

117TH CONGRESS  
1ST SESSION

# S. 1898

To ensure medications are affordable.

---

## IN THE SENATE OF THE UNITED STATES

MAY 27, 2021

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

---

## A BILL

To ensure medications are affordable.

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

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

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

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

Sec. 1. Short title; table of contents.

### TITLE I—TRANSPARENCY

Sec. 101. Drug manufacturer reporting.

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

## TITLE II—ACCESS AND AFFORDABILITY

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

## TITLE III—INNOVATION

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

## TITLE IV—CHOICE AND COMPETITION

- Sec. 401. Unlawful compensation for delay.  
 Sec. 402. 180-day exclusivity period amendments regarding first applicant status.  
 Sec. 403. 180-day exclusivity period amendments regarding agreements to defer commercial marketing.  
 Sec. 404. Increasing drug competition and preventing drug shortages.  
 Sec. 405. Disallowance of deduction for advertising for prescription drugs.  
 Sec. 406. Drug manufacturer duty to disclose drug prices to practitioners.

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-  
 12           enue Code of 1986 and exempt from taxation under

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

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

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

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

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

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

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

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

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

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

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

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

21 “(V) pursuing new or expanded  
22 indications for such drug through sup-  
23 plemental applications under section  
24 505 of the Federal Food, Drug, and  
25 Cosmetic Act;

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

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

9           “(VIII) marketing research;

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

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

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

23           “(B) the gross revenue, net revenue, gross  
24 profit, and net profit to the manufacturer;

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

5           “(D) pricing information, including—

6                   “(i) wholesale acquisition cost;

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

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

21           “(E) information, including the dollar  
22          value to the recipient of manufacturer patient  
23          assistance programs offered by the manufac-  
24          turer or a manufacturer patient assistance pro-

1           gram sponsored by or associated with the man-  
2           ufacturer, per patient, including—

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

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

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

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

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

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

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

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

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

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

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

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

20          “(H) the percentage of research and devel-  
21          opment expenditures on—

22                  “(i) activities conducted by the manu-  
23                  facturer;

24                  “(ii) activities funded by Federal enti-  
25                  ties; and



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

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

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

18                  “(4) any other information as the Secretary  
19                  may require.

20                  “(c) SUBMISSION OF REPORTS.—

21                         “(1) IN GENERAL.—

22                                 “(A) SUBMISSION BY DRUG MANUFACTUR-  
23                                 ERS.—Drug manufacturers shall submit the an-  
24                                 nual reports required under this section sub-

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

3           “(B) COLLATION BY THE SECRETARY.—

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

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

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

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

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

1 a searchable format. In publicizing such re-  
2 ports, the Secretary may redact such propri-  
3 etary information as the Secretary determines  
4 appropriate.

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 Affordable Medications Act (except  
14 as provided in subparagraph (B)) that includes  
15 the information required under subsection  
16 (b)(1) with respect to each calendar year since  
17 the drug for which the report is required was  
18 approved under section 505 of the Federal  
19 Food, Drug, and Cosmetic Act, licensed under  
20 section 351 of this Act, or received an exemp-  
21 tion under section 505(i) of the Federal Food,  
22 Drug, and Cosmetic Act or section 351(a)(3) of  
23 this Act, or the calendar year in which the man-  
24 ufacturer acquired the drug.

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

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

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

4 (a) INFORMATION REPORTING BY INDEPENDENT  
5 CHARITY PATIENT ASSISTANCE PROGRAMS.—Section  
6 6033(b) of the Internal Revenue Code of 1986 is amend-  
7 ed—

8 (1) in paragraph (15)(B), by striking “and” at  
9 the end,

10 (2) by redesignating paragraph (16) as para-  
11 graph (17), and

12 (3) by inserting after paragraph (15) the fol-  
13 lowing new paragraph:

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

19 (b) GAO STUDY AND REPORT ON IMPACT OF COPAY-  
20 MENT COUPONS AND OTHER PATIENT ASSISTANCE PRO-  
21 GRAMS ON PRESCRIPTION DRUG PRICING AND EXPENDI-  
22 TURES.—

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

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

3 (A) The extent to which copayment cou-  
4 pons and patient assistance programs con-  
5 tribute to inflated prescription drug prices and  
6 health insurance premiums, including with re-  
7 spect to—

8 (i) the Medicaid program under title  
9 XIX of the Social Security Act (42 U.S.C.  
10 1396 et seq.);

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

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

16 (iv) health care under the laws admin-  
17 istered by the Secretary of Veterans Af-  
18 fairs;

19 (v) the commercial health insurance  
20 market; and

21 (vi) the cash pay health market.

22 (B) The extent to which manufacturers of-  
23 fering copayment coupons and other patient as-  
24 sistance programs or sponsoring manufacturer  
25 patient assistance programs report obtaining

1 tax deductions for offering or sponsoring such  
2 assistance (either as business expenses or chari-  
3 table deductions), including—

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

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

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

23 (C) Oversight that is conducted to ensure  
24 that independent charity patient assistance pro-  
25 grams adhere to guidance from the Office of

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

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

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

## 15 **TITLE II—ACCESS AND** 16 **AFFORDABILITY**

### 17 **SEC. 201. NEGOTIATING FAIR PRICES FOR MEDICARE PRE-** 18 **SCRIPTION DRUGS.**

19 (a) NEGOTIATING FAIR PRICES.—

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

24 “(i) NEGOTIATING FAIR PRICES WITH DRUG MANU-  
 25 FACTURERS.—



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

1 drug, evidence on the drug’s effectiveness and safety  
2 compared to similar drugs, and the quality and  
3 quantity of clinical data and rigor of the applicable  
4 process of approval of a drug under section 505 of  
5 the Federal Food, Drug, and Cosmetic Act or a bio-  
6 logical product under section 351 of the Public  
7 Health Service Act.

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

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

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

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

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

12           “(B) The proportion of total spending  
13          under this title.

14           “(C) Unit price increases over the pre-  
15          ceding 5 years.

16           “(D) Initial launch price.

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

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

21           “(G) Any other criteria determined by the  
22          Secretary.

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

1 sor of a prescription drug plan, or an organization  
2 offering an MA–PD plan, from obtaining a discount  
3 or reduction of the price for a covered part D drug  
4 below the price negotiated under paragraph (1) or  
5 the price established under paragraph (2).

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

10 (2) EFFECTIVE DATE.—The amendments made  
11 by this subsection shall take effect on the date of the  
12 enactment of this Act and shall first apply to nego-  
13 tiations and prices for plan years beginning on Jan-  
14 uary 1, 2022.

15 (b) REQUIREMENT TO INCLUDE A LINK TO THE  
16 MEDICARE DRUG SPENDING DASHBOARD ON THE MEDI-  
17 CARE PLAN FINDER.—Beginning not later than January  
18 1, 2022, the Secretary of Health and Human Services  
19 shall ensure that the Medicare Plan Finder on the Medi-  
20 care.gov internet website includes a link to the Medicare  
21 Drug Spending Dashboard on the CMS.gov internet  
22 website. Such link shall be easily accessible on the Medi-  
23 care Plan Finder.

24 (c) REPORTS TO CONGRESS.—

25 (1) SECRETARY OF HHS.—

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

6 (i) The price negotiations conducted  
7 by the Secretary under section 1860D–  
8 11(i) of the Social Security Act (42 U.S.C.  
9 1395w–111(i)), as amended by subsection  
10 (a), including a description of—

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

17 (II) how such lower prices are  
18 passed through to Medicare bene-  
19 ficiaries;

20 (III) how such price negotiations  
21 are affecting drug prices in the pri-  
22 vate market; and

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

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

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

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

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

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

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

1 (B) PUBLIC AVAILABILITY OF REPORT.—

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

8 (2) MEDPAC.—

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

15 (i) how such price negotiations are  
16 achieving lower prices for covered part D  
17 drugs (as defined in section 1860D–2(e) of  
18 the Social Security Act (42 U.S.C. 1395w–  
19 102(e))) for Medicare beneficiaries;

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

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

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

7 (B) REPORT.—Not later than January 1,  
8 2024, 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 three  
20 of 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 Affordable  
23 Medications 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 drug described in paragraph (5)(A).

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

17                           (i) has the same meaning given such  
18                           term under section 1927(k)(1) of the So-  
19                           cial Security Act (42 U.S.C. 1396r-  
20                           8(k)(1)); or

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

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) INSPECTOR GENERAL.—The term “In-  
6 spector General” means the Inspector General  
7 of the Department of Health and Human Serv-  
8 ices.

9 (E) PRESCRIPTION DRUG.—

10 (i) IN GENERAL.—The term “pre-  
11 scription drug” means any drug (as de-  
12 fined in section 201(g) of the Federal  
13 Food, Drug, and Cosmetic Act (21 U.S.C.  
14 321(g))), including a combination product  
15 whose primary mode of action is deter-  
16 mined under section 503(g) of such Act  
17 (21 U.S.C. 353(g)) to be that of a drug,  
18 and that—

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

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

1 (ii) TREATMENT OF REFORMULATED  
2 DRUGS.—For purposes of this subsection,  
3 a prescription drug with respect to which  
4 the Secretary of Health and Human Serv-  
5 ices has approved any minor reformulation  
6 that does not produce a meaningful thera-  
7 peutic benefit, the drug that was approved  
8 prior to any such reformulation and the  
9 drug with any such reformulation shall be  
10 considered one prescription drug.

11 (F) PRICE SPIKE.—

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

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

21 (I) the average manufacturer  
22 price of a prescription drug in com-  
23 merce for the calendar year; exceeds

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

1 commerce for the calendar year pre-  
 2 ceding such year.

3 (iii) APPLICABLE PRICE INCREASE AL-  
 4 LOWANCE.—The applicable price increase  
 5 allowance for any calendar year is the per-  
 6 centage (rounded to the nearest one-tenth  
 7 of 1 percent) by which the C–CPI–U (as  
 8 defined in section 1(f)(6) of the Internal  
 9 Revenue Code of 1986) for that year ex-  
 10 ceeds the C–CPI–U for the preceding cal-  
 11 endar year.

12 (G) PRICE SPIKE REVENUE.—

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

16 (I) the gross price spike revenue;

17 minus

18 (II) the adjustment amount.

19 (ii) GROSS PRICE SPIKE REVENUE.—

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

23 (I) an amount equal to the dif-  
 24 ference between subclause (I) of sub-

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

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

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

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

15 (A) IN GENERAL.—For each prescription  
16 drug, the applicable entity shall submit to the  
17 Inspector General a quarterly report that in-  
18 cludes the following:

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

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

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

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

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

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

1 (B) PENALTY FOR FAILURE TO SUBMIT.—

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

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

13 (I) an amount, as determined ap-  
14 propriate by the Inspector General,  
15 which is—

16 (aa) not less than 0.5 per-  
17 cent of the gross revenues from  
18 sales of the prescription drug de-  
19 scribed in clause (i) for the pre-  
20 ceeding calendar year, and

21 (bb) not greater than 1 per-  
22 cent of the gross revenues from  
23 sales of such prescription drug  
24 for the preceding calendar year,  
25 and



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

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

6 (bb) the date on which the  
7 Inspector General receives the in-  
8 formation described in subpara-  
9 graph (A) from the applicable en-  
10 tity.

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

16 (3) ASSESSMENT BY INSPECTOR GENERAL.—

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

22 (i) complete an assessment of the in-  
23 formation the Inspector General received  
24 pursuant to paragraph (2)(A) with respect

1 to sales of prescription drugs in the pre-  
2 ceding calendar year; and

3 (ii) in the case of any prescription  
4 drug which satisfies the conditions de-  
5 scribed in subparagraph (A) or (B) of  
6 paragraph (4), submit a recommendation  
7 to the Secretary of Health and Human  
8 Services that such drug be exempted from  
9 application of the tax imposed under sec-  
10 tion 4191 of the Internal Revenue Code of  
11 1986 (as added by subsection (b) of this  
12 section) for such year.

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

15 (i) Identification of each price spike  
16 relating to a prescription drug in the pre-  
17 ceding calendar year.

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

20 (I) a determination of the price  
21 spike revenue;

22 (II) a determination regarding  
23 the accuracy of the information sub-  
24 mitted by the applicable entity regard-  
25 ing increased input costs; and

1 (III) an assessment of the ration-  
2 ale of the applicable entity for the  
3 price spike.

4 (4) EXEMPTION OF CERTAIN DRUGS.—

5 (A) IN GENERAL.—The Secretary of  
6 Health and Human Services, upon rec-  
7 ommendation of the Inspector General pursuant  
8 to paragraph (3)(A)(ii), may exempt any pre-  
9 scription drug which has been subject to a price  
10 spike during the preceding calendar year from  
11 application of the tax imposed under section  
12 4191 of the Internal Revenue Code of 1986 for  
13 such year, if the Secretary determines that—

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

18 (ii)(I) the prescription drug which has  
19 been subject to a price spike has an aver-  
20 age manufacturer price of not greater than  
21 \$10 for a 30-day supply; and

22 (II) such drug is marketed by not less  
23 than three other holders of applications ap-  
24 proved under subsection (c) or (j) of sec-  
25 tion 505 of the Federal Food, Drug, and

1           Cosmetic Act (21 U.S.C. 355), where such  
2           applications approved under such sub-  
3           section (j) use as a reference drug the drug  
4           so approved under such subsection (c).

5           (B) CLARIFICATION.—In considering,  
6           under subparagraph (A)(i), information sub-  
7           mitted pursuant to paragraph (2)(A)(ii), the  
8           Secretary—

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

12                   (ii) shall exclude from such consider-  
13                  ation any information submitted by the ap-  
14                  plicable entity threatening to curtail or  
15                  limit production of the prescription drug if  
16                  the Secretary does not grant an exemption  
17                  from the application of the tax under sec-  
18                  tion 4191 of the Internal Revenue Code of  
19                  1986.

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

22                   (A) IN GENERAL.—Subject to subpara-  
23                  graph (C), not later than the last day in Feb-  
24                  ruary of each year, the Inspector General shall  
25                  transmit to the Internal Revenue Service a re-

1 port on the findings of the Inspector General  
2 with respect to the information the Inspector  
3 General received under paragraph (2)(A) with  
4 respect to the preceding calendar year and the  
5 assessment carried out by the Inspector General  
6 under paragraph (3)(A) with respect to such in-  
7 formation.

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

11 (i) The information received under  
12 paragraph (2)(A) with respect to the pre-  
13 ceding calendar year.

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

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

19 (iv) The determinations and assess-  
20 ments made under subclauses (II) and  
21 (III) of clause (ii) of such paragraph.

22 (C) NOTICE AND OPPORTUNITY FOR HEAR-  
23 ING.—

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

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

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

7                   (II) notice of their right to a  
8                   hearing in regards to such assess-  
9                   ment.

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

15           (iii) REQUEST FOR HEARING.—Sub-  
16           ject to clause (v), an applicable entity may  
17           request a hearing before the Secretary of  
18           Health and Human Services not later than  
19           30 days after the date on which the notice  
20           under clause (ii) is received.

21           (iv) COMPLETION OF HEARING.—In  
22           the case of an applicable entity which re-  
23           quests a hearing pursuant to clause (iii),  
24           the Secretary of Health and Human Serv-  
25           ices shall, not later than 12 months after

1 the date on which the assessment under  
2 paragraph (3)(A) was completed by the In-  
3 spector General—

4 (I) make a final determination in  
5 regards the accuracy of such assess-  
6 ment; and

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

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

14 (D) PUBLICATION.—

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

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

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

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

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

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

18 **“Subchapter E—Prescription Drugs**

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

19 **“SEC. 4191. PRESCRIPTION DRUGS SUBJECT TO PRICE**  
20 **SPIKES.**

21 “(a) IMPOSITION OF TAX.—

22 “(1) IN GENERAL.—Subject to paragraph (3),  
23 for each taxable prescription drug sold by an appli-  
24 cable entity during the calendar year, there is hereby



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

3 “(A) the annual price spike tax for such  
4 prescription drug, or

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

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

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

19 “(b) ANNUAL PRICE SPIKE TAX.—

20 “(1) IN GENERAL.—The amount of the annual  
21 price spike tax shall be equal to the applicable per-  
22 centage of the price spike revenue received by the  
23 applicable entity on the sale of the taxable prescrip-  
24 tion drug during the calendar year.

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

4           “(A) in the case of a taxable prescription  
5 drug which has been subject to a price spike  
6 percentage greater than the applicable price in-  
7 crease allowance (as defined in section  
8 202(a)(1)(F)(iii) of the Affordable Medications  
9 Act) but less than 15 percent, 50 percent,

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

14           “(C) in the case of a taxable prescription  
15 drug which has been subject to a price spike  
16 percentage equal to or greater than 20 percent,  
17 100 percent.

18           “(c) CUMULATIVE PRICE SPIKE TAX.—

19           “(1) IN GENERAL.—The amount of the cumu-  
20 lative price spike tax shall be equal to the applicable  
21 percentage of the cumulative price spike revenue re-  
22 ceived by the applicable entity on the sale of the tax-  
23 able prescription drug during the calendar year.

24           “(2) APPLICABLE PERCENTAGE.—

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

4           “(i) in the case of a taxable prescrip-  
5 tion drug which has been subject to a cu-  
6 mulative price spike percentage greater  
7 than the cumulative price increase allow-  
8 ance but less than the first multi-year per-  
9 centage, 50 percent,

10           “(ii) 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 first multi-year percent-  
14 age but less than the second multi-year  
15 percentage, 75 percent, and

16           “(iii) in the case of a taxable prescrip-  
17 tion drug which has been subject to a cu-  
18 mulative price spike percentage equal to or  
19 greater than the second multi-year percent-  
20 age, 100 percent.

21           “(B) CUMULATIVE PRICE SPIKE PERCENT-  
22 AGE.—The cumulative price spike percentage is  
23 the percentage (if any) by which—

1 “(i) the average manufacturer price of  
 2 the taxable prescription drug in commerce  
 3 for the preceding calendar year, exceeds

4 “(ii) the average manufacturer price  
 5 of such prescription drug in commerce for  
 6 the base year.

7 “(C) CUMULATIVE PRICE INCREASE AL-  
 8 LOWANCE.—For purposes of clause (i) of sub-  
 9 paragraph (A), the cumulative price increase al-  
 10 lowance for any calendar year is the percentage  
 11 (rounded to the nearest one-tenth of 1 percent)  
 12 by which the C–CPI–U (as defined in section  
 13 1(f)(6)) for that year exceeds the C–CPI–U for  
 14 the base year.

15 “(D) MULTI-YEAR PERCENTAGES.—For  
 16 purposes of subparagraph (A), the first multi-  
 17 year percentage and second multi-year percent-  
 18 age shall be determined in accordance with the  
 19 following table:

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

20 “(E) APPLICABLE PERIOD AND BASE  
 21 YEAR.—

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

3                               “(I) the 5 preceding calendar  
4                   years,

5                               “(II) all calendar years beginning  
6                   after the date of enactment of this  
7                   section, or

8                               “(III) all calendar years in which  
9                   the taxable prescription drug was sold  
10                  in commerce.

11                   “(ii) BASE YEAR.—The base year  
12                  shall be the calendar year immediately pre-  
13                  ceding the applicable period.

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

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

19                                       “(i) an amount (not less than zero)  
20                               equal to—

21   “(I) the average manufacturer  
22                               price of such prescription drug in  
23                               commerce for the preceding calendar  
24                               year, minus

1                   “(II) the average manufacturer  
2                   price of such prescription drug in  
3                   commerce for the base year, and

4                   “(ii) the total number of units of such  
5                   prescription drug which were sold in com-  
6                   merce in the preceding calendar year,  
7                   minus

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

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

14                  “(1) TAXABLE PRESCRIPTION DRUG.—The  
15                  term ‘taxable prescription drug’ means a prescrip-  
16                  tion drug (as defined in section 202(a)(1)(E) of the  
17                  Affordable Medications Act) which has been identi-  
18                  fied by the Inspector General of the Department of  
19                  Health and Human Services, under section  
20                  202(a)(3)(B)(i) of such Act, as being subject to a  
21                  price spike.

22                  “(2) OTHER TERMS.—The terms ‘applicable en-  
23                  tity’, ‘average manufacturer price’, ‘price spike’,  
24                  ‘price spike percentage’, and ‘price spike revenue’

1 have the same meaning given such terms under sec-  
2 tion 202(a)(1) of the Affordable Medications Act.”.

3 (2) CLERICAL AMENDMENT.—The table of sub-  
4 chapters for chapter 32 of such Code is amended by  
5 inserting after the item relating to subchapter D the  
6 following new item:

“SUBCHAPTER E. PRESCRIPTION DRUGS”.

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

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

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

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

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

24 (4) reducing health insurance premiums.

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

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

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

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

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

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

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



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

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

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

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

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

22           “(A) means a prescription drug that—

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

1           tients, and marketed, in another permitted  
2           country;

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

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

16          “(iv) is labeled in accordance with—

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

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

24          “(B) with respect to importers only, in-  
25          cludes—

1 “(i) peritoneal dialysis solution;

2 “(ii) insulin;

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

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

11 “(v) intravenously infused drugs; and

12 “(C) does not include—

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

16 “(ii) an anesthetic drug inhaled dur-  
17 ing surgery; or

18 “(iii) a compounded drug.

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

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

1                   “(B) a covering practitioner.

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

7           “(d) ADDITIONAL CRITERIA.—

8                   “(1) CERTIFIED FOREIGN SELLERS.—

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

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

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

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

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

22                                   “(i) is a foreign wholesale distributor  
23 or licensed foreign pharmacy operating an  
24 establishment, which may include an online  
25 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 203(d) of the Affordable Medications Act, that impor-  
25 tation of qualifying prescription drugs from Canada under



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

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

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

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

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

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

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

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

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

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

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

1       ance with this section than the price that is charged,  
2       inclusive of rebates or other incentives to the coun-  
3       try from which the drug is exported, to another per-  
4       son that is in the same country and that does not  
5       import such a drug into the United States in accord-  
6       ance with this section;

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

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

1 purpose of avoiding sales by certified foreign sellers;  
2 or

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

8 “(i) INFORMATION AND RECORDS.—

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

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

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

19 “(C) the price paid by the importer for the  
20 drug.

21 “(2) MAINTENANCE OF RECORDS BY SEC-  
22 RETARY.—The Secretary shall maintain information  
23 and documentation submitted under paragraph (1)  
24 for such period of time as the Secretary determines  
25 to be appropriate.

1 “(j) SUSPENSION OF IMPORTATION.—

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

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

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

3 “(k) SUPPLY CHAIN SECURITY.—

4 “(1) PURCHASE FROM REGISTERED FACILITIES  
5 AND CERTIFIED FOREIGN SELLERS.—

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

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

1           enter into such a memorandum of under-  
2           standing or cooperative agreement with Canada  
3           and each country from which importation is  
4           permitted under subsection (e).

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

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

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

1 of prescription drugs, other than with respect to section  
2 801(d)(1) as provided in this section.”.

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

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

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

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

19 such person shall be imprisoned for not more than 10  
20 years or fined not more than \$250,000.”.

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



1 cluding common law, that provides a remedy for civil re-  
2 lief.

3 (d) REPORTS.—

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

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

1 **SEC. 204. 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, 2022, 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) 2022 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, 2022, and  
26 ending on December 31, 2022, 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, 2021, in the amount  
8           specified in paragraph (3) for any covered part D  
9           drug of the manufacturer dispensed after December  
10          31, 2021, 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)(8), 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)(8)(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)(8):

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           “(8) 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, 2022,  
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                           “(E) REPORTING REQUIREMENT RELATED  
25                           TO REBATE FOR REBATE ELIGIBLE MEDICARE

1 DRUG PLAN ENROLLEES.—Section 1860D–  
2 12(b)(8).”.

3 (c) DEPOSIT OF REBATES INTO MEDICARE PRE-  
4 SCRIPTION 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. 205. 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 “charges”; and

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

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

16 “(A) **2022.**—For plan years beginning in  
17 2022, the cost-sharing incurred under a health  
18 plan with respect to prescription drugs covered  
19 by the plan shall not exceed \$250 per month for  
20 each enrolled individual, or \$500 for each fam-  
21 ily.

22 “(B) **2023 AND LATER.**—

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

1 graph shall be equal to the applicable dol-  
2 lar amount under subparagraph (A) for  
3 plan years beginning in 2022, increased by  
4 an amount equal to the product of that  
5 amount and the medical care component of  
6 the consumer price index for all urban con-  
7 sumers (as published by the Bureau of  
8 Labor Statistics) for that year.

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

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

17 (1) by striking “annual”; and

18 (2) by striking “paragraph (1) of section  
19 1302(e)” and inserting “paragraphs (1) and (5) of  
20 section 1302(e) of the Patient Protection and Af-  
21 fordable Care Act”.

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



1 **SEC. 206. MODIFICATION OF TRADE NEGOTIATING OBJEC-**  
2 **TIVES RELATING TO INTELLECTUAL PROP-**  
3 **ERTY RIGHTS TO ENSURE ACCESS TO BIO-**  
4 **LOGICAL PRODUCTS.**

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

12 **TITLE III—INNOVATION**

13 **SEC. 301. INNOVATION INCENTIVE FUND FOR NEW AND**  
14 **MORE EFFECTIVE TREATMENTS OF BAC-**  
15 **TERIAL INFECTIONS.**

16 Part B of title IV of the Public Health Service Act  
17 (42 U.S.C. 284 et seq.) is amended by adding at the end  
18 the following:

19 **“SEC. 409K. INNOVATION INCENTIVE FUND FOR NEW AND**  
20 **MORE EFFECTIVE TREATMENTS OF BAC-**  
21 **TERIAL INFECTIONS.**

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

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

7       “(c) AWARDS.—

8           “(1) IN GENERAL.—During the 10-year period  
9 following the date of enactment of the Affordable  
10 Medications Act, the Director of the NIH, in accord-  
11 ance with the criteria under subsection (d) and the  
12 goals under subsection (e), shall award—

13           “(A) up to 3 market entry awards for  
14 qualifying products that provide added benefit  
15 for patients over existing therapies in the treat-  
16 ment of serious and life-threatening bacterial  
17 infections demonstrating in superiority trials;  
18 and

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

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

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

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

4 “(1) ESTABLISHMENT OF CRITERIA.—Not later  
5 than 120 days after the date of enactment of the Af-  
6 fordable Medications Act, the Director of NIH shall  
7 establish criteria for the selection of recipients and  
8 eligibility of persons for market entry rewards and  
9 open source dividend prizes under this section and  
10 criteria for determining the amounts of such prizes,  
11 through notice and comment rulemaking.

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

19 “(A) The number of patients in the United  
20 States and in other countries who would benefit  
21 from the qualifying product that treats a seri-  
22 ous or life-threatening bacterial infection, and  
23 the number of patients in the United States  
24 and in other countries projected to benefit dur-  
25 ing the upcoming 10-year period.

1           “(B) Whether the qualifying product  
2           treats, or has the potential to treat, a serious  
3           or life-threatening bacterial infection for which  
4           no other treatment is currently available or for  
5           which there is a high threat of resistance to ex-  
6           isting treatments.

7           “(C) The incremental and additional thera-  
8           peutic benefit to human in the United States  
9           and other countries of the qualifying product as  
10          compared to other treatments available to treat  
11          the bacterial infection, evaluating the incre-  
12          mental therapeutic benefit in comparison to  
13          treatments that were not recently developed.

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

17          “(E) The extent to which knowledge, data,  
18          materials, and technology that are openly  
19          sourced have contributed to the successful de-  
20          velopment of new treatments that provide an  
21          added benefit to patients, such as decreasing  
22          mortality or irreversible morbidity on patient-  
23          centered outcomes, significantly advancing the  
24          field of antibiotic research, or improving proc-

1           esses for manufacturing products used for the  
2           treatment.

3           “(F) Other criteria that the Director of  
4           NIH determines to be relevant and useful in  
5           ensuring that the prizes provide appropriate in-  
6           centives.

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

15          “(e) GOALS.—With respect to each year for which the  
16          Director of NIH awards market entry rewards and open  
17          source dividend prizes under subsection (c), the Director  
18          of NIH shall establish a framework of goals that a quali-  
19          fying product or contribution that significantly advances  
20          the field of antibiotic research is required to show promise  
21          to help meet in order for a person to be eligible to receive  
22          a market entry reward or open source dividend prize with  
23          respect to such product or such contribution. Such goals  
24          may include—

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

3           “(2) use of diagnostics prior to prescribing of  
4           drugs; and

5           “(3) use of innovative programs for antibiotic  
6           stewardship.

7           “(f) CONDITION ON RECEIPT OF MARKET ENTRY  
8           REWARD.—

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

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

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

19                 “(C) The recipient shall agree to submit to  
20                 the Director of NIH, for review and approval  
21                 by such director, in collaboration with the Com-  
22                 missioner of Food and Drugs and the Director  
23                 of the Centers for Disease Control and Preven-  
24                 tion, all marketing, sales, and other promotional  
25                 and educational activities associated with the

1           qualifying product, to ensure that such activi-  
2           ties align with, and advance the goals of, re-  
3           source conserving stewardship, protecting the  
4           utility of antibiotics, and encouraging and en-  
5           suring the correct use of antibiotics.

6           “(D) The recipient shall irrevocably  
7           waive—

8                   “(i) all periods of exclusivity available  
9                   to the product under chapter V of the Fed-  
10                  eral Food, Drug, and Cosmetic Act or sec-  
11                  tion 351 of this Act; and

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

14           “(E) Any other conditions the Director of  
15           NIH determines appropriate.

16           “(2) APPLICABILITY.—All conditions described  
17           in paragraph (1) shall apply to subsequent owners,  
18           licensees, producers, and manufacturers, and assign-  
19           ees of the product or any chemical component of the  
20           qualifying product for which the market entry re-  
21           ward was awarded.

22           “(3) REASONABLE PRICE.—

23                   “(A) IN GENERAL.—A recipient may sat-  
24           isfy the requirement to offer a qualifying prod-

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

3                   “(i)(I) providing open licensing of all  
4                   necessary rights to patents, manufacturing  
5                   processes, rights in data, and other intel-  
6                   lectual property rights needed to make and  
7                   sell the product to manufacturers of the  
8                   generic version of such product; or

9                   “(II) selling such product at a price  
10                  that is no more than twice the price of an-  
11                  tibiotic drugs approved under section  
12                  505(j) of the Federal Food, Drug, and  
13                  Cosmetic Act with similar manufacturing  
14                  costs; and

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

20                  “(B) CRITERIA.—For purposes of subpara-  
21                  graph (A)(ii), the Director of NIH shall iden-  
22                  tify, on an annual basis, the countries that have  
23                  a per capita income that is not less than half  
24                  the per capita income of the United States, se-  
25                  lect the 7 of such countries that have the larg-



1           est gross domestic product, and determine the  
2           median price charged for each qualifying prod-  
3           uct for which an award has been granted under  
4           subsection (c).

5           “(g) ENFORCEMENT.—If the market entry reward re-  
6           cipient, or subsequent owner, licensee, or assignee of the  
7           qualifying product, does not fulfill the conditions described  
8           subsection (f)(1), the Secretary, in collaboration with the  
9           Attorney General, shall take all necessary action to  
10          clawback the market entry reward.

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

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

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

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

24          “(j) STUDY.—

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

5           “(A) the use of innovation inducement re-  
6 ward funds and push financing mechanisms as  
7 ways to stimulate investments in biomedical re-  
8 search and development that de-links costs from  
9 product prices;

10           “(B) models of different possible means of  
11 de-linking research and development costs from  
12 drug prices, including the progressive replace-  
13 ment of the monopoly on new products with a  
14 combination of expanded research subsidies and  
15 new incentives from innovation inducement  
16 funds to stimulate the development of drugs, in-  
17 cluding drugs to treat bacterial infections, rare  
18 diseases, HIV/AIDS, and cancer;

19           “(C) the size of market entry rewards,  
20 open source dividends and other innovation in-  
21 ducement prizes that would be necessary to  
22 achieve innovation objectives and the relative  
23 cost effectiveness of incentives delinked from  
24 the prices of products and services in stimu-

1           lating innovation, compared to time-limited mo-  
2           nopolies; and

3                   “(D) methods of progressively imple-  
4           menting policies that delink research and devel-  
5           opment funding from prices of products and  
6           services, including to the progressive reduction  
7           in the effective term of exclusive rights, accom-  
8           panied by a progressive introduction and expan-  
9           sion of market entry rewards.

10           “(2) AUTHORIZATION OF APPROPRIATIONS.—

11           For the purpose of carrying out this subsection,  
12           there are authorized to be appropriated, and there  
13           are appropriated, \$3,000,000 for fiscal year 2022.  
14           Such funds shall remain available until expended.”.

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

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

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

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

21           “(a) IN GENERAL.—There is established within the  
22           National Institutes of Health the Center for Clinical Re-  
23           search, for the purpose of conducting clinical trials on  
24           drugs, as described in subsection (b), with the intention  
25           of obtaining approval of such drug under section 505 of

1 the Federal Food, Drug, and Cosmetic Act or section 351  
2 of this Act. The Director of NIH shall appoint a Director  
3 of the Center for Clinical Research referred to in this sec-  
4 tion as the ‘Director’) not later than 90 days after the  
5 date of enactment of the Affordable Medications Act.

6 “(b) CLINICAL TRIALS.—

7 “(1) IN GENERAL.—Each year, beginning not  
8 later than 1 year after the date of enactment of the  
9 Affordable Medications Act, the Director shall select  
10 at least 2 molecules, compounds, drugs, or biological  
11 products and conduct clinical trials on such mol-  
12 ecules, compounds, drugs, or biological products, or  
13 enter into contracts with other entities to conduct  
14 such clinical trials.

15 “(2) SELECTION OF DRUGS.—

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

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

1           dition in the case of a national emergency;  
2           and

3                   “(ii) are not solely drugs that private  
4           sector researchers with access to all avail-  
5           able information on such drugs chose not  
6           to develop.

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

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

18                   “(1) execute non-exclusive licenses to allow  
19          drug manufacturers to manufacture and sell the  
20          drug; or

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

23          “(d) PUBLIC INFORMATION.—

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

4           “(A)(i) submit all completed studies (and  
5 terminated studies, if terminated for safety or  
6 ethical reasons) for publication in a peer-re-  
7 viewed publication within 180 days of comple-  
8 tion or termination; and

9           “(ii) if a study submitted as described in  
10 clause (i) is not selected for publication, pub-  
11 licly disclose all de-identified primary clinical  
12 data not later than 180 days after the Sec-  
13 retary’s final decision not to pursue further  
14 submissions for publication; and

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

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

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

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

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

13             (1) by redesignating paragraph (25) as para-  
14 graph (26); and

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

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

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

19       (a) DRUG EXCLUSIVITY.—

20             (1) NEW CHEMICAL ENTITY EXCLUSIVITY.—

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

24                     (i) in subparagraph (B)—

1 (I) in clause (i), by inserting “ex-  
2 cept that such approval may not be  
3 made effective before the date that is  
4 5 years after the date on which the  
5 drug to which the application refers  
6 was approved under subsection (c)”  
7 before the period; and

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

15 (ii) in subparagraph (F)(ii)—

16 (I) by striking “expiration of five  
17 years” and inserting “expiration of 3  
18 years”;

19 (II) by striking “, except that  
20 such an application may be submitted  
21 under this subsection after the expira-  
22 tion of four years from the date of the  
23 approval of the subsection (b) applica-  
24 tion if it contains a certification of  
25 patent invalidity or noninfringement



1 described in subclause (IV) of para-  
2 graph (2)(A)(vii)”; and

3 (III) by striking “seven and one-  
4 half years” and inserting “6 and one-  
5 half years”.

6 (B) CONFORMING AMENDMENTS.—Chapter  
7 V of the Federal Food, Drug, and Cosmetic Act  
8 (21 U.S.C. 351 et seq.) is amended—

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

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

15 (I) by striking “five years” each  
16 place such term appears and inserting  
17 “3 years”;

18 (II) by striking “seven and one-  
19 half years” each place such term ap-  
20 pears and inserting “6 and one-half  
21 years”; and

22 (III) by striking “eight years”  
23 each place such term appears and in-  
24 serting “7 years”; and

1 (iii) in section 505E, by striking “the  
2 4- and 5-year periods described in sub-  
3 sections (c)(3)(E)(ii) and (j)(5)(F)(ii) of  
4 section 505, the 3-year periods described  
5 in clauses (iii) and (iv) of subsection  
6 (c)(3)(E) and clauses (iii) and (iv) of sub-  
7 section (j)(5)(F)” and inserting “the 4-  
8 and 5-year periods described in subsection  
9 (c)(3)(E)(ii) of section 505, the 3-year pe-  
10 riods described in clauses (iii) and (iv) of  
11 subsection (c)(3)(E) and clauses (ii), (iii),  
12 and (iv) of subsection (j)(5)(F)”.

13 (2) NEW CLINICAL INVESTIGATION EXCLU-  
14 SIVITY.—Section 505(c)(3)(E)(iv) of the Federal  
15 Food, Drug, and Cosmetic Act (21 U.S.C.  
16 355(c)(3)(E)(iv)) is amended by inserting “, and the  
17 supplement shows a significant clinical benefit over  
18 existing therapies manufactured by the applicant in  
19 the 5-year period preceding the submission of the  
20 application,” before “the Secretary”.

21 (3) BIOLOGICAL PRODUCT EXCLUSIVITY.—

22 (A) IN GENERAL.—Section 351(k)(7)(A) of  
23 the Public Health Service Act (42 U.S.C.  
24 262(k)(7)(A)) is amended by striking “12  
25 years” and inserting “7 years”.

1 (B) CONFORMING AMENDMENTS.—Para-  
2 graphs (2)(A) and (3)(A) of section 351(m) of  
3 the Public Health Service Act (42 U.S.C.  
4 262(m)) is amended by striking “12 years”  
5 each place it appears and inserting “7 years”.

6 (b) APPLICABILITY.—The amendments made by sub-  
7 section (a) apply only with respect to a drug or biological  
8 product for which the listed drug (as described in section  
9 505(j)(7) of the Federal Food, Drug, and Cosmetic Act  
10 (21 U.S.C. 355(j)(7))) or reference product (as such term  
11 is used in section 351 of the Public Health Service Act  
12 (42 U.S.C. 262)) is approved under section 505(c) of the  
13 Federal Food, Drug, and Cosmetic Act or licensed under  
14 section 351(a) of the Public Health Service Act, as appli-  
15 cable, on or after the date of enactment of this Act.

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

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

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

3 (C) the names of all drugs receiving such des-  
4 ignation during such period, including the date of  
5 approval and indication for which market exclusivity  
6 was granted; and

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

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

20 (3) for a sample of drugs (selected by the  
21 Comptroller General) so designated in the previous  
22 10-year period, to the extent feasible—

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

1 turer spending for marketing and patient as-  
2 sistance programs;

3 (B) the average price per drug and how  
4 those prices changed over time for the selected  
5 drugs based on industry drug pricing bench-  
6 marks; and

7 (C) the indications that were the basis of  
8 such designation and other approved indications  
9 for the drugs, and the indications for which  
10 each drug has most commonly been used, in-  
11 cluding non-approved indications for which the  
12 drug may be recommended by external organi-  
13 zations such as physician or patient organiza-  
14 tions.

15 **SEC. 304. IMPROVING PROGRAM INTEGRITY.**

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

19 **“SEC. 569E. CONDITIONS ON AWARD OF DRUG EXCLU-  
20 SIVITY.**

21 “(a) TERMINATION OF EXCLUSIVITY.—Notwith-  
22 standing any other provision of this Act, any period of  
23 exclusivity described in subsection (b) granted to a person  
24 or assigned to a person on or after the date of enactment  
25 of this section with respect to a drug shall be terminated

1 if the person to which such exclusivity was granted or any  
2 person to which such exclusivity is assigned commits a vio-  
3 lation described in subsection (c)(1) with respect to such  
4 drug.

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

8 “(1) Clause (ii), (iii), or (iv) of section  
9 505(c)(3)(E).

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

11 “(3) Clause (ii), (iii), or (iv) of section  
12 505(j)(5)(F).

13 “(4) Section 505A.

14 “(5) Section 505E.

15 “(6) Section 527.

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

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

21 “(c) VIOLATIONS.—

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

1           “(A) a criminal conviction of a person de-  
2           scribed in subsection (a);

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

5           “(C) a settlement agreement in which a  
6           person described in subsection (a) admits to  
7           fault.

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

10           “(A) The provisions of this Act that pro-  
11           hibit—

12           “(i) the adulteration or misbranding  
13           of a drug;

14           “(ii) the making of false statements to  
15           the Secretary or committing fraud; or

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

17           “(B) Section 3729 of title 31, United  
18           States Code.

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

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

24           “(E) Section 1927 of the Social Security  
25           Act.

1           “(F) A State law against fraud comparable  
2           to a law described in subparagraphs (A)  
3           through (E).

4           “(d) DATE OF EXCLUSIVITY TERMINATION.—The  
5           date on which the exclusivity shall be terminated as de-  
6           scribed in subsection (a) is the date on which, as applica-  
7           ble—

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

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

14          “(B) if there is no court order approving a set-  
15          tlement agreement described in subsection (c)(1)(C),  
16          a court order dismissing the applicable case, issued  
17          after the settlement agreement, is or becomes final  
18          and nonappealable.

19          “(e) REPORTING OF INFORMATION.—

20          “(1) IN GENERAL.—A person described in sub-  
21          section (a) that commits a violation described in  
22          subsection (c)(1) shall report such violation to the  
23          Secretary no later than 30 days after the date  
24          that—



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

4           “(B)(i) a settlement agreement described  
5           in subsection (c)(1)(C) is approved by a court  
6           order that is or becomes final and nonappeal-  
7           able; or

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

13          “(2) CIVIL PENALTY.—A person who fails to re-  
14          port a violation as required under paragraph (1)  
15          shall be subject to a civil penalty in the amount of  
16          \$200,000 for each day the failure to report con-  
17          tinues, beginning with the day after the date on  
18          which such report is due as described in paragraph  
19          (1).”.

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

1                   **TITLE IV—CHOICE AND**  
2                   **COMPETITION**

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

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

7   **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS**  
8                   **AND BIOSIMILARS.**

9           “(a) IN GENERAL.—

10                   “(1) ENFORCEMENT PROCEEDING.—The Com-  
11 mission may initiate a proceeding to enforce the pro-  
12 visions of this section against the parties to any  
13 agreement resolving or settling, on a final or interim  
14 basis, a patent infringement claim, in connection  
15 with the sale of a drug product or biological product.

16                   “(2) PRESUMPTION AND VIOLATION.—

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

21                                   “(i) an ANDA filer or a biosimilar bi-  
22 ological product application filer receives  
23 anything of value, including an exclusive li-  
24 cense; and

1           “(ii) the ANDA filer or biosimilar bio-  
2           logical product application filer agrees to  
3           limit or forego research, development,  
4           manufacturing, marketing, or sales of the  
5           ANDA product or biosimilar biological  
6           product, as applicable, for any period of  
7           time.

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

12                 “(i) the value described in subpara-  
13                 graph (A)(i) is compensation solely for  
14                 other goods or services that the ANDA  
15                 filer or biosimilar biological product appli-  
16                 cation filer has promised to provide; or

17                 “(ii) the procompetitive benefits of the  
18                 agreement outweigh the anticompetitive ef-  
19                 fects of the agreement.

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

23                 “(1) that entry would not have occurred until  
24                 the expiration of the relevant patent or statutory ex-  
25                 clusivity; or

1           “(2) that the agreement’s provision for entry of  
2           the ANDA product or biosimilar biological product  
3           prior to the expiration of the relevant patent or stat-  
4           utory exclusivity means that the agreement is pro-  
5           competitive.

6           “(c) EXCLUSIONS.—Nothing in this section shall pro-  
7           hibit a resolution or settlement of a patent infringement  
8           claim in which the consideration granted by the NDA  
9           holder or biological product license holder to the ANDA  
10          filer or biosimilar biological product application filer, re-  
11          spectively, as part of the resolution or settlement includes  
12          only one or more of the following:

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

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

18                   “(B) any patent right or other statutory  
19                   exclusivity that would prevent the marketing of  
20                   such ANDA product or biosimilar biological  
21                   product.

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

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

4           “(d) ENFORCEMENT.—

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

7           “(2) JUDICIAL REVIEW.—

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

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

16           “(ii) the United States Court of Ap-  
17 peals for the circuit in which the ultimate  
18 parent entity, as defined in section  
19 801.1(a)(3) of title 16, Code of Federal  
20 Regulations, or any successor thereto, of  
21 the NDA holder or biological product li-  
22 cense holder is incorporated as of the date  
23 that the NDA or biological product license  
24 application, as applicable, is filed with the  
25 Commissioner of Food and Drugs; or

1           “(iii) the United States Court of Ap-  
2           peals for the circuit in which the ultimate  
3           parent entity of the ANDA filer or bio-  
4           similar biological product application filer  
5           is incorporated as of the date that the  
6           ANDA or biosimilar biological product ap-  
7           plication is filed with the Commissioner of  
8           Food and 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 modify, impair, limit, or supersede the applicability  
16          of the antitrust laws as defined in subsection (a) of the  
17          first section of the Clayton Act (15 U.S.C. 12(a)), and  
18          of section 5 of this Act to the extent that section 5 applies  
19          to unfair methods of competition. Nothing in this section  
20          shall modify, impair, limit, or supersede the right of an  
21          ANDA filer or biosimilar biological product application  
22          filer to assert claims or counterclaims against any person,  
23          under the antitrust laws or other laws relating to unfair  
24          competition.

25          “(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 or biological product license holder,  
9 the penalty to the NDA holder or biological product  
10 license holder shall be sufficient to deter violations,  
11 but in no event greater than 3 times the value given  
12 to the ANDA filer or biosimilar biological product  
13 application filer reasonably attributable to the viola-  
14 tion of this section. Such penalty shall accrue to the  
15 United States and may be recovered in a civil action  
16 brought by the Commission, in its own name by any  
17 of its attorneys designated by it for such purpose, in  
18 a district court of the United States against any  
19 party that violates this section. In such actions, the  
20 United States district courts are empowered to grant  
21 mandatory injunctions and such other and further  
22 equitable relief as they deem appropriate.

23           “(2) CEASE AND DESIST.—

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

1 a party in an administrative adjudicative pro-  
2 ceeding under the authority of subsection  
3 (a)(1), an action brought pursuant to para-  
4 graph (1) may be commenced against such  
5 party at any time before the expiration of 1  
6 year after such order becomes final pursuant to  
7 section 5(g).

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

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

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

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



1           “(A) the nature, circumstances, extent,  
2           and gravity of the violation;

3           “(B) with respect to the violator, the de-  
4           gree of culpability, any history of violations, the  
5           ability to pay, any effect on the ability to con-  
6           tinue doing business, profits earned by the  
7           NDA holder or biological product license holder,  
8           compensation received by the ANDA filer or  
9           biosimilar biological product application filer,  
10          and the amount of commerce affected; and

11          “(C) other matters that justice requires.

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

18          “(g) DEFINITIONS.—In this section:

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

23                 “(2) AGREEMENT RESOLVING OR SETTLING A  
24                 PATENT INFRINGEMENT CLAIM.—The term ‘agree-  
25                 ment resolving or settling a patent infringement

1 claim' includes any agreement that is entered into  
2 within 30 days of the resolution or the settlement of  
3 the claim, or any other agreement that is contingent  
4 upon, provides a contingent condition for, or is oth-  
5 erwise related to the resolution or settlement of the  
6 claim.

7 “(3) ANDA.—The term ‘ANDA’ means an ab-  
8 breviated new drug application filed under section  
9 505(j) of the Federal Food, Drug, and Cosmetic Act  
10 (21 U.S.C. 355(j)) or a new drug application filed  
11 under section 505(b)(2) of the Federal Food, Drug,  
12 and Cosmetic Act (21 U.S.C. 355(b)(2)).

13 “(4) ANDA FILER.—The term ‘ANDA filer’  
14 means a party that owns or controls an ANDA filed  
15 with the Food and Drug Administration or has the  
16 exclusive rights under such ANDA to distribute the  
17 ANDA product.

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

22 “(6) BIOLOGICAL PRODUCT.—The term ‘bio-  
23 logical product’ has the meaning given such term in  
24 section 351(i)(1) of the Public Health Service Act  
25 (42 U.S.C. 262(i)(1)).

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

5           “(8) BIOLOGICAL PRODUCT LICENSE HOLD-  
6           ER.—The term ‘biological product license holder’  
7           means—

8                   “(A) the holder of an approved biological  
9                   product license application for a biological prod-  
10                  uct;

11                   “(B) a person owning or controlling en-  
12                   forcement of any patents that claim the biologi-  
13                   cal product that is the subject of such approved  
14                   application; or

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

23           “(9) BIOSIMILAR BIOLOGICAL PRODUCT.—The  
24           term ‘biosimilar biological product’ means the prod-  
25           uct to be manufactured under the biosimilar biologi-

1 cal product application that is the subject of the pat-  
2 ent infringement claim.

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

9 “(11) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-  
10 CATION FILER.—The term ‘biosimilar biological  
11 product application filer’ means a party that owns or  
12 controls a biosimilar biological product application  
13 filed with the Food and Drug Administration or has  
14 the exclusive rights under such application to dis-  
15 tribute the biosimilar biological product.

16 “(12) DRUG PRODUCT.—The term ‘drug prod-  
17 uct’ has the meaning given such term in section  
18 314.3(b) of title 21, Code of Federal Regulations (or  
19 any successor regulation).

20 “(13) NDA.—The term ‘NDA’ means a new  
21 drug application filed under section 505(b) of the  
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
23 355(b)).

24 “(14) NDA HOLDER.—The term ‘NDA holder’  
25 means—

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

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

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

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

19           “(16) PATENT INFRINGEMENT.—The term  
20 ‘patent infringement’ means infringement of any  
21 patent or of any filed patent application, extension,  
22 reissue, renewal, division, continuation, continuation  
23 in part, reexamination, patent term restoration, pat-  
24 ents of addition, and extensions thereof.

1           “(17) PATENT INFRINGEMENT CLAIM.—The  
2 term ‘patent infringement claim’ means any allega-  
3 tion made to an ANDA filer or biosimilar biological  
4 product application filer, whether or not included in  
5 a complaint filed with a court of law, that its ANDA  
6 or ANDA product, or biological product license ap-  
7 plication or biological product, may infringe any pat-  
8 ent held by, or exclusively licensed to, the NDA  
9 holder or biological product license holder of the  
10 drug product or biological product, as applicable.

11           “(18) STATUTORY EXCLUSIVITY.—The term  
12 ‘statutory exclusivity’ means those prohibitions on  
13 the approval of drug applications under clauses (ii)  
14 through (iv) of section 505(c)(3)(E) (5- and 3-year  
15 data exclusivity), section 527 (orphan drug exclu-  
16 sivity), or section 505A (pediatric exclusivity) of the  
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
18 355(c)(3)(E), 360cc, 355a), or on the licensing of  
19 biological product applications under section  
20 351(k)(7) (12-year exclusivity) or paragraph (2) or  
21 (3) of section 351(m) (pediatric exclusivity) of the  
22 Public Health Service Act (42 U.S.C. 262) or under  
23 section 527 of the Federal Food, Drug, and Cos-  
24 metic Act (orphan drug exclusivity).”.

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

8 **SEC. 402. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS RE-**  
9 **GARDING FIRST APPLICANT STATUS.**

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

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

15 (A) in clause (iv)(II)—

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

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

19 and

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

21 “(vi) FIRST APPLICANT DEFINED.—As used in  
22 this subsection, the term ‘first applicant’ means an  
23 applicant—

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

1 certification described in paragraph  
2 (2)(A)(vii)(IV) is submitted for approval of a  
3 drug, submits a substantially complete applica-  
4 tion that contains and lawfully maintains a cer-  
5 tification described in paragraph (2)(A)(vii)(IV)  
6 for the drug; and

7 “(bb) that has not entered into a disquali-  
8 fying agreement described under clause  
9 (viii)(II); or

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

14 “(bb) that has not entered into a disquali-  
15 fying agreement described under clause  
16 (vii)(II).

17 “(vii) REQUIREMENT.—The requirements de-  
18 scribed in this clause are the following:

19 “(I) The applicant described in clause  
20 (v)(II) submitted and lawfully maintains a cer-  
21 tification described in paragraph (2)(A)(vii)(IV)  
22 or a statement described in paragraph  
23 (2)(A)(viii) for each unexpired patent for which  
24 a first applicant described in clause (v)(I) had  
25 submitted a certification described in paragraph



1 (2)(A)(vii)(IV) on the first day on which a sub-  
2 stantially complete application containing such  
3 a certification was submitted.

4 “(II) With regard to each such unexpired  
5 patent for which the applicant described in  
6 clause (v)(II) submitted a certification de-  
7 scribed in paragraph (2)(A)(vii)(IV), no action  
8 for patent infringement was brought against  
9 such applicant within the 45-day period speci-  
10 fied in paragraph (5)(B)(iii); or if an action  
11 was brought within such time period, such an  
12 action was withdrawn or dismissed by a court  
13 (including a district court) without a decision  
14 that the patent was valid and infringed; or if an  
15 action was brought within such time period and  
16 was not withdrawn or so dismissed, such appli-  
17 cant has obtained the decision of a court (in-  
18 cluding a district court) that the patent is in-  
19 valid or not infringed (including any substantive  
20 determination that there is no cause of action  
21 for patent infringement or invalidity, and in-  
22 cluding a settlement order or consent decree  
23 signed and entered by the court stating that the  
24 patent is invalid or not infringed).

1           “(III) If an applicant described in clause  
 2           (v)(I) has begun commercial marketing of such  
 3           drug, the applicant described in clause (v)(II)  
 4           does not begin commercial marketing of such  
 5           drug until the date that is 30 days after the  
 6           date on which the applicant described in clause  
 7           (v)(I) began such commercial marketing.”.

8           (2) CONFORMING AMENDMENT.—Section  
 9           505(j)(5)(D)(i)(IV) of the Federal Food, Drug, and  
 10          Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(IV)) is  
 11          amended by striking “The first applicant” and in-  
 12          serting “The first applicant, as defined in subpara-  
 13          graph (B)(vi)(I),”.

14          (b) APPLICABILITY.—The amendments made by sub-  
 15          section (a) shall apply only with respect to an application  
 16          filed under section 505(j) of the Federal Food, Drug, and  
 17          Cosmetic Act (21 U.S.C. 355(j)) to which the amendments  
 18          made by section 1102(a) of the Medicare Prescription  
 19          Drug, Improvement, and Modernization Act of 2003 (Pub-  
 20          lic Law 108–173) apply.

21 **SEC. 403. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS RE-**  
 22 **GARDING AGREEMENTS TO DEFER COMMER-**  
 23 **CIAL MARKETING.**

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

1           (1) LIMITATIONS ON AGREEMENTS TO DEFER  
2           COMMERCIAL           MARKETING           DATE.—Section  
3           505(j)(5)(B) of the Federal Food, Drug, and Cos-  
4           metic Act (21 U.S.C. 355(j)(5)(B)), as amended by  
5           section 402, is further amended by adding at the  
6           end the following:

7           “(viii) AGREEMENT BY FIRST APPLICANT TO  
8           DEFER COMMERCIAL MARKETING; LIMITATION ON  
9           ACCELERATION OF DEFERRED COMMERCIAL MAR-  
10          KETING DATE.—

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

1 date after receiving an approval of its applica-  
2 tion that is made effective under this subpara-  
3 graph, subparagraph (F) of this paragraph, sec-  
4 tion 505A, or section 527, or (cc) to both items  
5 (aa) and (bb).

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

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

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

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

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

16 “(bb) 180 days after another first ap-  
17 plicant begins commercial marketing of  
18 such drug; and

19 “(II) the latest date set forth in the agree-  
20 ment on which that applicant can receive an ap-  
21 proval that is made effective under this sub-  
22 paragraph, subparagraph (F) of this paragraph,  
23 section 505A, or section 527, or begin the com-  
24 mercial marketing of such drug, without regard  
25 to any other provision of such agreement pursu-

1           ant to which commercial marketing could begin  
2           on an earlier date, shall be the date used to de-  
3           termine whether an applicant is disqualified  
4           from first applicant status pursuant to clause  
5           (viii)(II).”.

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

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

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

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

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

1       “(B) The notification described under subparagraph  
2 (A) shall be submitted not later than 10 business days  
3 after execution of the agreement described in subpara-  
4 graph (A)(i). Such notification is in addition to any notifi-  
5 cation required under section 1112 of the Medicare Pre-  
6 scription Drug, Improvement, and Modernization Act of  
7 2003.

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

17           (3) PROHIBITED ACTS.—Section 301(e) of the  
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
19 331(e)) is amended by striking “505 (i) or (k)” and  
20 inserting “505(i), 505(j)(11), 505(k)”.

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

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

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

7 (c) APPLICABILITY.—

8 (1) LIMITATIONS ON ACCELERATION OF DE-  
9 FERRED COMMERCIAL MARKETING DATE.—The  
10 amendment made by subsection (a)(1) shall apply  
11 only with respect to—

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

19 (B) an agreement described under section  
20 505(j)(5)(B)(viii)(I) of the Federal Food, Drug,  
21 and Cosmetic Act (as added by subsection  
22 (a)(1)) executed after the date of enactment of  
23 this Act.

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



1 shall apply only with respect to an agreement de-  
2 scribed under section 505(j)(5)(B)(viii)(I) of the  
3 Federal Food, Drug, and Cosmetic Act (as added by  
4 subsection (a)(1)) executed after the date of enact-  
5 ment of this Act.

6 **SEC. 404. INCREASING DRUG COMPETITION AND PRE-**  
7 **VENTING DRUG SHORTAGES.**

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

11 “(E)(i) The Commissioner shall—

12 “(I) not later than 9 months after the date of  
13 enactment of the Affordable Medications Act, pub-  
14 lish a complete, up-to-date list on the internet  
15 website of the Food and Drug Administration of all  
16 drugs, including authorized generics, together with,  
17 with respect to the drug, as applicable—

18 “(aa) the drug trade name;

19 “(bb) the established name;

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

22 “(dd) each generic drug facility;

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

1           “(ff) the date any authorized generic drug  
2 entered the market;

3           “(gg) the marketing status; and

4           “(hh) any other information the Secretary  
5 may require to mitigate or prevent drug short-  
6 ages;

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

9           “(III) designate each drug on the list that is an  
10 essential medicine, as identified by the World Health  
11 Organization, or another entity designated by the  
12 Secretary that meets evidence-based standards as re-  
13 quired by the Secretary; and

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

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

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

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

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

10 **SEC. 405. DISALLOWANCE OF DEDUCTION FOR ADVER-**  
 11 **TISING FOR PRESCRIPTION DRUGS.**

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

16 **“SEC. 280I. DISALLOWANCE OF DEDUCTION FOR DIRECT-**  
 17 **TO-CONSUMER ADVERTISING OF PRESCRIP-**  
 18 **TION DRUGS.**

19 “(a) IN GENERAL.—No deduction shall be allowed  
 20 under this chapter for expenses relating to direct-to-con-  
 21 sumer advertising of prescription drugs for any taxable  
 22 year.

23 “(b) DIRECT-TO-CONSUMER ADVERTISING.—For  
 24 purposes of this section, the term ‘direct-to-consumer ad-  
 25 vertising’ means any dissemination, by or on behalf of a

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

4 “(1) is in regard to such prescription drug  
 5 product, and

6 “(2) primarily targeted to the general public,  
 7 including through—

8 “(A) publication in journals, magazines,  
 9 other periodicals, and newspapers,

10 “(B) broadcasting through media such as  
 11 radio, television, telephone communication sys-  
 12 tems, direct mail, and billboards,

13 “(C) dissemination on the internet (includ-  
 14 ing social media), and

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

18 (b) CONFORMING AMENDMENT.—The table of sec-  
 19 tions for such part IX of the Internal Revenue Code of  
 20 1986 is amended by adding after the item relating to sec-  
 21 tion 280H the following new item:

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

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

1 curred after the date of the enactment of this Act, in tax-  
2 able years ending after such date.

3 (d) OVERSIGHT OF PRESCRIPTION DRUGS.—

4 (1) IN GENERAL.—The Secretary of Health and  
5 Human Services (referred to in this subsection as  
6 the “Secretary”), acting through the Commissioner  
7 of Food and Drugs and in coordination with other  
8 Federal agencies, shall conduct oversight of the risks  
9 and benefits of drugs that are on the market and  
10 how such risks are presented in drug advertisements  
11 for the purpose of correcting false or misleading in-  
12 formation published in direct-to-consumer advertise-  
13 ments and to disseminate corrective information to  
14 health care providers and the general public regard-  
15 ing the risks and benefits of a drug on an quarterly  
16 basis.

17 (2) PREREVIEW OF TELEVISION ADVERTISE-  
18 MENTS.—The Secretary, acting through the Com-  
19 missioner of Food and Drugs and in consultation  
20 with relevant stakeholders, shall issue new, or up-  
21 date current, guidance issued under section 503C of  
22 the Federal Food, Drug, and Cosmetic Act (21  
23 U.S.C. 353c). In carrying out this paragraph, the  
24 Secretary shall focus on drugs that present the  
25 greatest risk to consumers, drugs that represent the

1 greatest proportion of total spending in Federal pro-  
2 grams, drugs with high unit price increases over the  
3 preceding year, drugs with high launch prices, or  
4 any other priority drugs identified by the Secretary.

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

10 **SEC. 406. DRUG MANUFACTURER DUTY TO DISCLOSE DRUG**  
11 **PRICES TO PRACTITIONERS.**

12 (a) DUTY TO DISCLOSE.—Whenever a drug manu-  
13 facturer, including any representative of the manufac-  
14 turer, communicates with a health care practitioner about  
15 a drug manufactured by the drug manufacturer, including  
16 through promotional, educational, or marketing commu-  
17 nications, meetings or paid events, and the provision of  
18 goods, gifts, and samples, the drug manufacturer shall dis-  
19 close to the practitioner the wholesale acquisition cost (as  
20 defined in section 1847A(c)(6)(B) of the Social Security  
21 Act (42 U.S.C. 1395w–3a(c)(6)(B))) for a 30-day supply  
22 of the drug, which may include a brief qualitative expla-  
23 nation of reduced cost availability for certain consumers.

24 (b) ENFORCEMENT BY FEDERAL TRADE COMMIS-  
25 SION.—

1           (1) UNFAIR OR DECEPTIVE ACTS OR PRAC-  
2           TICES.—A violation of subsection (a) by a person  
3           with respect to whom the Commission is empowered  
4           under section 5(a)(2) of the Federal Trade Commis-  
5           sion Act (15 U.S.C. 45(a)(2)) shall be treated as a  
6           violation of a rule defining an unfair or deceptive act  
7           or practice prescribed under section 18(a)(1)(B) of  
8           the Federal Trade Commission Act (15 U.S.C.  
9           57a(a)(1)(B)).

10           (2) POWERS OF FEDERAL TRADE COMMIS-  
11           SION.—

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

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

1       (c) RULEMAKING.—The Federal Trade Commission  
2 shall promulgate in accordance with section 553 of title  
3 5, United States Code, such rules as may be necessary  
4 to carry out this section.

5       (d) SAVINGS PROVISION.—Nothing in this section  
6 shall be construed to limit, impair, or supersede the oper-  
7 ation of the Federal Trade Commission Act (15 U.S.C.  
8 41 et seq.) or any other provision of Federal law.

○