

116TH CONGRESS
2D SESSION

S. 3166

To lower the cost of drugs for all Americans.

IN THE SENATE OF THE UNITED STATES

JANUARY 8, 2020

Mr. BOOKER (for himself, Mr. SANDERS, and Ms. HARRIS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To lower the cost of drugs for all Americans.

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.**

4 This Act may be cited as the “Prescription Drug Af-
5 fordability and Access Act”.

6 **SEC. 2. ESTABLISHMENT OF THE BUREAU OF PRESCRIP-**
7 **TION DRUG AFFORDABILITY AND ACCESS.**

8 (a) ESTABLISHMENT.—

9 (1) IN GENERAL.—There is established within
10 the Department of Health and Human Services an
11 independent bureau, known as the Bureau of Pre-

1 prescription Drug Affordability and Access (in this Act
2 referred to as the “Bureau”) to carry out the duties
3 described in this section. The purposes of the Bu-
4 reau are to—

5 (A) attain lower prescription drug costs for
6 patients;

7 (B) decrease government expenditures on
8 prescription drugs; and

9 (C) ensure access to prescription drugs.

10 (2) EXECUTIVE AGENCY.—The Bureau shall be
11 considered an Executive agency, as defined in sec-
12 tion 105 of title 5, United States Code.

13 (3) DIRECTOR.—

14 (A) APPOINTMENT.—The Bureau shall be
15 headed by a Director (in this Act referred to as
16 the “Director”) who shall be appointed by the
17 President, by and with the advice and consent
18 of the Senate.

19 (B) QUALIFICATION.—The President shall
20 nominate the Director from among individuals
21 who are citizens of the United States.

22 (C) TERM.—The Director shall serve for a
23 term of 5 years. The term of the first Director
24 to be appointed shall begin on the date that is

1 180 days after the date of enactment of this
2 Act.

3 (4) CONSULTATION.—

4 (A) IN GENERAL.—In carrying out the du-
5 ties under this section, the Bureau shall regu-
6 larly consult with relevant stakeholders, includ-
7 ing patients, representatives of relevant Federal
8 agencies, and medical and health care finance
9 experts. The Bureau shall have regular public
10 meetings to solicit input from relevant stake-
11 holders.

12 (B) PATIENT ENGAGEMENT.—

13 (i) IN GENERAL.—The Director shall
14 ensure that patients or organizations rep-
15 resenting patients have opportunities to
16 meaningfully engage with the Bureau as it
17 conducts its work, including while the Bu-
18 reau makes appropriate price determina-
19 tions under section 3(d). Such opportuni-
20 ties may include holding regular panels, fo-
21 rums, and other meetings for patient en-
22 gagement.

23 (ii) PETITION.—The Director shall es-
24 tablish a process by which patients can pe-

1 tition the entity and raise concerns about
2 the price of their prescription drugs.

3 (C) CONSUMER ADVISORY COUNCIL.—

4 (i) ESTABLISHMENT.—The Director
5 shall establish a Consumer Advisory Coun-
6 cil to advise and consult with the Bureau
7 as it conducts its work.

8 (ii) MEMBERSHIP.—The Council es-
9 tablished under this subparagraph shall be
10 composed of not fewer than 6 members ap-
11 pointed by the Director. In appointing
12 members to the Council, the Director shall
13 ensure that at least half of the members of
14 the Council are patients or organizations
15 representing patients, particularly those
16 who have been significantly impacted by
17 high priced medications. The Director shall
18 also seek to appoint members to the Coun-
19 cil who are experts in relevant areas, in-
20 cluding medicine and health care finance.

21 (iii) MEETINGS.—The Consumer Ad-
22 visory Council shall meet from time to time
23 at the call of the Director but shall meet
24 at least twice a year.

25 (5) EMPLOYMENT CONDITION.—

1 (A) IN GENERAL.—An individual who has
2 a conflict of interest shall not be appointed to
3 be a member of, or employed by, the Bureau,
4 including the Consumer Advisory Council estab-
5 lished under paragraph (4)(C).

6 (B) DISCLOSURE.—Individuals under con-
7 sideration for employment by, or appointment
8 to, the Bureau, including the Consumer Advi-
9 sory Council, must disclose any potential con-
10 flict of interest, including the type, nature, and
11 magnitude of the interests involved.

12 (b) DUTIES.—The Bureau shall carry out the fol-
13 lowing duties:

14 (1) Carry out the provisions of section 3.

15 (2) Submit the annual reports under subsection
16 (c).

17 (3) Any other duty that the Director determines
18 appropriate.

19 (c) ANNUAL REPORTING.—

20 (1) IN GENERAL.—Not later than January 1,
21 2021, and annually thereafter, the Director shall
22 submit to Congress a report on the activities of the
23 Bureau.

24 (2) CONTENTS.—Each report under paragraph

25 (1) shall contain the following:

1 (A) A description of the activities of the
2 Bureau, including—

3 (i) the total estimated savings
4 achieved by the Bureau since the most re-
5 cent report;

6 (ii) the disaggregated savings achieved
7 since the most recent report, including by
8 each therapeutic class of prescription
9 drugs;

10 (iii) a summary of the information
11 submitted by prescription drug manufac-
12 turers as required under section 3; and

13 (iv) the impact of the Bureau's work
14 on patient affordability and access to pre-
15 scription drugs.

16 (B) Recommendations for such legislation
17 and administrative action as the Bureau deter-
18 mines appropriate.

19 (C) A copy of each report submitted by
20 drug manufacturers as required under section
21 3.

22 (D) Other items that the Bureau deter-
23 mines appropriate.

24 (d) FUNDING.—There are appropriated, from
25 amounts in the Treasury not otherwise appropriated,

1 \$50,000,000 for fiscal year 2020 and each subsequent fis-
 2 cal year to carry out the activities of the Bureau. Amounts
 3 appropriated under the preceding sentence shall remain
 4 available until expended.

5 **SEC. 3. PRESCRIPTION DRUG CONSUMER PRICE PROTEC-**
 6 **TIONS.**

7 (a) REVIEW OF PRICES.—

8 (1) IN GENERAL.—The Bureau shall conduct
 9 reviews of the prices of prescription drugs to ensure
 10 that the wholesale acquisition cost of each such drug
 11 is appropriate.

12 (2) INFORMATION ON PRESCRIPTION DRUGS AP-
 13 PROVED AS OF ENACTMENT.—

14 (A) MANUFACTURER SUBMISSION.—With
 15 respect to any prescription drug that, as of the
 16 date of enactment of this Act, has in effect an
 17 application approved under section 505 of the
 18 Federal Food, Drug, and Cosmetic Act (21
 19 U.S.C. 355) or section 351 of the Public Health
 20 Service Act (42 U.S.C. 262), each manufac-
 21 turer, not later than 180 days after such date
 22 of enactment, shall provide to the Bureau the
 23 following information:

24 (i) The name of the prescription drug.

1 (ii) A description of the prescription
2 drug and its approved indications.

3 (iii) The number of individuals in the
4 United States and globally for which such
5 prescription drug is clinically indicated.

6 (iv) A list of patents that claim the
7 prescription drug, a use of the prescription
8 drug, a form of the prescription drug, a
9 method of use of the prescription drug, or
10 a method of manufacture of the prescrip-
11 tion drug.

12 (v) A list of government-granted
13 exclusivities that prohibit the submission
14 or approval of a prescription drug and the
15 date that each such government-granted
16 exclusivity was granted.

17 (vi) The date on which the prescrip-
18 tion drug was approved under such section
19 505 or such section 351 of the Public
20 Health Service Act.

21 (vii) The total expenditures of the
22 manufacturer on—

23 (I) domestic and foreign research
24 and development, including an
25 itemized description of—

1 (aa) clinical research, includ-
2 ing the cost of each clinical trial
3 associated with the prescription
4 drug, reported separately for
5 each clinical trial;

6 (bb) the development of al-
7 ternative dosage forms and
8 strengths for the prescription
9 drug molecule or combinations,
10 including the molecule;

11 (cc) other prescription drug
12 development activities, such as
13 nonclinical laboratory studies and
14 record and report maintenance;

15 (dd) pursuing new or ex-
16 panded indications for such pre-
17 scription drug through supple-
18 mental applications under such
19 section 505 or such section 351;

20 (ee) carrying out postmarket
21 requirements related to such pre-
22 scription drug, including under
23 subsection (o) of such section
24 505 or such section 351;

1 (ff) carrying out risk evalua-
2 tion and mitigation strategies in
3 accordance with section 505–1 of
4 the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 355–1)
6 or such section 351; and

7 (gg) marketing research;

8 (II) the acquisition of prescrip-
9 tion drug components and packaging,
10 in total and per unit sold, broken out
11 by source and cost and identifying
12 specific costs that reflect internal
13 transfers within the manufacturer’s
14 company;

15 (III) other acquisitions relating
16 to the prescription drug, including for
17 the purchase of patents and licensing
18 or acquisition of any corporate entity
19 owning any rights to the drug during
20 or after development of the prescrip-
21 tion drug;

22 (IV) the cost of manufacturing
23 the prescription drug;

24 (V) marketing, advertising, and
25 educating for the promotion of a pre-

1 scription drug, including a breakdown
2 of amounts aimed at consumers, pre-
3 scribers, managed care organizations,
4 and others, irrespective of whether a
5 prescription drug is mentioned in
6 marketing, advertising, or educating;
7 and

8 (VI) patient assistance and co-
9 pay programs that the manufacturer
10 sponsors or contributes to.

11 (viii) The gross revenue, net revenue,
12 gross profit, and net profit of the manufac-
13 turer with respect to such prescription
14 drug.

15 (ix) The total number of units of such
16 prescription drug that were sold in inter-
17 state commerce.

18 (x) Pricing information with respect
19 to the sale of such prescription drug, in-
20 cluding—

21 (I) the current wholesale acquisi-
22 tion cost;

23 (II) the introductory wholesale
24 acquisition cost;

1 (III) the net average price real-
2 ized by pharmacy benefit managers
3 for such prescription drug provided to
4 individuals in the United States, after
5 accounting for any rebates or other
6 payments from the manufacturer to
7 the pharmacy benefit manager and
8 from the pharmacy benefit manager
9 to the manufacturer;

10 (IV) the list price of such pre-
11 scription drug charged to purchasers
12 in each applicable prescription drug
13 reference country;

14 (V) the net price of such pre-
15 scription drug, after accounting for
16 discounts, rebates, or other financial
17 considerations, charged to purchasers
18 in each applicable prescription drug
19 reference country;

20 (VI) a description of all price
21 changes of the prescription drug since
22 the introductory wholesale acquisition
23 cost; and

24 (VII) the average net price of
25 such prescription drug for each year

1 since first being sold in the United
2 States.

3 (xi) Any Federal benefits and
4 amounts and periods of impact for each
5 such benefit received by the manufacturer
6 with respect to the prescription drug, in-
7 cluding tax credits, Federal grants, patent
8 applications that benefitted from such
9 grants, patent extensions, exclusivity peri-
10 ods, and waivers of fees.

11 (xii) The percentage of research and
12 development expenditures described in this
13 section that were derived from Federal
14 funds.

15 (xiii) Executive compensation for the
16 chief executive officer, chief financial offi-
17 cer, and the three other most highly com-
18 pensated executive officers, including bo-
19 nuses, paid by such manufacturer, and
20 stock options affiliated with the manufac-
21 turer that were offered to or accrued by
22 such officers.

23 (xiv) Other information as the Direc-
24 tor may require.

1 (B) BUREAU REVIEW PRIORITIES.—In re-
2 viewing submissions under subparagraph (A),
3 the Bureau shall prioritize prescription drugs
4 that meet any of the following criteria:

5 (i) In the top 50th percentile of net
6 spending on prescription drugs under any
7 Federal program, including the Medicare
8 program under title XVIII of the Social
9 Security Act (42 U.S.C. 1395 et seq.) or
10 the Medicaid program under title XIX of
11 such Act (42 U.S.C. 1396 et seq.).

12 (ii) In the top 50th percentile of utili-
13 zation under any Federal program, includ-
14 ing such Medicare program or such Med-
15 icaid program.

16 (iii) Experienced an increase in the
17 wholesale acquisition cost of 25 percent or
18 more over the preceding 3 years.

19 (iv) Other qualifications, as deter-
20 mined by the Director.

21 (3) INFORMATION ON PRESCRIPTION DRUGS AP-
22 PROVED AFTER ENACTMENT.—With respect to any
23 prescription drug approved under section 505 of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 355) or section 351 of the Public Health Service Act

1 (42 U.S.C. 262) after the date of enactment of this
2 Act, each manufacturer, not later than 45 days prior
3 to introducing such prescription drug into interstate
4 commerce in the United States, shall provide to the
5 Bureau the following information:

6 (A) The information described in the fol-
7 lowing provisions of paragraph (2)(A):

8 (i) Clauses (i) through (vi).

9 (ii) Subclauses (I) through (IV) of
10 clause (vii).

11 (iii) Clauses (xi) through (xiv).

12 (B) Pricing information with respect to the
13 sale of such prescription drug, including—

14 (i) the planned introductory wholesale
15 acquisition cost;

16 (ii) the list price of such prescription
17 drug charged or planned to be charged to
18 purchasers in each applicable prescription
19 drug reference country; and

20 (iii) the net price of such prescription
21 drug, after accounting for discounts, re-
22 bates, or other financial considerations,
23 charged or planned to be charged to pur-
24 chasers in each applicable prescription

1 drug reference country, as defined in this
2 Act.

3 (C) The estimated annual profit and rev-
4 enue that will be generated by the prescription
5 drug, both domestically and globally.

6 (D) Other information as the Director may
7 require.

8 (b) REVIEW OF CERTAIN PRICE INCREASES.—

9 (1) IN GENERAL.—The Bureau shall conduct a
10 review of the price of a prescription drug for which
11 a submission is required under paragraph (2).

12 (2) NOTIFICATION OF INTENTION TO INCREASE
13 PRICE.—If a manufacturer intends to increase the
14 wholesale acquisition cost of a prescription drug by
15 more than the percentage by which the Consumer
16 Price Index for All Urban Consumers for that year
17 exceeds such index for the preceding calendar year,
18 such manufacturer, not later than 60 days before
19 the price increase takes effect, shall submit to the
20 Bureau the following information:

21 (A) The information described in sub-
22 section (a)(2)(A).

23 (B) The planned increase in the wholesale
24 acquisition cost and the planned date the in-
25 crease will go into effect.

1 (C) A justification of the planned increase
2 in wholesale acquisition cost.

3 (D) Any other information as the Sec-
4 retary may require.

5 (c) REVENUE BENCHMARK REVIEW.—

6 (1) IN GENERAL.—The Bureau shall conduct a
7 review of a prescription drug when revenue for such
8 prescription drug surpasses the revenue benchmark
9 in order to ensure that the wholesale acquisition cost
10 of the prescription drug remains appropriate.

11 (2) REQUIRED SUBMISSION.—Not later than 60
12 days before the manufacturer of a prescription drug
13 anticipates the global revenue for such drug will sur-
14 pass the revenue benchmark, the manufacturer shall
15 submit to the Bureau the information outlined in
16 subsection (a)(2)(A).

17 (3) REVENUE BENCHMARK.—

18 (A) IN GENERAL.—Subject to subpara-
19 graph (B), for purposes of this subsection, the
20 revenue benchmark is \$5,000,000,000 in global
21 revenue.

22 (B) UPDATE.—The Bureau may update
23 the amount of the global benchmark over time.

24 (d) GENERAL AUTHORITY TO REVIEW.—

1 (1) IN GENERAL.—The Bureau may at any
2 time review the wholesale acquisition cost of a pre-
3 scription drug to determine if such price is appro-
4 priate, including in response to a patient petition as
5 described in section (2)(a)(3)(B)(ii).

6 (2) PROCEDURE.—The Bureau shall notify the
7 manufacturer of a prescription drug it wishes to re-
8 view pursuant to the authority under this subsection,
9 and, within 45 days of receiving such a notification,
10 the manufacturer shall submit to the Bureau infor-
11 mation the Bureau determines necessary for its re-
12 view.

13 (e) APPROPRIATE PRICE DETERMINATIONS.—

14 (1) CONSIDERATIONS.—In determining whether
15 the wholesale acquisition cost or proposed wholesale
16 acquisition cost of a prescription drug is appro-
17 priate, the Bureau shall consider the following:

18 (A) The size of the affected patient popu-
19 lation.

20 (B) The therapeutic benefits of the pre-
21 scription drug to patients.

22 (C) The impact of the price on access to
23 the prescription drug, including for patients
24 who are uninsured, and the associated financial

1 burden on patients that utilize such prescription
2 drug.

3 (D) The total annual Federal Government
4 expenditures on the prescription drug and the
5 budgetary impact of Federal health programs
6 providing coverage of the prescription drug.

7 (E) The risk-adjusted value of Federal
8 Government subsidies and investments related
9 to the prescription drug.

10 (F) The costs associated with the develop-
11 ment of the prescription drug.

12 (G) The number of similarly effective pre-
13 scription drugs or alternative treatment regi-
14 mens for each approved use of such prescription
15 drug.

16 (H) Whether the prescription drug pro-
17 vided a significant improvement in health out-
18 comes, compared to other therapies available at
19 the time of its approval, as determined through
20 clinical effectiveness.

21 (I) The current wholesale acquisition cost
22 of comparable prescription drugs in the United
23 States, to the extent that those prices have been
24 deemed appropriate.

1 (J) The cumulative and expected global
2 revenue generated by the prescription drug.

3 (K) The price of the drug in other coun-
4 tries, including in the prescription drug ref-
5 erence countries.

6 (L) The public health benefit of the drug.

7 (M) The information that the manufac-
8 turer submits to the Bureau as required under
9 this section.

10 (N) Any other information, as the Bureau
11 requires.

12 (2) SPECIAL RULES.—

13 (A) INTERIM APPROPRIATE PRICE OF PRE-
14SCRIPTION DRUGS.—

15 (i) IN GENERAL.—For each prescrip-
16 tion drug described in clause (ii), the Bu-
17 reau shall—

18 (I) establish an interim appro-
19 priate price, which shall be the lesser
20 of—

21 (aa) the median list price of
22 the prescription drug in the pre-
23 scription drug reference coun-
24 tries; or

1 (bb) if applicable, the appro-
2 priate price determination made
3 by the Bureau; and

4 (II) direct the manufacturer to
5 set the wholesale acquisition cost at a
6 level that does not exceed the interim
7 appropriate price.

8 (ii) APPLICABLE DRUGS.—A prescrip-
9 tion drug described in this clause is a pre-
10 scription drug—

11 (I) that—

12 (aa) as of the date of the en-
13 actment of this Act, has in effect
14 an application approved under
15 section 505(c) of the Federal
16 Food, Drug, and Cosmetic Act
17 (21 U.S.C. 355(c)) or section
18 351(a) of the Public Health Serv-
19 ice Act (42 U.S.C. 262(a)); and

20 (bb) is not a listed drug or
21 a reference product for more
22 than 2 prescription drugs or bio-
23 logical products approved and
24 currently marketed under section
25 505(j) of the Federal Food,

1 Drug, and Cosmetic Act (21
2 U.S.C. 355(j)) or under section
3 351(k) of the Public Health
4 Service Act (42 U.S.C. 262(k));
5 or

6 (II) with respect to which the
7 Secretary has authorized under sub-
8 section (g) the use of any patent, clin-
9 ical trial data, or other government-
10 granted exclusivity related to such
11 drug by another sponsor, until the
12 date that is 1 year after the date on
13 which another application for such
14 drug, for which the sponsor relies
15 upon a such authorization under sub-
16 section (g), is approved under such
17 section 505 or such section 351.

18 (B) SPIKE IN PRICE.—If a manufacturer
19 increases the wholesale acquisition cost of a
20 prescription drug by more than the percentage
21 by which the Consumer Price Index for All
22 Urban Consumers for that year exceeds such
23 index for the preceding calendar year, such pre-
24 scription drug shall be deemed to have a whole-
25 sale acquisition cost that is not appropriate un-

1 less the Bureau determines, based on the infor-
2 mation submitted under paragraphs (2) and (3)
3 of subsection (a) and under subsection (b)(2)
4 and the considerations described in paragraph
5 (1), that the wholesale acquisition cost is appro-
6 priate.

7 (3) OPPORTUNITY TO COMMENT.—Prior to
8 making a determination on whether the wholesale
9 acquisition cost of a prescription drug is appro-
10 priate, the Bureau shall ensure relevant stake-
11 holders, including patients, have an opportunity to
12 comment.

13 (f) REQUIRED ACTIONS IF PRICE IS NOT APPRO-
14 PRIATE.—

15 (1) NOTICE AND REQUIREMENT TO REMIT EX-
16 CESS.—If the Bureau determines that the wholesale
17 acquisition cost of a prescription drug is not appro-
18 priate, the Bureau shall notify and direct the manu-
19 facturer to lower the wholesale acquisition cost to a
20 level that would be deemed appropriate. The Bureau
21 shall also require the manufacturer to remit the ex-
22 cess revenue earned as a result of the prescription
23 drug having a price that is not appropriate.

24 (2) PATIENT REBATE.—The Director of the
25 Bureau shall establish a process to distribute funds

1 remitted under paragraph (1) to patients who were
2 impacted by the prescription drug having a price
3 that is not appropriate.

4 (g) ENFORCEMENT.—

5 (1) IN GENERAL.—If, within 30 days of receiv-
6 ing a notice that the wholesale acquisition cost of a
7 prescription drug is not appropriate, the manufac-
8 turer of such prescription drug fails to lower the
9 wholesale acquisition cost of a prescription drug or
10 fails to remit excessive revenue earned in accordance
11 with subsection (f), the Director shall notify the Sec-
12 retary and the Secretary shall authorize the use of
13 any patent, clinical trial data, or other government-
14 granted exclusivity by an entity for purposes of man-
15 ufacturing such prescription drug for sale. An entity
16 that wishes to manufacture such prescription drug
17 for sale must agree to—

18 (A) set the wholesale acquisition cost of
19 such prescription drug at or below the level that
20 the Bureau determines is appropriate; and

21 (B) provide the prescription drug manufac-
22 turer with reasonable compensation, which shall
23 be determined by the Bureau, based on the in-
24 formation submitted by the manufacturer under
25 this section including—

1 (i) the risk-adjusted value of any Fed-
2 eral Government subsidies and investments
3 in research and development used to sup-
4 port the development of such drug;

5 (ii) the risk-adjusted value of any in-
6 vestment made by such manufacturer in
7 the research and development of such
8 drug;

9 (iii) the impact of the price, including
10 license compensation payments, on meeting
11 the medical need of all patients;

12 (iv) the relationship between the price
13 of such drug, including compensation pay-
14 ments and the health benefits of such
15 drug; and

16 (v) other relevant information deter-
17 mined appropriate by the Secretary, in co-
18 ordination with the Director.

19 (2) POST LICENSING.—

20 (A) IN GENERAL.—Any manufacturer of a
21 prescription drug that fails to comply with the
22 interim appropriate price under subsection
23 (e)(2)(A)(i)(I) shall be subject to a civil mone-
24 tary penalty of not less than an amount equal
25 to 150 percent of all revenues obtained by the

1 manufacturer that are in excess of the expected
2 revenues at the interim appropriate price.

3 (B) PROCEDURE.—The provisions of sec-
4 tion 1128A, other than subsections (a) and (b)
5 and the first sentence of subsection (c)(1) of
6 such section, shall apply to civil monetary pen-
7 alties under this paragraph in the same manner
8 as such provisions apply to a penalty or pro-
9 ceeding under section 1128A.

10 (C) TRANSFER TO NATIONAL INSTITUTES
11 OF HEALTH.—The civil monetary penalties col-
12 lected under this paragraph shall be transferred
13 to the National Institutes of Health to supple-
14 ment activities related to pharmaceutical re-
15 search and development.

16 (h) DEFINITIONS.—In this Act:

17 (1) CONFLICT OF INTEREST.—The term “con-
18 flict of interest” means an association, including a
19 financial or personal association, or past employ-
20 ment, that has the potential to bias or have the ap-
21 pearance of biasing an individual’s decisions.

22 (2) EXCESS REVENUE.—The term “excess rev-
23 enue” means the difference between a prescription
24 drug’s wholesale acquisition cost at the time of the
25 Bureau review under this section and the maximum

1 wholesale acquisition price for the prescription drugs
2 that the Bureau determines to be appropriate.

3 (3) GOVERNMENT-GRANTED EXCLUSIVITY.—
4 The term “government-granted exclusivity” means
5 prohibitions on the submission or effective approval
6 of prescription drug applications granted under any
7 of the following:

8 (A) Clauses (ii) through (v) of section
9 505(c)(3)(E) of the Federal Food, Drug, and
10 Cosmetic Act (21 U.S.C. 355(c)(3)(E)).

11 (B) Section 505(j)(5)(B)(iv) of such Act
12 (21 U.S.C. 355(j)(5)(B)(iv)) or clause (ii), (iii),
13 or (iv) of section 505(j)(5)(F) of such Act.

14 (C) Section 505A of such Act (21 U.S.C.
15 355a).

16 (D) Section 505E of such Act (21 U.S.C.
17 355f).

18 (E) Section 527 of such Act (21 U.S.C.
19 360cc).

20 (F) Section 351(k)(7) of such Act (42
21 U.S.C. 262(k)(7)).

22 (G) Any other provision of law that pro-
23 vides for exclusivity (or extension of exclusivity)
24 with respect to a drug.

1 (4) LISTED DRUG.—The term “listed drug”
2 means a drug listed under section 505(j)(7) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 355(j)(7)).

5 (5) MANUFACTURER.—The term “manufac-
6 turer”, with respect to a prescription drug, means
7 an entity that—

8 (A) is the holder of the approved applica-
9 tion under section 505 of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 355) or
11 under section 351 of the Public Health Service
12 Act (42 U.S.C. 262); and

13 (B) is responsible for setting the price of
14 the prescription drug.

15 (6) PRESCRIPTION DRUG.—The term “prescrip-
16 tion drug” means any drug subject to section 505 of
17 the Federal Food, Drug, and Cosmetic Act or sec-
18 tion 351 of the Public Health Service Act and to
19 section 503(b)(2) of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 353(b)(2)).

21 (7) PRESCRIPTION DRUG REFERENCE COUN-
22 TRY.—The term “prescription drug reference coun-
23 try” means Japan, Germany, the United Kingdom,
24 France, Italy, Canada, Australia, Spain, the Nether-
25 lands, Switzerland, and Sweden.

1 (8) REFERENCE PRODUCT.—The term “ref-
 2 erence product” has the meaning given the term in
 3 section 351(i) of the Public Health Service Act (42
 4 U.S.C. 262(i)).

5 (9) SECRETARY.—The term “Secretary” means
 6 the Secretary of Health and Human Services.

7 (10) WHOLESALE ACQUISITION COST.—The
 8 term “wholesale acquisition cost” has the meaning
 9 given that term in section 1847A(c)(6)(B) of the So-
 10 cial Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).

11 **SEC. 4. REPEAL OF MEDICARE’S NONINTERFERENCE**
 12 **CLAUSE.**

13 Section 1860D–11 of the Social Security Act (42
 14 U.S.C. 1395w–111) is amended by striking subsection (i).

○