish other terms and conditions
17 of the rebate agreement under this subsection, in-
18 cluding terms and conditions related to compliance,
19 that are consistent with this subsection.

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

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

24 “(i) a subsidy eligible individual (as
25 defined in section 1860D-14(a)(3)(A));

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

4 “(iii) any part D eligible individual
5 not described in clause (i) or (ii) who is de-
6 termined for purposes of the State plan
7 under title XIX to be eligible for medical
8 assistance under clause (i), (iii), or (iv) of
9 section 1902(a)(10)(E).

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

13 (b) REPORTING REQUIREMENT FOR THE DETER-
14 MINATION AND PAYMENT OF REBATES BY MANUFACTUR-
15 ERS RELATED TO REBATE FOR REBATE ELIGIBLE MEDI-
16 CARE DRUG PLAN ENROLLEES.—

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

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

1 “(A) IN GENERAL.—For purposes of the
2 rebate under section 1860D–2(f) for contract
3 years beginning on or after January 1, 2019,
4 each contract entered into with a PDP sponsor
5 under this part with respect to a prescription
6 drug plan shall require that the sponsor comply
7 with subparagraphs (B) and (C).

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

12 “(i) information (by National Drug
13 Code number) on the total number of units
14 of each dosage, form, and strength of each
15 drug of such manufacturer dispensed to re-
16 bate eligible Medicare drug plan enrollees
17 under any prescription drug plan operated
18 by the PDP sponsor during the rebate pe-
19 riod;

20 “(ii) information on the price dis-
21 counts, price concessions, and rebates for
22 such drugs for such form, strength, and
23 period;

24 “(iii) information on the extent to
25 which such price discounts, price conces-

1 sions, and rebates apply equally to rebate
2 eligible Medicare drug plan enrollees and
3 PDP enrollees who are not rebate eligible
4 Medicare drug plan enrollees; and

5 “(iv) any additional information that
6 the Secretary determines is necessary to
7 enable the Secretary to calculate the aver-
8 age Medicare drug program rebate eligible
9 rebate amount (as defined in paragraph
10 (3)(C) of such section), and to determine
11 the amount of the rebate required under
12 this section, for such form, strength, and
13 period.

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

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

22 “(D) CONFIDENTIALITY OF INFORMA-
23 TION.—The provisions of subparagraph (D) of
24 section 1927(b)(3), relating to confidentiality of
25 information, shall apply to information reported

1 by PDP sponsors under this paragraph in the
2 same manner that such provisions apply to in-
3 formation disclosed by manufacturers or whole-
4 salers under such section, except—

5 “(i) that any reference to ‘this sec-
6 tion’ in clause (i) of such subparagraph
7 shall be treated as being a reference to this
8 section;

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

14 “(iii) clause (iv) of such subparagraph
15 shall not apply.

16 “(E) OVERSIGHT.—Information reported
17 under this paragraph may be used by the In-
18 spector General of the Department of Health
19 and Human Services for the statutorily author-
20 ized purposes of audit, investigation, and eval-
21 uations.

22 “(F) PENALTIES FOR FAILURE TO PRO-
23 VIDE TIMELY INFORMATION AND PROVISION OF
24 FALSE INFORMATION.—In the case of a PDP
25 sponsor—

1 “(i) that fails to provide information
2 required under subparagraph (B) on a
3 timely basis, the sponsor is subject to a
4 civil money penalty in the amount of
5 \$10,000 for each day in which such infor-
6 mation has not been provided; or

7 “(ii) that knowingly (as defined in
8 section 1128A(i)) provides false informa-
9 tion under such subparagraph, the sponsor
10 is subject to a civil money penalty in an
11 amount not to exceed \$100,000 for each
12 item of false information.

13 Such civil money penalties are in addition to
14 other penalties as may be prescribed by law.
15 The provisions of section 1128A (other than
16 subsections (a) and (b)) shall apply to a civil
17 money penalty under this subparagraph in the
18 same manner as such provisions apply to a pen-
19 alty or proceeding under section 1128A(a).”.

20 (2) APPLICATION TO MA ORGANIZATIONS.—Sec-
21 tion 1857(f)(3) of the Social Security Act (42
22 U.S.C. 1395w-27(f)(3)) is amended by adding at
23 the end the following:

24 “(D) REPORTING REQUIREMENT RELATED
25 TO REBATE FOR REBATE ELIGIBLE MEDICARE

1 DRUG PLAN ENROLLEES.—Section 1860D–
2 12(b)(7).”.

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

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

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

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

20 (2) EXCLUSION FROM AVERAGE MANUFAC-
21 Turer Price Determination.—Section
22 1927(k)(1)(B)(i) of the Social Security Act (42
23 U.S.C. 1396r–8(k)(1)(B)(i)) is amended—

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

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

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

4 “(VI) amounts paid under a re-
5 bate agreement under section 1860D-
6 2(f).”.

7 **SEC. 206. CAP ON PRESCRIPTION DRUG COST-SHARING.**

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

11 (1) in paragraph (3)(A)(i), by inserting “(in-
12 cluding cost-sharing with respect to prescription
13 drugs covered by the plan)” after “copayments”;
14 and

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

16 “(5) **PRESCRIPTION DRUG COST-SHARING.**—

17 “(A) **2019.**—For plan years beginning in
18 2019 or later, the cost-sharing incurred under
19 a health plan with respect to prescription drugs
20 covered by the plan shall not exceed \$250 per
21 month for each enrolled individual, or \$500 for
22 each family.

23 “(B) **2020 AND LATER.**—

24 “(i) **IN GENERAL.**—In the case of any
25 plan year beginning in a calendar year

1 after 2019, the limitation under this para-
2 graph shall be equal to the applicable dol-
3 lar amount under subparagraph (A) for
4 plan years beginning in 2019, increased by
5 an amount equal to the product of that
6 amount and the medical care component of
7 the consumer price index for all urban con-
8 sumers (as published by the Bureau of
9 Labor Statistics) for that year.

10 “(ii) ADJUSTMENT TO AMOUNT.—If
11 the amount of any increase under clause
12 (i) is not a multiple of \$5, such increase
13 shall be rounded to the next lowest mul-
14 tiple of \$5.”.

15 (b) GROUP HEALTH PLANS.—Section 2707(b) of the
16 Public Health Service Act (42 U.S.C. 300gg–6(b)) is
17 amended by striking “paragraph (1) of section 1302(c)”
18 and inserting “paragraphs (1) and (5) of section 1302(c)
19 of the Patient Protection and Affordable Care Act”.

20 (c) EFFECTIVE DATE.—The amendments made by
21 subsections (a) and (b) shall take effect with respect to
22 the first plan year that begins after the date on which
23 initial reports are required to be submitted under section
24 399V–7(c)(3) of the Public Health Service Act, as added
25 by section 101.

1 **TITLE III—INNOVATION**

2 **SEC. 301. PRIZE FUND FOR NEW AND MORE EFFECTIVE**
3 **TREATMENTS OF BACTERIAL INFECTIONS.**

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

7 **“SEC. 409K. PRIZE FUND FOR NEW AND MORE EFFECTIVE**
8 **TREATMENTS OF BACTERIAL INFECTIONS.**

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

14 “(b) AMOUNTS CREDITED TO THE FUND.—There
15 are hereby authorized to be appropriated, and appro-
16 priated, to the Antibiotics Prize Fund, for fiscal year
17 2018, out of any monies in the Treasury not otherwise
18 appropriated, \$2,000,000,000. Such funds shall remain
19 available until expended.

20 “(c) AWARDS.—

21 “(1) IN GENERAL.—During the 10-year period
22 following the date of enactment of the Improving
23 Access To Affordable Prescription Drugs Act, the
24 Director of the NIH, in accordance with the criteria

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

3 “(A) up to 3 prizes for qualifying products
4 that provide added benefit for patients over ex-
5 isting therapies in the treatment of serious and
6 life-threatening bacterial infections dem-
7 onstrating in superiority trials; and

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

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

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

17 “(1) ESTABLISHMENT OF CRITERIA.—Not later
18 than 120 days after the date of enactment of the
19 Improving Access To Affordable Prescription Drugs
20 Act, the Director of NIH shall establish criteria for
21 the selection of recipients and eligibility of persons
22 for prizes under this section and criteria for deter-
23 mining the amounts of such prizes, through notice
24 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 prizes under paragraph (1), the Director of NIH,
5 in consultation with other agencies as appropriate,
6 shall consider the following:

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

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

20 “(C) The incremental and additional thera-
21 peutic benefit to human in the United States
22 and other countries of the qualifying product as
23 compared to other treatments available to treat
24 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 prizes under subsection (c), the
5 Director of NIH shall establish a framework of goals that
6 a qualifying product or contribution that significantly ad-
7 vances the field of antibiotic research is required to show
8 promise to help meet in order for a person to be eligible
9 to receive a prize with respect to such product or such
10 contribution. Such goals may include—

11 “(1) reduced hospital admissions or readmis-
12 sions;

13 “(2) use of diagnostics prior to prescribing of
14 drugs; and

15 “(3) use of innovative programs for antibiotic
16 stewardship.

17 “(f) CONDITION ON RECEIPT OF PRIZE.—

18 “(1) IN GENERAL.—Each prize for a qualifying
19 product offered under this section shall be condi-
20 tioned on the following:

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

24 “(B) Subject to applicable patient privacy
25 protections, the recipient shall agree to publicly

1 disclose all pre-clinical and clinical trial data
2 with respect to the qualifying product.

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

15 “(D) The recipient shall irrevocably
16 waive—

17 “(i) all periods of exclusivity available
18 to the product under chapter V of the Fed-
19 eral Food, Drug, and Cosmetic Act or sec-
20 tion 351 of this Act; and

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

23 “(E) Any other conditions the Director of
24 NIH determines appropriate.

1 “(2) APPLICABILITY.—All conditions described
2 in paragraph (1) shall apply to subsequent owners,
3 licensees, producers, and manufacturers, and assign-
4 ees of the product or any chemical component of the
5 qualifying product for which the prize was awarded.

6 “(3) REASONABLE PRICE.—

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

11 “(i)(I) providing open licensing of all
12 necessary rights to patents, manufacturing
13 processes, rights in data, and other intel-
14 lectual property rights needed to make and
15 sell the product to manufacturers of the
16 generic version of such product; or

17 “(II) selling such product at a price
18 that is no more than twice the price of an-
19 tibiotic drugs approved under section
20 505(j) of the Federal Food, Drug, and
21 Cosmetic Act with similar manufacturing
22 costs; and

23 “(ii) selling such product at a price
24 that is not higher than the median price
25 charged, at the time of such sale, in the

1 applicable 7 countries, as determined
2 under in subparagraph (B).

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

13 “(g) ENFORCEMENT.—If the prize recipient, or sub-
14 sequent owner, licensee, or assignee of the qualifying prod-
15 uct, does not fulfill the conditions described subsection
16 (f)(1), the Secretary, in collaboration with the Attorney
17 General, shall take all necessary action to clawback the
18 prize.

19 “(h) TRANSPARENCY.—With respect to each prize
20 awarded under this section, the Director of NIH shall
21 make public—

22 “(1) the methodology used and criteria analyzed
23 in determining the prize recipient; and

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

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

6 “(j) STUDY.—

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

11 “(A) the use of innovation inducement
12 prize funds and push financing mechanisms as
13 ways to stimulate investments in biomedical re-
14 search and development that de-links costs from
15 product prices;

16 “(B) models of different possible means of
17 de-linking research and development costs from
18 drug prices, including the replacement of the
19 monopoly on new products as an incentive, with
20 innovation inducement prize funds and push fi-
21 nancing mechanisms as new incentives to stim-
22 ulate the development of drugs, including drugs
23 to treat bacterial infections, rare diseases, HIV/
24 AIDS, and cancer; and

1 “(C) the size of prizes awarded under this
2 section and the effectiveness of such prizes in
3 stimulating innovation.

4 “(2) AUTHORIZATION OF APPROPRIATIONS.—
5 For the purpose of carrying out this subsection,
6 there are authorized to be appropriated, and there
7 are appropriated, \$3,000,000 for fiscal year 2018.
8 Such funds shall remain available until expended.”.

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

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

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

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

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

1 “(b) CLINICAL TRIALS.—

2 “(1) IN GENERAL.—Each year, beginning not
3 later than 1 year after the date of enactment of the
4 Improving Access To Affordable Prescription Drugs
5 Act, the Director shall select at least 2 molecules,
6 compounds, drugs, or biological products and con-
7 duct clinical trials on such molecules, compounds,
8 drugs, or biological products, or enter into contracts
9 with other entities to conduct such clinical trials.

10 “(2) SELECTION OF DRUGS.—

11 “(A) CRITERIA.—The Director shall estab-
12 lish criteria, which shall be made public, for ac-
13 quiring the patent rights for, and selecting,
14 drugs under paragraph (1) to ensure that the
15 drugs selected for clinical trials through the
16 Center—

17 “(i) have the potential to address an
18 existing or emerging need, including drugs
19 that can be repurposed to treat a new con-
20 dition in the case of a national emergency;
21 and

22 “(ii) are not solely drugs that private
23 sector researchers with access to all avail-
24 able information on such drugs chose not
25 to develop.

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

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

12 “(1) execute non-exclusive licenses to allow
13 drug manufacturers to manufacture the drug; or

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

16 “(d) PUBLIC INFORMATION.—

17 “(1) RESEARCH DATA AND FINDINGS.—Subject
18 to applicable patient privacy protections, the Sec-
19 retary shall—

20 “(A)(i) submit all completed studies (and
21 terminated studies, if terminated for safety or
22 ethical reasons) for publication in a peer-re-
23 viewed publication within 180 days of comple-
24 tion or termination; and

1 “(ii) if a study submitted as described in
2 clause (i) is not selected for publication, pub-
3 licly disclose all de-identified primary clinical
4 data not later than 180 days after the Sec-
5 retary’s final decision not to pursue further
6 submissions for publication; and

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

10 “(2) FINANCIAL INFORMATION.—The Director
11 shall make public all costs to the Federal Govern-
12 ment associated with carrying out clinical trials by
13 the Center for Clinical Research and with sub-
14 contract agreements under this section.

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

18 “(f) APPROPRIATIONS.—For the purpose of carrying
19 out this section, in addition to any other funds available
20 for such purpose, there are authorized to be appropriated,
21 and there are appropriated, \$1,000,000,000 for each of
22 fiscal years 2017 through 2027, to remain available until
23 expended.”.

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

4 (1) by redesignating paragraph (25) as para-
5 graph (26); and

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

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

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

10 (a) DRUG EXCLUSIVITY.—

11 (1) NEW CHEMICAL ENTITY EXCLUSIVITY.—

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

15 (i) in subparagraph (B)—

16 (I) in clause (i), by inserting “ex-
17 cept that such approval may not be
18 made effective before the date that is
19 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 clause (ii), by inserting
24 “except that such approval may not
25 be made effective before the date that

1 is 5 years after the date on which the
2 drug to which the application refers
3 was approved under subsection (c)”
4 before the period; and

5 (ii) in subparagraph (F)(ii)—

6 (I) by striking “expiration of five
7 years” and inserting “expiration of 3
8 years”;

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

18 (III) by striking “seven and one-
19 half years” and inserting “6 and one-
20 half years”.

21 (B) CONFORMING AMENDMENTS.—Chapter
22 V of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 351 et seq.) is amended—

24 (i) in subsection (v)(2)(A)(i)(II) of
25 section 505, by inserting “the 3-year exclu-

1 sivity period referred to” before “under
2 clause (ii) of subsection (j)(5)(F)”;

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

5 (I) by striking “five years” each
6 place such term appears and inserting
7 “3 years”;

8 (II) by striking “seven and one-
9 half years” each place such term ap-
10 pears and inserting “6 and one-half
11 years”; and

12 (III) by striking “eight years”
13 each place such term appears and in-
14 serting “7 years”; and

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

1 subsection (c)(3)(E) and clauses (ii), (iii),
2 and (iv) of subsection (j)(5)(F)”;

3 (2) NEW CLINICAL INVESTIGATION EXCLU-
4 SIVITY.—Section 505(c)(3)(E)(iv) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C.
6 355(c)(3)(E)(iv)) is amended by inserting “, and the
7 supplement shows a significant clinical benefit over
8 existing therapies manufactured by the applicant in
9 the 5-year period preceding the submission of the
10 application,” before “the Secretary”.

11 (3) BIOLOGICAL PRODUCT EXCLUSIVITY.—

12 (A) IN GENERAL.—Section 351(k)(7)(A) of
13 the Public Health Service Act (42 U.S.C.
14 262(k)(7)(A)) is amended by striking “12
15 years” and inserting “7 years”.

16 (B) CONFORMING AMENDMENTS.—Para-
17 graphs (2)(A) and (3)(A) of section 351(m) of
18 the Public Health Service Act (42 U.S.C.
19 262(m)) is amended by striking “12 years”
20 each place it appears and inserting “7 years”.

21 (b) APPLICABILITY.—The amendments made by sub-
22 section (a) apply only with respect to a drug or biological
23 product for which the listed drug (as described in section
24 505(j)(7) of the Federal Food, Drug, and Cosmetic Act
25 (21 U.S.C. 355(j)(7)) or reference product (as such term

1 is used in section 351 of the Public Health Service Act
2 (42 U.S.C. 262)) is approved under section 505(c) of the
3 Federal Food, Drug, and Cosmetic Act or licensed under
4 section 351(a) of the Public Health Service Act, as appli-
5 cable, on or after the date of enactment of this Act.

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

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

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

18 (C) the names of all drugs receiving such des-
19 igation during such period, including the date of
20 approval and indication for which market exclusivity
21 was granted; and

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

24 (2) for each drug so designated as a drug for
25 a rare disease or condition in the previous 10-year

1 period, the total annual expenditures for such drugs
2 under the Medicare program under title XVIII of
3 the Social Security Act (42 U.S.C. 1395 et seq.) and
4 the Medicaid program under title XIX of the Social
5 Security Act (42 U.S.C. 1396 et seq.), the number
6 of Medicare and Medicaid beneficiaries who used
7 each such drug each year during such time period,
8 and any changes in price per unit during such time
9 period; and

10 (3) for a sample of drugs (selected by the
11 Comptroller General) so designated in the previous
12 10-year period, to the extent feasible—

13 (A) gross revenues of the manufacturers
14 with respect to each such drug, and manufac-
15 turer spending for marketing and patient as-
16 sistance programs;

17 (B) the average price per drug and how
18 those prices changed over time for the selected
19 drugs based on industry drug pricing bench-
20 marks; and

21 (C) the indications that were the basis of
22 such designation and other approved indications
23 for the drugs, and the indications for which
24 each drug has most commonly been used, in-
25 cluding non-approved indications for which the

1 drug may be recommended by external organi-
2 zations such as physician or patient organiza-
3 tions.

4 **SEC. 304. IMPROVING PROGRAM INTEGRITY.**

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

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

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

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

22 “(1) Clause (ii), (iii), or (iv) of section
23 505(c)(3)(E).

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

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

3 “(4) Section 505A.

4 “(5) Section 505E.

5 “(6) Section 527.

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

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

11 “(c) VIOLATIONS.—

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

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

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

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

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

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

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

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

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

8 “(B) Section 3729 of title 31, United
9 States Code.

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

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

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

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

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

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

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

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

12 “(e) REPORTING OF INFORMATION.—

13 “(1) IN GENERAL.—A person described in sub-
14 section (a) that commits a violation described in
15 subsection (c)(1) shall report such violation to the
16 Secretary no later than 30 days after the date
17 that—

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

21 “(B)(i) a settlement agreement described
22 in subsection (c)(1)(C) is approved by a court
23 order that is or becomes final and nonappeal-
24 able; or

1 “(ii) if there is no court order approving a
2 settlement agreement described in subsection
3 (c)(1)(C), a court order dismissing the applica-
4 ble case, issued after the settlement agreement,
5 is or becomes final and nonappealable.

6 “(2) CIVIL PENALTY.—A person who fails to re-
7 port a violation as required under paragraph (1)
8 shall be subject to a civil penalty in the amount of
9 \$200,000 for each day the failure to report con-
10 tinues, beginning with the day after the date on
11 which such report is due as described in paragraph
12 (1)..”.

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

18 **TITLE IV—CHOICE AND** 19 **COMPETITION**

20 **SEC. 401. PRESERVING ACCESS TO AFFORDABLE** 21 **GENERICS.**

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

1 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE**
2 **GENERICIS.**

3 “(a) IN GENERAL.—

4 “(1) ENFORCEMENT PROCEEDING.—The Com-
5 mission may initiate a proceeding to enforce the pro-
6 visions of this section against the parties to any
7 agreement resolving or settling, on a final or interim
8 basis, a patent infringement claim, in connection
9 with the sale of a drug product.

10 “(2) PRESUMPTION AND VIOLATION.—

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

15 “(i) an ANDA filer receives anything
16 of value, including an exclusive license; and

17 “(ii) the ANDA filer agrees to limit or
18 forego research, development, manufac-
19 turing, marketing, or sales of the ANDA
20 product for any period of time.

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

25 “(i) the value described in subpara-
26 graph (A)(i) is compensation solely for

1 other goods or services that the ANDA
2 filer has promised to provide; or

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

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

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

12 “(2) that the agreement’s provision for entry of
13 the ANDA product prior to the expiration of the rel-
14 evant patent or statutory exclusivity means that the
15 agreement is procompetitive.

16 “(c) EXCLUSIONS.—Nothing in this section shall pro-
17 hibit a resolution or settlement of a patent infringement
18 claim in which the consideration granted by the NDA
19 holder to the ANDA filer as part of the resolution or set-
20 tlement includes only one or more of the following:

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

23 “(A) any patent that is the basis for the
24 patent infringement claim; or

1 “(B) any patent right or other statutory
2 exclusivity that would prevent the marketing of
3 such drug.

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

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

8 “(d) ENFORCEMENT.—

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

11 “(2) JUDICIAL REVIEW.—

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

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

20 “(ii) the United States Court of Ap-
21 peals for the circuit in which the ultimate
22 parent entity, as defined in section
23 801.1(a)(3) of title 16, Code of Federal
24 Regulations, or any successor thereto, of
25 the NDA holder is incorporated as of the

1 date that the NDA is filed with the Com-
2 missioner of Food and Drugs; or

3 “(iii) the United States Court of Ap-
4 peals for the circuit in which the ultimate
5 parent entity of the ANDA filer is incor-
6 porated as of the date that the ANDA is
7 filed with the Commissioner of Food and
8 Drugs.

9 “(B) TREATMENT OF FINDINGS.—In a
10 proceeding for judicial review of a final order of
11 the Commission, the findings of the Commis-
12 sion as to the facts, if supported by evidence,
13 shall be conclusive.

14 “(e) ANTITRUST LAWS.—Nothing in this section
15 shall be construed to modify, impair, or supersede the ap-
16 plicability of the antitrust laws as defined in subsection
17 (a) of the first section of the Clayton Act (15 U.S.C.
18 12(a)), and of section 5 of this Act to the extent that sec-
19 tion 5 applies to unfair methods of competition. Nothing
20 in this section shall modify, impair, limit, or supersede the
21 right of an ANDA filer to assert claims or counterclaims
22 against any person, under the antitrust laws or other laws
23 relating to unfair competition.

24 “(f) PENALTIES.—

1 “(1) FORFEITURE.—Each party that violates or
2 assists in the violation of this section shall forfeit
3 and pay to the United States a civil penalty suffi-
4 cient to deter violations of this section, but in no
5 event greater than 3 times the value received by the
6 party that is reasonably attributable to the violation
7 of this section. If no such value has been received by
8 the NDA holder, the penalty to the NDA holder
9 shall be sufficient to deter violations, but in no event
10 greater than 3 times the value given to the ANDA
11 filer reasonably attributable to the violation of this
12 section. Such penalty shall accrue to the United
13 States and may be recovered in a civil action
14 brought by the Commission, in its own name by any
15 of its attorneys designated by it for such purpose, in
16 a district court of the United States against any
17 party that violates this section. In such actions, the
18 United States district courts are empowered to grant
19 mandatory injunctions and such other and further
20 equitable relief as they deem appropriate.

21 “(2) CEASE AND DESIST.—

22 “(A) IN GENERAL.—If the Commission has
23 issued a cease and desist order with respect to
24 a party in an administrative adjudicative pro-
25 ceeding under the authority of subsection

1 (a)(1), an action brought pursuant to para-
2 graph (1) may be commenced against such
3 party at any time before the expiration of 1
4 year after such order becomes final pursuant to
5 section 5(g).

6 “(B) EXCEPTION.—In an action under
7 subparagraph (A), the findings of the Commis-
8 sion as to the material facts in the administra-
9 tive adjudicative proceeding with respect to the
10 violation of this section by a party shall be con-
11 clusive unless—

12 “(i) the terms of such cease and de-
13 sist order expressly provide that the Com-
14 mission’s findings shall not be conclusive;
15 or

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

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

23 “(A) the nature, circumstances, extent,
24 and gravity of the violation;

1 “(B) with respect to the violator, the de-
2 gree of culpability, any history of violations, the
3 ability to pay, any effect on the ability to con-
4 tinue doing business, profits earned by the
5 NDA holder, compensation received by the
6 ANDA filer, and the amount of commerce af-
7 fected; and

8 “(C) other matters that justice requires.

9 “(4) REMEDIES IN ADDITION.—Remedies pro-
10 vided in this subsection are in addition to, and not
11 in lieu of, any other remedy provided by Federal
12 law. Nothing in this paragraph shall be construed to
13 affect any authority of the Commission under any
14 other provision of law.

15 “(g) DEFINITIONS.—In this section:

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

20 “(2) AGREEMENT RESOLVING OR SETTling A
21 PATENT INFRINGEMENT CLAIM.—The term ‘agree-
22 ment resolving or settling a patent infringement
23 claim’ includes any agreement that is entered into
24 within 30 days of the resolution or the settlement of
25 the claim, or any other agreement that is contingent

1 upon, provides a contingent condition for, or is oth-
2 erwise related to the resolution or settlement of the
3 claim.

4 “(3) ANDA.—The term ‘ANDA’ means an ab-
5 breviated new drug application filed under section
6 505(j) of the Federal Food, Drug, and Cosmetic Act
7 (21 U.S.C. 355(j)) or a new drug application filed
8 under section 505(b)(2) of the Federal Food, Drug,
9 and Cosmetic Act (21 U.S.C. 355(b)(2)).

10 “(4) ANDA FILER.—The term ‘ANDA filer’
11 means a party that owns or controls an ANDA filed
12 with the Commission of Food and Drugs or has the
13 exclusive rights under such ANDA to distribute the
14 ANDA product.

15 “(5) ANDA PRODUCT.—The term ‘ANDA
16 product’ means the product to be manufactured
17 under the ANDA that is the subject of the patent
18 infringement claim.

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

23 “(7) NDA.—The term ‘NDA’ means a new
24 drug application filed under section 505(b) of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 355(b)).

3 “(8) NDA HOLDER.—The term ‘NDA holder’
4 means—

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

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

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

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

22 “(10) PATENT INFRINGEMENT.—The term
23 ‘patent infringement’ means infringement of any
24 patent or of any filed patent application, extension,
25 reissue, renewal, division, continuation, continuation

1 in part, reexamination, patent term restoration, pat-
2 ents of addition, and extensions thereof.

3 “(11) PATENT INFRINGEMENT CLAIM.—The
4 term ‘patent infringement claim’ means any allega-
5 tion made to an ANDA filer, whether or not in-
6 cluded in a complaint filed with a court of law, that
7 its ANDA or ANDA product may infringe any pat-
8 ent held by, or exclusively licensed to, the NDA
9 holder of the drug product.

10 “(12) STATUTORY EXCLUSIVITY.—The term
11 ‘statutory exclusivity’ means those prohibitions on
12 the approval of drug applications under clauses (ii)
13 through (iv) of section 505(c)(3)(E) (5- and 3-year
14 data exclusivity), section 527 (orphan drug exclu-
15 sivity), or section 505A (pediatric exclusivity) of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 355(c)(3)(E), 360cc, 355a).”.

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

1 **SEC. 402. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS RE-**
2 **GARDING FIRST APPLICANT STATUS.**

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

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

8 (A) in clause (iv)(II)—

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

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

12 and

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

14 “(v) FIRST APPLICANT DEFINED.—As used in
15 this subsection, the term ‘first applicant’ means an
16 applicant—

17 “(I)(aa) that, on the first day on which a
18 substantially complete application containing a
19 certification described in paragraph
20 (2)(A)(vii)(IV) is submitted for approval of a
21 drug, submits a substantially complete applica-
22 tion that contains and lawfully maintains a cer-
23 tification described in paragraph (2)(A)(vii)(IV)
24 for the drug; and

1 “(bb) that has not entered into a disquali-
2 fying agreement described under clause
3 (vii)(II); or

4 “(II)(aa) for the drug that is not described
5 in subclause (I) and that, with respect to the
6 applicant and drug, each requirement described
7 in clause (vi) is satisfied; and

8 “(bb) that has not entered into a disquali-
9 fying agreement described under clause
10 (vii)(II).

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

13 “(I) The applicant described in clause
14 (v)(II) submitted and lawfully maintains a cer-
15 tification described in paragraph (2)(A)(vii)(IV)
16 or a statement described in paragraph
17 (2)(A)(viii) for each unexpired patent for which
18 a first applicant described in clause (v)(I) had
19 submitted a certification described in paragraph
20 (2)(A)(vii)(IV) on the first day on which a sub-
21 stantially complete application containing such
22 a certification was submitted.

23 “(II) With regard to each such unexpired
24 patent for which the applicant described in
25 clause (v)(II) submitted a certification de-

1 scribed in paragraph (2)(A)(vii)(IV), no action
2 for patent infringement was brought against
3 such applicant within the 45-day period speci-
4 fied in paragraph (5)(B)(iii); or if an action
5 was brought within such time period, such an
6 action was withdrawn or dismissed by a court
7 (including a district court) without a decision
8 that the patent was valid and infringed; or if an
9 action was brought within such time period and
10 was not withdrawn or so dismissed, such appli-
11 cant has obtained the decision of a court (in-
12 cluding a district court) that the patent is in-
13 valid or not infringed (including any substantive
14 determination that there is no cause of action
15 for patent infringement or invalidity, and in-
16 cluding a settlement order or consent decree
17 signed and entered by the court stating that the
18 patent is invalid or not infringed).

19 “(III) If an applicant described in clause
20 (v)(I) has begun commercial marketing of such
21 drug, the applicant described in clause (v)(II)
22 does not begin commercial marketing of such
23 drug until the date that is 30 days after the
24 date on which the applicant described in clause
25 (v)(I) began such commercial marketing.”.

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

7 (b) APPLICABILITY.—The amendments made by sub-
8 section (a) shall apply only with respect to an application
9 filed under section 505(j) of the Federal Food, Drug, and
10 Cosmetic Act (21 U.S.C. 355(j)) to which the amendments
11 made by section 1102(a) of the Medicare Prescription
12 Drug, Improvement, and Modernization Act of 2003 (Pub-
13 lic Law 108–173) apply.

14 **SEC. 403. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS RE-**
15 **GARDING AGREEMENTS TO DEFER COMMER-**
16 **CIAL MARKETING.**

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

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

1 “(vii) AGREEMENT BY FIRST APPLICANT TO
2 DEFER COMMERCIAL MARKETING; LIMITATION ON
3 ACCELERATION OF DEFERRED COMMERCIAL MAR-
4 KETING DATE.—

5 “(I) AGREEMENT TO DEFER APPROVAL OR
6 COMMERCIAL MARKETING DATE.—An agree-
7 ment described in this subclause is an agree-
8 ment between a first applicant and the holder
9 of the application for the listed drug or an
10 owner of one or more of the patents as to which
11 any applicant submitted a certification quali-
12 fying such applicant for the 180-day exclusivity
13 period whereby that applicant agrees, directly
14 or indirectly, (aa) not to seek an approval of its
15 application that is made effective on the earliest
16 possible date under this subparagraph, subpara-
17 graph (F) of this paragraph, section 505A, or
18 section 527, (bb) not to begin the commercial
19 marketing of its drug on the earliest possible
20 date after receiving an approval of its applica-
21 tion that is made effective under this subpara-
22 graph, subparagraph (F) of this paragraph, sec-
23 tion 505A, or section 527, or (cc) to both items
24 (aa) and (bb).

1 “(II) AGREEMENT THAT DISQUALIFIES AP-
2 PLICANT FROM FIRST APPLICANT STATUS.—An
3 agreement described in this subclause is an
4 agreement between an applicant and the holder
5 of the application for the listed drug or an
6 owner of one or more of the patents as to which
7 any applicant submitted a certification quali-
8 fying such applicant for the 180-day exclusivity
9 period whereby that applicant agrees, directly
10 or indirectly, not to seek an approval of its ap-
11 plication or not to begin the commercial mar-
12 keting of its drug until a date that is after the
13 expiration of the 180-day exclusivity period
14 awarded to another applicant with respect to
15 such drug (without regard to whether such 180-
16 day exclusivity period is awarded before or after
17 the date of the agreement).

18 “(viii) LIMITATION ON ACCELERATION.—If an
19 agreement described in clause (vii)(I) includes more
20 than 1 possible date when an applicant may seek an
21 approval of its application or begin the commercial
22 marketing of its drug—

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

1 “(aa) the latest date set forth in the
2 agreement on which that applicant can re-
3 ceive an approval that is made effective
4 under this subparagraph, subparagraph
5 (F) of this paragraph, section 505A, or
6 section 527, or begin the commercial mar-
7 keting of such drug, without regard to any
8 other provision of such agreement pursu-
9 ant to which the commercial marketing
10 could begin on an earlier date; or

11 “(bb) 180 days after another first ap-
12 plicant begins commercial marketing of
13 such drug; and

14 “(II) the latest date set forth in the agree-
15 ment on which that applicant can receive an ap-
16 proval that is made effective under this sub-
17 paragraph, subparagraph (F) of this paragraph,
18 section 505A, or section 527, or begin the com-
19 mercial marketing of such drug, without regard
20 to any other provision of such agreement pursu-
21 ant to which commercial marketing could begin
22 on an earlier date, shall be the date used to de-
23 termine whether an applicant is disqualified
24 from first applicant status pursuant to clause
25 (vii)(II).”.

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

5 “(11)(A) The holder of an abbreviated application
6 under this subsection shall submit to the Secretary a noti-
7 fication that includes—

8 “(i)(I) the text of any agreement entered into
9 by such holder described under paragraph
10 (5)(B)(vii)(I); or

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

15 “(ii) the text, or a written detailed description
16 in the event of an agreement that has not been re-
17 duced to text, of any other agreements that are con-
18 tingent upon, provide a contingent condition for, or
19 are otherwise related to an agreement described in
20 clause (i).

21 “(B) The notification described under subparagraph
22 (A) shall be submitted not later than 10 business days
23 after execution of the agreement described in subpara-
24 graph (A)(i). Such notification is in addition to any notifi-
25 cation required under section 1112 of the Medicare Pre-

1 scription Drug, Improvement, and Modernization Act of
2 2003.

3 “(C) Any information or documentary material filed
4 with the Secretary pursuant to this paragraph shall be ex-
5 empt from disclosure under section 552 of title 5, United
6 States Code, and no such information or documentary ma-
7 terial may be made public, except as may be relevant to
8 any administrative or judicial action or proceeding. Noth-
9 ing in this paragraph is intended to prevent disclosure to
10 either body of the Congress or to any duly authorized com-
11 mittee or subcommittee of the Congress.”.

12 (3) PROHIBITED ACTS.—Section 301(e) of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 331(e)) is amended by striking “505 (i) or (k)” and
15 inserting “505 (i), (j)(11), or (k)”.

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

19 “(7) The exclusive remedy under this section for an
20 infringement of a patent for which the Secretary of Health
21 and Human Services has published information pursuant
22 to subsection (b)(1) or (c)(2) of section 505 of the Federal
23 Food, Drug, and Cosmetic Act shall be an action brought
24 under this subsection within the 45-day period described

1 in subsection (j)(5)(B)(iii) or (c)(3)(C) of section 505 of
2 the Federal Food, Drug, and Cosmetic Act.”.

3 (c) APPLICABILITY.—

4 (1) LIMITATIONS ON ACCELERATION OF DE-
5 FERRED COMMERCIAL MARKETING DATE.—The
6 amendment made by subsection (a)(1) shall apply
7 only with respect to—

8 (A) an application filed under section
9 505(j) of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 355(j)) to which the
11 amendments made by section 1102(a) of the
12 Medicare Prescription Drug, Improvement, and
13 Modernization Act of 2003 (Public Law 108–
14 173) apply; and

15 (B) an agreement described under section
16 505(j)(5)(B)(vii)(I) of the Federal Food, Drug,
17 and Cosmetic Act (as added by subsection
18 (a)(1)) executed after the date of enactment of
19 this Act.

20 (2) NOTIFICATION OF FDA.—The amendments
21 made by paragraphs (2) and (3) of subsection (a)
22 shall apply only with respect to an agreement de-
23 scribed under section 505(j)(5)(B)(vii)(I) of the
24 Federal Food, Drug, and Cosmetic Act (as added by

1 subsection (a)(1)) executed after the date of enact-
2 ment of this Act.

3 **SEC. 404. INCREASING GENERIC DRUG COMPETITION.**

4 (a) LISTING OF GENERIC DRUGS AT LIST OF BEING
5 IN SHORTAGE.—Chapter V of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by
7 inserting after section 506E the following:

8 **“SEC. 506E-1. LISTING OF GENERIC DRUGS.**

9 “(a) DATABASE FOR MANUFACTURERS OF GENERIC
10 DRUGS.—The Commissioner shall—

11 “(1) not later than 9 months after the date of
12 enactment of the Improving Access To Affordable
13 Prescription Drugs Act, publish a complete, up-to-
14 date list on the Internet website of the Food and
15 Drug Administration of all generic drugs (including
16 drug trade name, active pharmaceutical ingredient
17 manufacturer, active finished dosage form manufac-
18 turer, any contract manufacturing organization, the
19 date the authorized generic drug entered the market,
20 and marketing status);

21 “(2) designate each drug on the list that is a
22 sole-source drug; and

23 “(3) maintain a confidential list of the identity
24 and address of each manufacturer and labeler asso-
25 ciated with a drug reported under this section, and

1 publicly report on the website only the city and State
2 or country of each such manufacturer and labeler.

3 “(b) PUBLIC HEALTH EXCEPTION.—The Commis-
4 sioner may choose not to make information collected under
5 subsection (a) publicly available if the Secretary deter-
6 mines that disclosure of such information would adversely
7 affect the public health (such as by increasing the possi-
8 bility of hoarding or other disruption of the availability
9 of drug products to patients).

10 “(c) NOTIFICATION.—The Commissioner shall notify
11 relevant Federal agencies, including the Centers for Medi-
12 care & Medicaid Services and the Federal Trade Commis-
13 sion, when the Commissioner first publishes the informa-
14 tion under subsection (a) that the information has been
15 published and will be updated regularly.

16 “(d) DEFINITIONS.—In this section:

17 “(1) The term ‘manufacturer’ means a person
18 engaged in the manufacture of an active pharma-
19 ceutical ingredient or finished dosage form, as de-
20 fined in section 744A.

21 “(2) The term ‘sole-source’ means—

22 “(A) A drug for which there is only one
23 approved manufacturer listed in the active sec-
24 tion of the Approved Drug Products With

1 Therapeutic Equivalence Evaluations (com-
2 monly known as the ‘FDA Orange Book’); and

3 “(B) for which there are no blocking pat-
4 ents or exclusivities that may receive expedited
5 review, except where the drug was approved
6 pursuant to a suitability petition under section
7 505(j)(2)(C).”.

8 (b) REPORT ON CONTRACTS.—Section 510(j) of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j))
10 is amended by adding at the end the following:

11 “(5) Each person who registers with the Secretary
12 under this section shall report to the Secretary any con-
13 tract with a contract manufacturing organization with re-
14 spect to any drug such person manufactures, distributes,
15 or compounds, including the start date and end date of
16 such contract.”.

17 (c) DISCONTINUANCE OR INTERRUPTION IN THE
18 PRODUCTION OF LIFE-SAVING DRUGS.—Section 506C(a)
19 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 356c(a)) is amended by striking “of a drug—” and all
21 that follows through the end of paragraph (2) and insert-
22 ing “of a drug”.

23 (d) DECREASE IN MANUFACTURERS OF DRUGS.—
24 Chapter V of the Federal Food, Drug, and Cosmetic Act

1 (21 U.S.C. 351 et seq.) is amended by inserting after sec-
2 tion 506C–1 the following:

3 **“SEC. 506C-2. DECREASE IN MANUFACTURERS OF GENERIC**
4 **DRUGS.**

5 “(a) IN GENERAL.—If the Secretary determines that
6 the number of manufacturers of a drug approved under
7 section 505 or a biological product licensed under section
8 351 is less than 2, the Secretary may—

9 “(1) with respect to a manufacturer with fewer
10 than 500 employees, including employees of affiliates
11 of the manufacturer, waive the prescription drug ap-
12 plication fees under sections 736(a), 744B(a), or
13 744H(a);

14 “(2) expedite the review of applications for the
15 drug under section 505(j) or section 351(k) of the
16 Public Health Service Act until the number of man-
17 ufacturers of the drug is at least 4; and

18 “(3) after consultation with the Federal Trade
19 Commission to ensure that the manufacturer has not
20 engaged in anticompetitive tactics to remove other
21 manufacturers from the market in order to
22 incentivize such a contract, establish and prioritize
23 purchase contracts with manufacturers who are
24 holders of applications approved under section
25 505(j) or section 351(k) of the Public Health Serv-

1 ice Act for the drug but who are not currently man-
2 ufacturing such drug.

3 “(b) GUIDELINES FOR PURCHASE CONTRACTS.—

4 “(1) IN GENERAL.—The Secretary shall pro-
5 mulgate regulations to establish guidelines for the
6 drugs with respect to which the Secretary may es-
7 tablish purchase contracts in accordance with sub-
8 section (a)(3). Such guidelines shall provide that any
9 such purchase contract may be only with respect to
10 a drug that is listed as an essential medicine by the
11 World Health Organization, or another external enti-
12 ty, as the Secretary may specify, that meets evi-
13 dence-based standards as the Secretary may require.

14 “(2) PRICING.—If a manufacturer enters into
15 purchase contract in accordance with subsection
16 (a)(3), the Secretary, in cooperation with the Office
17 of the Inspector General, shall establish a limit on
18 the retail price at which the drug may be made
19 available to consumers in the United States.”.

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 this section shall apply to amounts paid or incurred after
10 the date of the enactment of this Act, in taxable years
11 ending after such date.

12 **SEC. 406. PRODUCT HOPPING.**

13 (a) DEFINITIONS.—In this section—

14 (1) the term “biological product” has the mean-
15 ing given that term in section 351 of the Public
16 Health Service Act (42 U.S.C. 262);

17 (2) the term “drug” has the meaning given that
18 term in section 201 of the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 321); and

20 (3) the term “product hopping” means a cir-
21 cumstance in which—

22 (A) a manufacturer reformulates a drug or
23 biological product in such a way that allows the
24 manufacturer to submit a new drug application

1 under section 505(b) of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 355(b)) or
3 new application for a license under section
4 351(a) of the Public Health Service Act (42
5 U.S.C. 262(a)) with respect to such new formu-
6 lation;

7 (B) the new formulation described in sub-
8 paragraph (A) is intended for the treatment of
9 the same medical condition as the drug or bio-
10 logical product that was reformulated; and

11 (C) actions are taken to reduce or elimi-
12 nate demand for the original drug or biological
13 product.

14 (b) REPORT.—The Federal Trade Commission shall
15 submit to Congress a report on the extent to which—

16 (1) manufacturers of drugs and biological prod-
17 ucts engage in product hopping, including an anal-
18 ysis of the timing of the introduction of the reformu-
19 lated product relative to the market entry of a drug
20 approved under section 505(j) of the Federal Food,
21 Drug, and Cosmetic Act or biological product li-
22 censed under section 351(k) of the Public Health
23 Service Act, the types of changes made in the new
24 product, the patents and market exclusivities award-

1 ed to reformulated products, and the various forms
2 of product hopping manufacturers employ;

3 (2) manufacturers assess the profitability of a
4 new product based whether it launches before (or
5 how long before) generic entry occurs on the original
6 product;

7 (3) the effect of product-hopping behavior on
8 consumers, including the total estimated annual cost
9 to consumers of physicians prescribing the sub-
10 stituted drug in place of a generic version of the
11 original product;

12 (4) the effect of product-hopping on insurance
13 prices and availability, including cost increases and
14 coverage reductions attributable to the economic
15 losses described in paragraph (3);

16 (5) product hopping affects manufacturer prof-
17 its, revenues, unit sales, and prices; and

18 (6) product hopping affects the unit sales, man-
19 ufacturer profits, and prices of the generic version of
20 the original product.