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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.

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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

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# 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.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Life-Sustaining Prescription Drug Price Relief Act of 2019''.

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

(a) IN GENERAL.—The Secretary, not later than 1 year after the date of enactment of this Act, shall establish a process to conduct a review of all life-sustaining prescription drugs, not less frequently than once per calendar year, under which the Secretary determines under subsection (b) whether the price of each such drug is excessive.

(b) EXCESSIVE PRICE DETERMINATIONS.—

(1) INTERNATIONAL REFERENCE PRICE.—

(A) IN GENERAL.—The Secretary shall determine that any life-sustaining prescription drug for which the domestic average manufacturing price exceeds 110 percent of the average price charged for such drug in the 5 reference countries to have an excessive price. In assessing the extent to which the price is excessive, the Secretary shall consider the factors described in paragraph (2).

(B) REFERENCE COUNTRIES.—In this Act, the term ''reference countries'' means Canada, the United Kingdom, Germany, France, and Japan.

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

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

(2) DETERMINATIONS BASED ON OTHER FACTORS.—With respect to any life-sustaining prescription drug that is not determined to have an excessive price by operation of paragraph (1) (including any drug for which there is insufficient data to make such a determination under such paragraph), the Secretary shall determine that such drug has an excessive price if the price of the drug is higher than reasonable taking into account the following factors:

(A) The size of the affected patient population.

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

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

(D) Whether the drug provided a significant improvement in health outcomes, compared to other therapies available at the time of its approval.

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

(F) 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.

(G) 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

(ii) make public the reasons why the Secretary has declined to make such a determination.

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

(3) PUBLIC AVAILABILITY.—The Secretary shall make any petitions submitted under this subsection, together with any documentation related to the petitions and the Secretary's determinations on such petitions and rationale for such determinations, publicly available, including by posting such information on the database under section 5.

**SEC. 3. ABOLISHING THE PROHIBITION ON MEDICARE NEGOTIATION OF DRUG PRICES AND REQUIRING THE SECRETARY OF HEALTH AND HUMAN SERVICES TO NEGOTIATE PRICES OF LIFE-SUSTAINING PRESCRIPTION DRUGS FURNISHED UNDER PART D OF THE MEDICARE PROGRAM.**

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

"(i) REQUIREMENT TO NEGOTIATE PRICES WITH RESPECT TO CERTAIN LIFE-SUSTAINING PRESCRIPTION DRUGS.—

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

''(2) PRICE LIMITATION.—In the case of a life-sustaining prescription drug that is negotiated by the Secretary pursuant to paragraph (1), the total payment described in such paragraph may not exceed 110 percent of the average price charged for such drug in the 5 reference countries described in section 2(b)(1)(B) of such Act (in this section referred to as the 'international reference price').

''(3) ENFORCEMENT.—

"(A) IN GENERAL.—In the case of a manufacturer of a life-sustaining prescription drug for which the Secretary has made a determination described in paragraph (1) that fails to enter into a negotiation and agree on a total payment with respect to such drugs as described in such paragraph within 9 months of such determination—

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

"(ii) if such drug has an international reference price, the Secretary shall assess a civil monetary penalty equal to 50 percent of the revenue from all United States sales of the drug in the first 90 days after

the date that is 9 months after such determination, 75 percent of the value of all revenue from such sales during the following 90 days, and 95 percent of all revenue from such sales in subsequent days until such time as an agreement is reached or an international reference price is available.

''(B) DEPOSIT INTO TRUST FUND.—Civil monetary penalties collected pursuant to subparagraph (A) shall be deposited into the Federal Hospital Insurance Trust Fund.''.

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

(a) EXCESSIVE DRUG PRICE DATABASE.—

(1) IN GENERAL.—The Secretary shall establish and maintain a comprehensive, up-to-date database of life-sustaining prescription drugs and the excessive price determinations for such drugs under section 2.

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

(A) the name of the drug;

(B) the manufacturer;

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

(D) the number of petitions the Secretary received under section 2(c) to make an excessive price determination for the drug, together with the information described in section 2(c)(3).

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

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

(1) the total number of drugs that were reviewed;

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

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

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

(4) the extent to which the prices of the drugs identified under section 2 were higher than reasonable, on average;

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

(6) a list of any manufacturers who failed to report information as required under section 6; and

(7) other appropriate information, as the Secretary determines or as Congress requests.

(c) PUBLIC AVAILABILITY.—The Secretary shall make the information in the database described in subsection (a) and the report in subsection (b) publicly available, including on the internet website of the Food and Drug Administration, in a manner that is easy to find and understand.

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

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

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

(1) The average manufacturer price of the drug in the United States and in the reference countries, for the entire year, and broken down for each quarter of the year.

(2) The wholesale acquisition cost of the drug in the United States and in the reference countries, for the entire year, and broken down for each quarter of the year.

(3) Cumulative global revenues generated by the drug.

(4) Annual net sales revenue generated by the drug in the United States and in the reference countries, for the entire year, and broken down for each quarter of the year.

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

(A) basic and preclinical research;

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

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

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

(E) pursuing new or expanded indications for such drug through supplemental applications under section 505 of the Federal Food, Drug, and Cosmetic Act; and

(F) carrying out postmarket requirements related to such drug, including under section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act.

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

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

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

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

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

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

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

(c) PENALTY FOR NONCOMPLIANCE.—

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

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

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

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

calendar year of the drug for which the information was not submitted; and

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

(B) the number of days in the period between—

(i) the report due date under subsection (b); and

(ii) the date on which the Secretary receives the information required to be reported by the manufacturer under this section.

(3) USE OF CIVIL PENALTY.—The Secretary shall collect the civil penalties under this subsection and shall use such funds to support competitive research grant programs of the National Institutes of Health.

**SEC. 6. DEFINITIONS.**

For the purposes of this Act:

(1) AVERAGE MANUFACTURER PRICE.—

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

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

(B) APPLICATION TO REFERENCE COUNTRIES.—With respect to reference countries, the term ''average manufacturer price'', as defined in subparagraph (A), shall be determined based on the price of the drug in the applicable reference country.

(2) BIOSIMILAR BIOLOGICAL PRODUCT.—The term ''biosimilar biological product'' means a biological product licensed pursuant to an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

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

(4) LIFE-SUSTAINING PRESCRIPTION DRUG.—The term ''life-sustaining prescription drug'' means a drug that is—

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

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

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

(5) MANUFACTURER.—The term ''manufacturer'' means the holder of an application approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or of a license issued under section 351 of the Public Health Service Act (42 U.S.C. 262).

(6) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

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