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S.L.C.

Sanders #2

AMENDMENT NO._____ Calendar No._____

Purpose: 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—117th Cong., 2d Sess.

S. 3799

To prepare for, and respond to, existing viruses, emerging new threats, and pandemics.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

At the end, add the following:

TITLE VI—PRESCRIPTION DRUG PRICE RELIEF ACT OF 2022

SEC. 601. SHORT TITLE.

This title may be cited as the "Prescription Drug Price Relief Act of 2022".

SEC. 602. IDENTIFICATION OF EXCESSIVELY PRICED 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 brand name 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 brand name drug for which the domestic average manufacturing price exceeds the median 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 title, the term "reference countries" means Canada, the United Kingdom, Germany, France, and Japan.

(C) REQUIREMENT WITH RESPECT TO DRUGS FOR WHICH CERTAIN REFERENCE COUNTRY INFORMATION IS NOT AVAILABLE.—The Secretary shall make a determination under subparagraph (A) for every brand name 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 brand name 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 value of the drug to patients, including the impact of the price on access to the drug and the relationship of the price of the drug to its therapeutic health benefits.

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

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

(E) Whether the drug provided a significant improvement in health outcomes, compared 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

(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 605.

SEC. 603. ENDING GOVERNMENT-GRANTED MONOPOLIES FOR EXCESSIVELY PRICED DRUGS.

(a) EXCESSIVE DRUG PRICE AUTHORITY.—With respect to any brand name drug, if the Secretary determines under section 602 that the price of the drug is excessive, the Secretary—

(1) shall waive or void any government-granted exclusivities with respect to such drug, effective on the date that the excessive price determination under section 602 is made for such drug; and

(2) shall grant open, non-exclusive licenses allowing any person to make, use, offer to sell or sell, or import into the United States such drug, and to

rely upon the regulatory test data of such drug, in accordance with section 604.

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

(c) CIVIL ACTIONS.—If the Secretary determines that the manufacturer of an excessively priced drug (as determined under section 602(a)) has increased the price of such drug during the period beginning on the date on which such price determination is made and ending on the date on which an entity begins manufacturing the drug under an open, non-exclusive license under subsection (a)(2), the Secretary may file a civil action in the United States district court for the district in which the manufacturer is located, or in the United States district court for the District of Columbia, to recover damages in an amount equal to not less than the total amount of revenue derived by the manufacturer as a result of any such price increase during such period. In actions brought under this subsection, the district courts shall have jurisdiction to grant all appropriate relief including, but not limited to, injunctive relief and compensatory damages.

SEC. 604. EXCESSIVE DRUG PRICE LICENSE.

(a) REASONABLE ROYALTY.—

(1) IN GENERAL.—An entity accepting an open, non-exclusive license under section 603(a)(2) shall pay a reasonable royalty to the holder of a patent that claims the drug or that claims a use of the drug or to the holder of an application approved under subsection 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act for which any government-granted exclusivity with respect to the drug was terminated under section 605(a)(1).

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

(A) a percentage of sales, where the percentage rate is no higher than the average royalty rate estimated from the data provided by the Internal Revenue Service for pharmaceutical manufacturer Federal income tax returns; or

(B) an amount as determined by the Secretary, taking into account—

(i) the value of the drug to patients;

(ii) the size of the affected patient population;

(iii) the risk adjusted value of the Federal Government subsidies and investments related to the drug;

(iv) whether the drug provided a significant improvement in health outcomes, compared to other therapies available at the time of the approval;

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

(vi) any other information the Secretary determines appropriate.

(b) REQUIREMENTS.—

(1) IN GENERAL.—A royalty rate under subsection (a) shall be consistent with making drugs available to purchasers, including Federal, State, local, and nongovernmental purchasers and individuals, at prices that are affordable and reasonable. Under no condition shall a royalty be set at a rate that would cause a product for which an open, nonexclusive license was issued under section 603 to be

sold at an excessive price, as determined under section 602.

(2) MULTIPLE AFFECTED PARTIES.—In the case that there is one or more holders or investors in the patented inventions related to the drug in addition to the brand name manufacturer, the royalty rate shall be divided among the holders or investors (including such manufacturer) in a manner agreed upon by the manufacturer and other holders or investors, or, in the absence of such an agreement, in a manner the Secretary determines to be appropriate.

(3) PRICE.—An entity accepting an open, nonexclusive license under section 603(a)(2) shall sell the drug at a price not higher than the excessive price determined for that drug under section 602(b).

SEC. 605. 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 brand name drugs and the excessive price determinations for such drugs under section 602.

(2) CONTENTS.—The database shall include, at a minimum, for each brand name drug, for the applicable calendar year—

(A) the name of the drug;

(B) the manufacturer;

(C) whether the drug was determined under section 602(b) to have an excessive price;

(D) the number of petitions the Secretary received under section 602(c) to make an excessive price determination for the drug, together with the information described in section 602(c)(3);

(E) the number of open, non-exclusive licenses the Secretary has granted under section 603(a)(2) for generic drug or biosimilar biological product versions of the drug; and

(F) the number of applications under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act or under section 351(k) of the Public Health Service Act submitted to the Secretary, pursuant to such a license granted under section 603(a)(2), and the number of such applications that have been approved.

(3) CERTAIN DETERMINATIONS.—With respect to a determination made under section 602(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 606.

(b) ANNUAL REPORTS TO CONGRESS.—Not later than 60 days after the first excessive price review under section 602 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 602(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 602 were higher than reasonable, on average;

(5) the total number of drugs for which an open-non-exclusive license has been granted under section 603(a)(2);

(6) the total number of generic drug or biosimilar biological product applications received and approved that reference a drug so licensed;

(7) the median approval time for generic drug or biosimilar biological product applications that reference a drug so licensed;

(8) the total number of petitions the Secretary received under section 602(c) to make excessive price determinations for drugs;

(9) a list of any manufacturers who failed to report information as required under section 606; and

(10) 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. 606. 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 information for each brand name 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 title, 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. 607. PROHIBITION OF ANTICOMPETITIVE BEHAVIOR.

No manufacturer may engage in anticompetitive behavior violating section 5(a) of the Federal Trade Commission Act (15 U.S.C. 45(a)) with another manufacturer that may interfere with the issuance and implementation of open, non-exclusive licenses under this title or otherwise

run contrary to the public interest in the availability of affordable prescription drugs.

SEC. 608. DEFINITIONS.

For the purposes of this title:

(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) BRAND NAME DRUG.—The term "brand name drug" means a drug that is—

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

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

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

(4) GENERIC DRUG.—The term "generic drug" means a drug approved pursuant to an application under section (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

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

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

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

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

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

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

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

(G) Any other provision of law that provides for exclusivity (or extension of exclusivity) with respect to a drug.

(6) 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).

(7) OPEN, NON-EXCLUSIVE LICENSE.—The term "open, non-exclusive license" means a license that authorizes any person to use a patent held by a manufacturer that claims a brand name drug or

a use of a brand name drug or rely upon regulatory test data for such drug, including patents held in common by the manufacturer and other entities, needed to produce, manufacture, import, export, distribute, offer in liquidation, sell, buy, or use such brand name drug.

(8) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.