

116TH CONGRESS
1ST SESSION

H. R. 5039

To lower the prices of excessively costly life-sustaining prescription drugs under part D of the Medicare program by requiring the Secretary of Health and Human Services to negotiate their prices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 12, 2019

Mr. LIPINSKI introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To lower the prices of excessively costly life-sustaining prescription drugs under part D of the Medicare program by requiring the Secretary of Health and Human Services to negotiate their prices, and for other purposes.

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 “Life-Sustaining Pre-
5 scription Drug Price Relief Act of 2019”.

1 **SEC. 2. IDENTIFICATION OF EXCESSIVELY PRICED LIFE-**
2 **SUSTAINING PRESCRIPTION DRUGS.**

3 (a) IN GENERAL.—The Secretary, not later than 1
4 year after the date of enactment of this Act, shall establish
5 a process to conduct a review of all life-sustaining pre-
6 scription drugs, not less frequently than once per calendar
7 year, under which the Secretary determines under sub-
8 section (b) whether the price of each such drug is exces-
9 sive.

10 (b) EXCESSIVE PRICE DETERMINATIONS.—

11 (1) INTERNATIONAL REFERENCE PRICE.—

12 (A) IN GENERAL.—The Secretary shall de-
13 termine that any life-sustaining prescription
14 drug for which the domestic average manufac-
15 turing price exceeds 110 percent of the average
16 price charged for such drug in the 5 reference
17 countries to have an excessive price. In assess-
18 ing the extent to which the price is excessive,
19 the Secretary shall consider the factors de-
20 scribed in paragraph (2).

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

25 (C) REQUIREMENT WITH RESPECT TO
26 DRUGS FOR WHICH CERTAIN REFERENCE COUN-

1 TRY INFORMATION IS NOT AVAILABLE.—The
2 Secretary shall make a determination under
3 paragraph (1) for every life-sustaining prescrip-
4 tion drug for which pricing information is avail-
5 able for at least 3 of the 5 reference countries.

6 (2) DETERMINATIONS BASED ON OTHER FAC-
7 TORS.—With respect to any life-sustaining prescrip-
8 tion drug that is not determined to have an excessive
9 price by operation of paragraph (1) (including any
10 drug for which there is insufficient data to make
11 such a determination under such paragraph), the
12 Secretary shall determine that such drug has an ex-
13 cessive price if the price of the drug is higher than
14 reasonable taking into account the following factors:

15 (A) The size of the affected patient popu-
16 lation.

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

20 (C) The costs associated with development
21 of the drug.

22 (D) Whether the drug provided a signifi-
23 cant improvement in health outcomes, com-
24 pared to other therapies available at the time of
25 its approval.

1 (E) The cumulative global revenues gen-
2 erated by the drug.

3 (F) Whether the domestic average manu-
4 facturer price of the drug increased during any
5 annual quarter by a percentage that is more
6 than the percentage increase in the consumer
7 price index for all urban consumers for the re-
8 spective annual quarter.

9 (G) Other factors the Secretary determines
10 appropriate.

11 (c) PETITION FOR DETERMINATION.—

12 (1) IN GENERAL.—Any person may petition the
13 Secretary, in accordance with section 553(e) of title
14 5, United States Code, to make an excessive drug
15 price determination for an applicable drug under
16 subsection (b)(2). Not later than 90 days after the
17 date of receipt of such a petition, subject to para-
18 graph (2), the Secretary shall—

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

21 (B)(i) decline to make such a determina-
22 tion; and

23 (ii) make public the reasons why the Sec-
24 retary has declined to make such a determina-
25 tion.

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

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

12 **SEC. 3. ABOLISHING THE PROHIBITION ON MEDICARE NE-**
13 **GOTIATION OF DRUG PRICES AND REQUIR-**
14 **ING THE SECRETARY OF HEALTH AND**
15 **HUMAN SERVICES TO NEGOTIATE PRICES OF**
16 **LIFE-SUSTAINING PRESCRIPTION DRUGS**
17 **FURNISHED UNDER PART D OF THE MEDI-**
18 **CARE PROGRAM.**

19 Section 1860D–11 of the Social Security Act (42
20 U.S.C. 1395w–111) is amended by striking subsection (i)
21 and inserting the following new subsection:

22 “(i) REQUIREMENT TO NEGOTIATE PRICES WITH
23 RESPECT TO CERTAIN LIFE-SUSTAINING PRESCRIPTION
24 DRUGS.—

1 “(1) IN GENERAL.—With respect to any life-
2 sustaining prescription drug (as defined in section
3 6(4) of the Life-Sustaining Prescription Drug Price
4 Relief Act of 2019), if the Secretary determines
5 under section 2 of such Act that the price of the
6 drug is excessive, the Secretary shall, notwith-
7 standing any other provision of law, negotiate with
8 manufacturers, prescription drug plan sponsors, and
9 MA organizations the total payment (including any
10 discounts, rebates, and other price concessions) that
11 may be made by such sponsors and organizations
12 during a negotiated price period (as specified by the
13 Secretary) for such drugs with respect to such drugs
14 furnished to individuals who are enrolled under a
15 prescription drug plan or under an MA–PD plan of-
16 fered by such sponsor or organization, respectively.

17 “(2) PRICE LIMITATION.—In the case of a life-
18 sustaining prescription drug that is negotiated by
19 the Secretary pursuant to paragraph (1), the total
20 payment described in such paragraph may not ex-
21 ceed 110 percent of the average price charged for
22 such drug in the 5 reference countries described in
23 section 2(b)(1)(B) of such Act (in this section re-
24 ferred to as the ‘international reference price’).

25 “(3) ENFORCEMENT.—

1 “(A) IN GENERAL.—In the case of a man-
2 ufacturer of a life-sustaining prescription drug
3 for which the Secretary has made a determina-
4 tion described in paragraph (1) that fails to
5 enter into a negotiation and agree on a total
6 payment with respect to such drugs as de-
7 scribed in such paragraph within 9 months of
8 such determination—

9 “(i) if such drug has an international
10 reference price, the Secretary shall assess
11 a civil monetary penalty equal to 2 times
12 the difference between the total revenue for
13 such drug from all sales in the United
14 States made beginning after the date that
15 is 9 months after such determination and
16 the total revenue for such drug from all
17 such sales made after such date that would
18 have been received if the manufacturer
19 charged the international reference price
20 for such drug; and

21 “(ii) if such drug has an international
22 reference price, the Secretary shall assess
23 a civil monetary penalty equal to 50 per-
24 cent of the revenue from all United States
25 sales of the drug in the first 90 days after

1 the date that is 9 months after such deter-
2 mination, 75 percent of the value of all
3 revenue from such sales during the fol-
4 lowing 90 days, and 95 percent of all rev-
5 enue from such sales in subsequent days
6 until such time as an agreement is reached
7 or an international reference price is avail-
8 able.

9 “(B) DEPOSIT INTO TRUST FUND.—Civil
10 monetary penalties collected pursuant to sub-
11 paragraph (A) shall be deposited into the Fed-
12 eral Hospital Insurance Trust Fund.”.

13 **SEC. 4. PUBLIC EXCESSIVE DRUG PRICE DATABASE.**

14 (a) EXCESSIVE DRUG PRICE DATABASE.—

15 (1) IN GENERAL.—The Secretary shall establish
16 and maintain a comprehensive, up-to-date database
17 of life-sustaining prescription drugs and the exces-
18 sive price determinations for such drugs under sec-
19 tion 2.

20 (2) CONTENTS.—The database shall include, at
21 a minimum, for each life-sustaining prescription
22 drug, for the applicable calendar year—

23 (A) the name of the drug;

24 (B) the manufacturer;

1 (C) whether the drug was determined
2 under section 2(b) to have an excessive price;
3 and

4 (D) the number of petitions the Secretary
5 received under section 2(c) to make an exces-
6 sive price determination for the drug, together
7 with the information described in section
8 2(c)(3).

9 (3) CERTAIN DETERMINATIONS.—With respect
10 to a determination made under section 2(b)(1), the
11 Secretary shall publish on the database such deter-
12 mination in accordance with paragraph (1) within
13 30 days of receiving domestic and international pric-
14 ing information from manufacturers under section 6.

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

21 (1) the total number of drugs that were re-
22 viewed;

23 (2) the total number of drugs determined to be
24 excessively priced under each of paragraphs (1) and

1 (2) of section 2(b), and the name and manufacturer
2 of each such drug;

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

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

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

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

13 (7) other appropriate information, as the Sec-
14 retary determines or as Congress requests.

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

21 **SEC. 5. DRUG MANUFACTURER REPORTING.**

22 (a) IN GENERAL.—Each manufacturer shall submit
23 to the Secretary, in such format as the Secretary may re-
24 quire, an annual report that includes the following infor-

1 mation for each life-sustaining prescription drug of the
2 manufacturer, with respect to the previous calendar year:

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

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

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

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

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

20 (A) basic and preclinical research;

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

23 (C) development of alternative dosage
24 forms and strengths for the drug molecule or
25 combinations, including the molecule;

1 (D) other drug development activities, such
2 as nonclinical laboratory studies and record and
3 report maintenance;

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

8 (F) carrying out postmarket requirements
9 related to such drug, including under section
10 505(o)(3) of the Federal Food, Drug, and Cos-
11 metic Act.

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

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

21 (8) The estimated size of the affected patient
22 population.

23 (9) Additional information the manufacturer
24 chooses to provide related to drug pricing decisions,

1 such as information related to the methodology used
2 to set the price of the drug.

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

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

10 (c) PENALTY FOR NONCOMPLIANCE.—

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

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

21 (A) an amount, as determined appropriate
22 by the Secretary, which is—

23 (i) not less than 0.5 percent of the
24 gross revenues from sales for the previous

1 calendar year of the drug for which the in-
2 formation was not submitted; and

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

6 (B) the number of days in the period be-
7 tween—

8 (i) the report due date under sub-
9 section (b); and

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

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

19 **SEC. 6. DEFINITIONS.**

20 For the purposes of this Act:

21 (1) AVERAGE MANUFACTURER PRICE.—

22 (A) IN GENERAL.—The term “average
23 manufacturer price”, with respect to a drug,
24 subject to subparagraph (B), has the meaning
25 given such term in section 1927(k)(1) of the

1 Social Security Act (42 U.S.C. 1396r–8(k)(1));
2 or with respect to a drug for which there is no
3 average manufacturer price as so defined, such
4 term shall mean the wholesale acquisition cost
5 (as defined in section 1847A(e)(6)(B) of the
6 Social Security Act (42 U.S.C. 1395w–
7 3a(c)(6)(B)) of the drug.

8 (B) APPLICATION TO REFERENCE COUN-
9 TRIES.—With respect to reference countries,
10 the term “average manufacturer price”, as de-
11 fined in subparagraph (A), shall be determined
12 based on the price of the drug in the applicable
13 reference country.

14 (2) BIOSIMILAR BIOLOGICAL PRODUCT.—The
15 term “biosimilar biological product” means a biologi-
16 cal product licensed pursuant to an application
17 under section 351(k) of the Public Health Service
18 Act (42 U.S.C. 262(k)).

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

23 (4) LIFE-SUSTAINING PRESCRIPTION DRUG.—
24 The term “life-sustaining prescription drug” means
25 a drug that is—

1 (A) approved under subsection (c) or (j) of
2 section 505 of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 355) or a biological
4 product licensed under subsection (a) or (k) of
5 section 351 of the Public Health Service Act
6 (42 U.S.C. 262);

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

10 (C) life-sustaining (as such term is defined
11 in regulation pursuant to section 506C of the
12 Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 356c)).

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

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

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