

116TH CONGRESS
1ST SESSION

S. 102

To significantly lower prescription drug prices for patients in the United States by ending government-granted monopolies for manufacturers who charge drug prices that are higher than the median prices at which the drugs are available in other countries.

IN THE SENATE OF THE UNITED STATES

JANUARY 10, 2019

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

A BILL

To significantly lower prescription drug prices for patients in the United States by ending government-granted monopolies for manufacturers who charge drug prices that are higher than the median prices at which the drugs are available in other countries.

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
5 Price Relief Act of 2019”.

1 **SEC. 2. IDENTIFICATION OF EXCESSIVELY PRICED DRUGS.**

2 (a) IN GENERAL.—The Secretary, not later than 1
3 year after the date of enactment of this Act, shall establish
4 a process to conduct a review of all brand name drugs,
5 not less frequently than once per calendar year, under
6 which the Secretary determines under subsection (b)
7 whether the price of each such drug is excessive.

8 (b) EXCESSIVE PRICE DETERMINATIONS.—

9 (1) INTERNATIONAL REFERENCE PRICE.—

10 (A) IN GENERAL.—The Secretary shall de-
11 termine that any brand name drug for which
12 the domestic average manufacturing price ex-
13 ceeds the median price charged for such drug in
14 the 5 reference countries to have an excessive
15 price. In assessing the extent to which the price
16 is excessive, the Secretary shall consider the
17 factors described in paragraph (2).

18 (B) REFERENCE COUNTRIES.—In this Act,
19 the term “reference countries” means Canada,
20 the United Kingdom, Germany, France, and
21 Japan.

22 (C) REQUIREMENT WITH RESPECT TO
23 DRUGS FOR WHICH CERTAIN REFERENCE COUN-
24 TRY INFORMATION IS NOT AVAILABLE.—The
25 Secretary shall make a determination under
26 paragraph (1) for every brand name drug for

1 which pricing information is available for at
2 least 3 of the 5 reference countries.

3 (2) DETERMINATIONS BASED ON OTHER FAC-
4 TORS.—With respect to any brand name drug that
5 is not determined to have an excessive price by oper-
6 ation of paragraph (1) (including any drug for which
7 there is insufficient data to make such a determina-
8 tion under such paragraph), the Secretary shall de-
9 termine that such drug has an excessive price if the
10 price of the drug is higher than reasonable taking
11 into account the following factors:

12 (A) The size of the affected patient popu-
13 lation.

14 (B) The value of the drug to patients, in-
15 cluding the impact of the price on access to the
16 drug and the relationship of the price of the
17 drug to its therapeutic health benefits.

18 (C) The risk adjusted value of Federal
19 Government subsidies and investments related
20 to the drug.

21 (D) The costs associated with development
22 of the drug.

23 (E) Whether the drug provided a signifi-
24 cant improvement in health outcomes, com-

pared to other therapies available at the time of its approval.

(F) The cumulative global revenues generated by the drug.

(G) Whether the domestic average manufacturer price of the drug increased during any annual quarter by a percentage that is more than the percentage increase in the consumer price index for all urban consumers for the respective annual quarter.

(H) Other factors the Secretary determines appropriate.

(c) PETITION FOR DETERMINATION.—

(1) IN GENERAL.—Any person may petition the Secretary, in accordance with section 553(e) of title 5, United States Code, to make an excessive drug price determination for an applicable drug under subsection (b)(2). Not later than 90 days after the date of receipt of such a petition, subject to paragraph (2), the Secretary shall—

(A) make a determination under subsection (b)(2) regarding such drug; or

(B)(i) decline to make such a determination; and

1 (ii) make public the reasons why the Sec-
 2 retary has declined to make such a determina-
 3 tion.

4 (2) EXCEPTION.—The Secretary shall not make
 5 a determination under subsection (b)(2) for a drug
 6 in response to a petition under this section more fre-
 7 quently than once per calendar year.

8 (3) PUBLIC AVAILABILITY.—The Secretary
 9 shall make any petitions submitted under this sub-
 10 section, together with any documentation related to
 11 the petitions and the Secretary's determinations on
 12 such petitions and rationale for such determinations,
 13 publicly available, including by posting such informa-
 14 tion on the database under section 5.

15 **SEC. 3. ENDING GOVERNMENT-GRANTED MONOPOLIES FOR**
 16 **EXCESSIVELY PRICED DRUGS.**

17 (a) EXCESSIVE DRUG PRICE AUTHORITY.—With re-
 18 spect to any brand name drug, if the Secretary determines
 19 under section 2 that the price of the drug is excessive,
 20 the Secretary—

21 (1) shall waive or void any government-granted
 22 exclusivities with respect to such drug, effective on
 23 the date that the excessive price determination under
 24 section 2 is made for such drug; and

1 (2) shall grant open, non-exclusive licenses al-
2 lowing any person to make, use, offer to sell or sell,
3 or import into the United States such drug, and to
4 rely upon the regulatory test data of such drug, in
5 accordance with section 4.

6 (b) EXPEDITED REVIEW.—The Secretary shall
7 prioritize the review of, and act within 8 months of the
8 date of the submission of a generic drug application or
9 a biosimilar biological product application if such applica-
10 tion references a drug licensed under subsection (a)(2).

11 (c) CIVIL ACTIONS.—If the Secretary determines that
12 the manufacturer of an excessively priced drug (as deter-
13 mined under section 2(a)) has increased the price of such
14 drug during the period beginning on the date on which
15 such price determination is made and ending on the date
16 on which an entity begins manufacturing the drug under
17 an open, non-exclusive license under subsection (a)(2), the
18 Secretary may file a civil action in the United States dis-
19 trict court for the district in which the manufacturer is
20 located, or in the United States district court for the Dis-
21 trict of Columbia, to recover damages in an amount equal
22 to not less than the total amount of revenue derived by
23 the manufacturer as a result of any such price increase
24 during such period. In actions brought under this sub-
25 section, the district courts shall have jurisdiction to grant

1 all appropriate relief including, but not limited to, injunc-
 2 tive relief and compensatory damages.

3 **SEC. 4. EXCESSIVE DRUG PRICE LICENSE.**

4 (a) REASONABLE ROYALTY.—

5 (1) IN GENERAL.—An entity accepting an open,
 6 non-exclusive license under section 3(a)(2) shall pay
 7 a reasonable royalty to the holder of a patent that
 8 claims the drug or that claims a use of the drug or
 9 to the holder of an application approved under sub-
 10 section 505(c) of the Federal Food, Drug, and Cos-
 11 metic Act or section 351(a) of the Public Health
 12 Service Act for which any government-granted exclu-
 13 sivity with respect to the drug was terminated under
 14 section 5(a)(1).

15 (2) ROYALTY RATE.—Such royalty rate shall
 16 be—

17 (A) a percentage of sales, where the per-
 18 centage rate is no higher than the average roy-
 19 alty rate estimated from the data provided by
 20 the Internal Revenue Service for pharma-
 21 ceutical manufacturer Federal income tax re-
 22 turns; or

23 (B) an amount as determined by the Sec-
 24 retary, taking into account—

25 (i) the value of the drug to patients;

1 (ii) the size of the affected patient
2 population;

3 (iii) the risk adjusted value of the
4 Federal Government subsidies and invest-
5 ments related to the drug;

6 (iv) whether the drug provided a sig-
7 nificant improvement in health outcomes,
8 compared to other therapies available at
9 the time of the approval;

10 (v) the extent to which the brand
11 name drug manufacturer has recovered
12 risk adjusted investments related to the
13 drug, including the investments related to
14 the invention, regulatory test data and any
15 other relevant research and development
16 costs; and

17 (vi) any other information the Sec-
18 retary determines appropriate.

19 (b) REQUIREMENTS.—

20 (1) IN GENERAL.—A royalty rate under sub-
21 section (a) shall be consistent with making drugs
22 available to purchasers, including Federal, State,
23 local, and nongovernmental purchasers and individ-
24 uals, at prices that are affordable and reasonable.
25 Under no condition shall a royalty be set at a rate

1 that would cause a product for which an open, non-
2 exclusive license was issued under section 3 to be
3 sold at an excessive price, as determined under sec-
4 tion 2.

5 (2) MULTIPLE AFFECTED PARTIES.—In the
6 case that there is one or more holders or investors
7 in the patented inventions related to the drug in ad-
8 dition to the brand name manufacturer, the royalty
9 rate shall be divided among the holders or investors
10 (including such manufacturer) in a manner agreed
11 upon by the manufacturer and other holders or in-
12 vestors, or, in the absence of such an agreement, in
13 a manner the Secretary determines to be appro-
14 priate.

15 (3) PRICE.—An entity accepting an open, non-
16 exclusive license under section 3(a)(2) shall sell the
17 drug at a price not higher than the excessive price
18 determined for that drug under section 2(b).

19 **SEC. 5. PUBLIC EXCESSIVE DRUG PRICE DATABASE.**

20 (a) EXCESSIVE DRUG PRICE DATABASE.—

21 (1) IN GENERAL.—The Secretary shall establish
22 and maintain a comprehensive, up-to-date database
23 of brand name drugs and the excessive price deter-
24 minations for such drugs under section 2.

1 (2) CONTENTS.—The database shall include, at
2 a minimum, for each brand name drug, for the ap-
3 plicable calendar year—

4 (A) the name of the drug;

5 (B) the manufacturer;

6 (C) whether the drug was determined
7 under section 2(b) to have an excessive price;

8 (D) the number of petitions the Secretary
9 received under section 2(c) to make an exces-
10 sive price determination for the drug, together
11 with the information described in section
12 2(c)(3);

13 (E) the number of open, non-exclusive li-
14 censes the Secretary has granted under section
15 3(a)(2) for generic drug or biosimilar biological
16 product versions of the drug; and

17 (F) the number of applications under sub-
18 section (b)(2) or (j) of section 505 of the Fed-
19 eral Food, Drug, and Cosmetic Act or under
20 section 351(k) of the Public Health Service Act
21 submitted to the Secretary, pursuant to such a
22 license granted under section 3(a)(2), and the
23 number of such applications that have been ap-
24 proved.

1 (3) CERTAIN DETERMINATIONS.—With respect
2 to a determination made under section 2(b)(1), the
3 Secretary shall publish on the database such deter-
4 mination in accordance with paragraph (1) within
5 30 days of receiving domestic and international pric-
6 ing information from manufacturers under section 6.

7 (b) ANNUAL REPORTS TO CONGRESS.—Not later
8 than 60 days after the first excessive price review under
9 section 2 is complete, and annually thereafter, the Sec-
10 retary shall submit to Congress a report describing the
11 excessive drug price review for the preceding year. The
12 report shall contain summary data regarding—

13 (1) the total number of drugs that were re-
14 viewed;

15 (2) the total number of drugs determined to be
16 excessively priced under each of paragraphs (1) and
17 (2) of section 2(b), and the name and manufacturer
18 of each such drug;

19 (3) the total number of drugs determined to be
20 excessively priced, listed by manufacturer;

21 (4) the extent to which the prices of the drugs
22 identified under section 2 were higher than reason-
23 able, on average;

1 (5) the total number of drugs for which an
2 open-non-exclusive license has been granted under
3 section 3(a)(2);

4 (6) the total number of generic drug or bio-
5 similar biological product applications received and
6 approved that reference a drug so licensed;

7 (7) the median approval time for generic drug
8 or biosimilar biological product applications that ref-
9 erence a drug so licensed;

10 (8) the total number of petitions the Secretary
11 received under section 2(c) to make excessive price
12 determinations for drugs;

13 (9) a list of any manufacturers who failed to re-
14 port information as required under section 6; and

15 (10) other appropriate information, as the Sec-
16 retary determines or as Congress requests.

17 (c) PUBLIC AVAILABILITY.—The Secretary shall
18 make the information in the database described in sub-
19 section (a) and the report in subsection (b) publicly avail-
20 able, including on the internet website of the Food and
21 Drug Administration, in a manner that is easy to find and
22 understand.

23 **SEC. 6. DRUG MANUFACTURER REPORTING.**

24 (a) IN GENERAL.—Each manufacturer shall submit
25 to the Secretary, in such format as the Secretary may re-

1 quire, an annual report that includes the following infor-
2 mation for each brand name drug of the manufacturer,
3 with respect to the previous calendar year:

4 (1) The average manufacturer price of the drug
5 in the United States and in the reference countries,
6 for the entire year, and broken down for each quar-
7 ter of the year.

8 (2) The wholesale acquisition cost of the drug
9 in the United States and in the reference countries,
10 for the entire year, and broken down for each quar-
11 ter of the year.

12 (3) Cumulative global revenues generated by
13 the drug.

14 (4) Annual net sales revenue generated by the
15 drug in the United States and in the reference coun-
16 tries, for the entire year, and broken down for each
17 quarter of the year.

18 (5) Total expenditures on domestic and foreign
19 drug research and development related to the drug,
20 itemized by—

21 (A) basic and preclinical research;

22 (B) clinical research, reported separately
23 for each clinical trial;

1 (C) development of alternative dosage
2 forms and strengths for the drug molecule or
3 combinations, including the molecule;

4 (D) other drug development activities, such
5 as nonclinical laboratory studies and record and
6 report maintenance;

7 (E) pursuing new or expanded indications
8 for such drug through supplemental applica-
9 tions under section 505 of the Federal Food,
10 Drug, and Cosmetic Act; and

11 (F) carrying out postmarket requirements
12 related to such drug, including under section
13 505(o)(3) of the Federal Food, Drug, and Cos-
14 metic Act.

15 (6) Total expenditures on domestic and foreign
16 marketing and advertising related to the drug.

17 (7) Investments in human clinical trials related
18 to the drug, by each trial and each year, including
19 grants, research contracts, tax credits or deductions,
20 and reimbursements from public or private health
21 plans or insurance, and any other public sector sub-
22 sidies or incentives, such as the fair market value or
23 priority review vouchers or other considerations.

24 (8) The estimated size of the affected patient
25 population.

1 (9) Additional information the manufacturer
2 chooses to provide related to drug pricing decisions,
3 such as information related to the methodology used
4 to set the price of the drug.

5 (10) Additional information as the Secretary
6 determines necessary to carry out this Act, including
7 information for previous years.

8 (b) REPORT DUE DATE.—Applicable manufacturers
9 shall submit the reports described in subsection (a) not
10 later than January 15 of the year following the date of
11 enactment of this Act, and of each year thereafter.

12 (c) PENALTY FOR NONCOMPLIANCE.—

13 (1) IN GENERAL.—Any manufacturer that fails
14 to submit information for a drug as required by this
15 section on a timely basis or that knowingly provides
16 false information shall be liable for a civil monetary
17 penalty, as determined by the Secretary under para-
18 graph (2), in addition to any other penalty under
19 other applicable provisions of law.

20 (2) AMOUNT OF PENALTY.—The amount of a
21 civil penalty under paragraph (1) shall be equal to
22 the product of—

23 (A) an amount, as determined appropriate
24 by the Secretary, which is—

1 (i) not less than 0.5 percent of the
 2 gross revenues from sales for the previous
 3 calendar year of the drug for which the in-
 4 formation was not submitted; and

5 (ii) not greater than 1 percent of the
 6 gross revenues from sales for the previous
 7 calendar year of such drug; and

8 (B) the number of days in the period be-
 9 tween—

10 (i) the report due date under sub-
 11 section (b); and

12 (ii) the date on which the Secretary
 13 receives the information required to be re-
 14 ported by the manufacturer under this sec-
 15 tion.

16 (3) USE OF CIVIL PENALTY.—The Secretary
 17 shall collect the civil penalties under this subsection
 18 and shall use such funds to support competitive re-
 19 search grant programs of the National Institutes of
 20 Health.

21 **SEC. 7. PROHIBITION OF ANTICOMPETITIVE BEHAVIOR.**

22 No manufacturer may engage in anticompetitive be-
 23 havior violating section 5(a) of the Federal Trade Com-
 24 mission Act (15 U.S.C. 45(a)) with another manufacturer
 25 that may interfere with the issuance and implementation

1 of open, non-exclusive licenses under this Act or otherwise
 2 run contrary to the public interest in the availability of
 3 affordable prescription drugs.

4 **SEC. 8. DEFINITIONS.**

5 For the purposes of this Act:

6 (1) AVERAGE MANUFACTURER PRICE.—

7 (A) IN GENERAL.—The term “average
 8 manufacturer price”, with respect to a drug,
 9 subject to subparagraph (B), has the meaning
 10 given such term in section 1927(k)(1) of the
 11 Social Security Act (42 U.S.C. 1396r–8(k)(1));
 12 or with respect to a drug for which there is no
 13 average manufacturer price as so defined, such
 14 term shall mean the wholesale acquisition cost
 15 (as defined in section 1847A(c)(6)(B) of the
 16 Social Security Act (42 U.S.C. 1395w–
 17 3a(c)(6)(B)) of the drug.

18 (B) APPLICATION TO REFERENCE COUN-
 19 TRIES.—With respect to reference countries,
 20 the term “average manufacturer price”, as de-
 21 fined in subparagraph (A), shall be determined
 22 based on the price of the drug in the applicable
 23 reference country.

24 (2) BIOSIMILAR BIOLOGICAL PRODUCT.—The
 25 term “biosimilar biological product” means a biologi-

1 cal product licensed pursuant to an application
2 under section 351(k) of the Public Health Service
3 Act (42 U.S.C. 262(k)).

4 (3) BRAND NAME DRUG.—The term “brand
5 name drug” means a drug that is—

6 (A) approved under section 505(c) of the
7 Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 355(c)) or a biological product licensed
9 under section 351(a) of the Public Health Serv-
10 ice Act (42 U.S.C. 262(a));

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

14 (C) claimed in a patent or the use of which
15 is claimed in a patent.

16 (4) GENERIC DRUG.—The term “generic drug”
17 means a drug approved pursuant to an application
18 under section (b)(2) or (j) of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 355).

20 (5) GOVERNMENT-GRANTED EXCLUSIVITY.—
21 The term “government-granted exclusivity” means
22 prohibitions on the submission or approval of drug
23 applications granted under any of the following:

1 (A) Clauses (ii) through (v) of section
2 505(c)(3)(E) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 355(c)(3)(E)).

4 (B) Section 505(j)(5)(B)(iv) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C.
6 355(j)(5)(B)(iv)) or clause (ii), (iii), or (iv) of
7 section 505(j)(5)(F) of such Act.

8 (C) Section 505A of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 355a).

10 (D) Section 505E of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 355f).

12 (E) Section 527 of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 360cc).

14 (F) Section 351(k)(7) of the Public Health
15 Service Act (42 U.S.C. 262(k)(7)).

16 (G) Any other provision of law that pro-
17 vides for exclusivity (or extension of exclusivity)
18 with respect to a drug.

19 (6) MANUFACTURER.—The term “manufac-
20 turer” means the holder of an application approved
21 under section 505 of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 355) or of a license issued
23 under section 351 of the Public Health Service Act
24 (42 U.S.C. 262).

1 (7) OPEN, NON-EXCLUSIVE LICENSE.—The
2 term “open, non-exclusive license” means a license
3 that authorizes any person to use a patent held by
4 a manufacturer that claims a brand name drug or
5 a use of a brand name drug or rely upon regulatory
6 test data for such drug, including patents held in
7 common by the manufacturer and other entities,
8 needed to produce, manufacture, import, export, dis-
9 tribute, offer in liquidation, sell, buy, or use such
10 brand name drug.

11 (8) SECRETARY.—The term “Secretary” means
12 the Secretary of Health and Human Services.

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