

Ben Sanders
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. 4348

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

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:

1 At the end, add the following:

2 **TITLE X—PRESCRIPTION DRUG**

3 **PRICE RELIEF**

4 **SEC. 1001. SHORT TITLE.**

5 This title may be cited as the “Prescription Drug

6 Price Relief Act of 2022”.

1 **SEC. 1002. IDENTIFICATION OF EXCESSIVELY PRICED**
2 **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 brand name drugs,
6 not less frequently than once per calendar year, under
7 which the Secretary determines under subsection (b)
8 whether the price of each such drug is excessive.

9 (b) EXCESSIVE PRICE DETERMINATIONS.—

10 (1) INTERNATIONAL REFERENCE PRICE.—

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

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

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

1 paragraph (1) for every brand name drug for
2 which pricing information is available for at
3 least 3 of the 5 reference countries.

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

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

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

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

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

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

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

3 (F) The cumulative global revenues gen-
4 erated by the drug.

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

11 (H) Other factors the Secretary determines
12 appropriate.

13 (c) PETITION FOR DETERMINATION.—

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

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

23 (B)(i) decline to make such a determina-
24 tion; 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 1005.

15 (d) PROHIBITION ON DISCRIMINATION.—In deter-
16 mining whether the price of a drug is excessive under this
17 section, the Secretary shall not use evidence or findings
18 from a methodology to assess the cost-effectiveness or
19 value of the drug in a manner that treats extending the
20 life of an elderly, disabled, terminally ill, or chronically ill
21 individual as of lower value than extending the life of an
22 individual who is younger, nondisabled, not terminally ill,
23 or not chronically ill.

1 **SEC. 1003. ENDING GOVERNMENT-GRANTED MONOPOLIES**
2 **FOR EXCESSIVELY PRICED DRUGS.**

3 (a) **EXCESSIVE DRUG PRICE AUTHORITY.**—With re-
4 spect to any brand name drug, if the Secretary determines
5 under section 1002 that the price of the drug is excessive,
6 the Secretary—

7 (1) shall waive or void any government-granted
8 exclusivities with respect to such drug, effective on
9 the date that the excessive price determination under
10 section 1002 is made for such drug; and

11 (2) shall grant open, non-exclusive licenses al-
12 lowing any person to make, use, offer to sell or sell,
13 or import into the United States such drug, and to
14 rely upon the regulatory test data of such drug, in
15 accordance with section 1004.

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

21 (c) **CIVIL ACTIONS.**—If the Secretary determines that
22 the manufacturer of an excessively priced drug (as deter-
23 mined under section 1002(a)) has increased the price of
24 such drug during the period beginning on the date on
25 which such price determination is made and ending on the
26 date on which an entity begins manufacturing the drug

1 under an open, non-exclusive license under subsection
2 (a)(2), the Secretary may file a civil action in the United
3 States district court for the district in which the manufac-
4 turer is located, or in the United States district court for
5 the District of Columbia, to recover damages in an amount
6 equal to not less than the total amount of revenue derived
7 by the manufacturer as a result of any such price increase
8 during such period. In actions brought under this sub-
9 section, the district courts shall have jurisdiction to grant
10 all appropriate relief including, but not limited to, injunc-
11 tive relief and compensatory damages.

12 **SEC. 1004. EXCESSIVE DRUG PRICE LICENSE.**

13 (a) REASONABLE ROYALTY.—

14 (1) IN GENERAL.—An entity accepting an open,
15 non-exclusive license under section 1003(a)(2) shall
16 pay a reasonable royalty to the holder of a patent
17 that claims the drug or that claims a use of the drug
18 or to the holder of an application approved under
19 subsection 505(c) of the Federal Food, Drug, and
20 Cosmetic Act or section 351(a) of the Public Health
21 Service Act for which any government-granted exclu-
22 sivity with respect to the drug was terminated under
23 section 1005(a)(1).

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

1 (A) a percentage of sales, where the per-
2 centage rate is no higher than the average roy-
3 alty rate estimated from the data provided by
4 the Internal Revenue Service for pharma-
5 ceutical manufacturer Federal income tax re-
6 turns; or

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

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

10 (ii) the size of the affected patient
11 population;

12 (iii) the risk adjusted value of the
13 Federal Government subsidies and invest-
14 ments related to the drug;

15 (iv) whether the drug provided a sig-
16 nificant improvement in health outcomes,
17 compared to other therapies available at
18 the time of the approval;

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

1 (vi) any other information the Sec-
2 retary determines appropriate.

3 (b) REQUIREMENTS.—

4 (1) IN GENERAL.—A royalty rate under sub-
5 section (a) shall be consistent with making drugs
6 available to purchasers, including Federal, State,
7 local, and nongovernmental purchasers and individ-
8 uals, at prices that are affordable and reasonable.
9 Under no condition shall a royalty be set at a rate
10 that would cause a product for which an open, non-
11 exclusive license was issued under section 1003 to be
12 sold at an excessive price, as determined under sec-
13 tion 1002.

14 (2) MULTIPLE AFFECTED PARTIES.—In the
15 case that there is one or more holders or investors
16 in the patented inventions related to the drug in ad-
17 dition to the brand name manufacturer, the royalty
18 rate shall be divided among the holders or investors
19 (including such manufacturer) in a manner agreed
20 upon by the manufacturer and other holders or in-
21 vestors, or, in the absence of such an agreement, in
22 a manner the Secretary determines to be appro-
23 priate.

24 (3) PRICE.—An entity accepting an open, non-
25 exclusive license under section 1003(a)(2) shall sell

1 the drug at a price not higher than the excessive
2 price determined for that drug under section
3 1002(b).

4 (4) PROHIBITION ON DISCRIMINATION.—In de-
5 termining a royalty rate under subsection (a), the
6 Secretary shall not use evidence or findings from a
7 methodology to assess the cost-effectiveness or value
8 of a drug in a manner that treats extending the life
9 of an elderly, disabled, terminally ill, or chronically
10 ill individual as of lower value than extending the
11 life of an individual who is younger, nondisabled, not
12 terminally ill, or not chronically ill.

13 **SEC. 1005. 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 brand name drugs and the excessive price deter-
18 minations for such drugs under section 1002.

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

22 (A) the name of the drug;

23 (B) the manufacturer;

1 (C) whether the drug was determined
2 under section 1002(b) to have an excessive
3 price;

4 (D) the number of petitions the Secretary
5 received under section 1002(c) to make an ex-
6 cessive price determination for the drug, to-
7 gether with the information described in section
8 1002(c)(3);

9 (E) the number of open, non-exclusive li-
10 censes the Secretary has granted under section
11 1003(a)(2) for generic drug or biosimilar bio-
12 logical product versions of the drug; and

13 (F) the number of applications under sub-
14 section (b)(2) or (j) of section 505 of the Fed-
15 eral Food, Drug, and Cosmetic Act or under
16 section 351(k) of the Public Health Service Act
17 submitted to the Secretary, pursuant to such a
18 license granted under section 1003(a)(2), and
19 the number of such applications that have been
20 approved.

21 (3) CERTAIN DETERMINATIONS.—With respect
22 to a determination made under section 1002(b)(1),
23 the Secretary shall publish on the database such de-
24 termination in accordance with paragraph (1) within
25 30 days of receiving domestic and international pric-

1 ing information from manufacturers under section
2 1006.

3 (b) ANNUAL REPORTS TO CONGRESS.—Not later
4 than 60 days after the first excessive price review under
5 section 1002 is complete, and annually thereafter, the Sec-
6 retary shall submit to Congress a report describing the
7 excessive drug price review for the preceding year. The
8 report shall contain summary data regarding—

9 (1) the total number of drugs that were re-
10 viewed;

11 (2) the total number of drugs determined to be
12 excessively priced under each of paragraphs (1) and
13 (2) of section 1002(b), and the name and manufac-
14 turer of each such drug;

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

17 (4) the extent to which the prices of the drugs
18 identified under section 1002 were higher than rea-
19 sonable, on average;

20 (5) the total number of drugs for which an
21 open-non-exclusive license has been granted under
22 section 1003(a)(2);

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

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

4 (8) the total number of petitions the Secretary
5 received under section 1002(c) to make excessive
6 price determinations for drugs;

7 (9) a list of any manufacturers who failed to re-
8 port information as required under section 1006;
9 and

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

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

18 **SEC. 1006. DRUG MANUFACTURER REPORTING.**

19 (a) IN GENERAL.—Each manufacturer shall submit
20 to the Secretary, in such format as the Secretary may re-
21 quire, an annual report that includes the following infor-
22 mation for each brand name drug of the manufacturer,
23 with respect to the previous calendar year:

24 (1) The average manufacturer price of the drug
25 in the United States and in the reference countries,

1 for the entire year, and broken down for each quar-
2 ter of the year.

3 (2) The wholesale acquisition cost 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 (3) Cumulative global revenues generated by
8 the drug.

9 (4) Annual net sales revenue generated by the
10 drug in the United States and in the reference coun-
11 tries, for the entire year, and broken down for each
12 quarter of the year.

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

16 (A) basic and preclinical research;

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

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

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

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

5 (F) carrying out postmarket requirements
6 related to such drug, including under section
7 505(o)(3) of the Federal Food, Drug, and Cos-
8 metic Act.

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

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

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

20 (9) Additional information the manufacturer
21 chooses to provide related to drug pricing decisions,
22 such as information related to the methodology used
23 to set the price of the drug.

1 (10) Additional information as the Secretary
2 determines necessary to carry out this title, includ-
3 ing information for previous years.

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

8 (c) PENALTY FOR NONCOMPLIANCE.—

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

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

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

21 (i) not less than 0.5 percent of the
22 gross revenues from sales for the previous
23 calendar year of the drug for which the in-
24 formation was not submitted; and

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

4 (B) the number of days in the period be-
5 tween—

6 (i) the report due date under sub-
7 section (b); and

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

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

17 **SEC. 1007. PROHIBITION OF ANTICOMPETITIVE BEHAVIOR.**

18 No manufacturer may engage in anticompetitive be-
19 havior violating section 5(a) of the Federal Trade Com-
20 mission Act (15 U.S.C. 45(a)) with another manufacturer
21 that may interfere with the issuance and implementation
22 of open, non-exclusive licenses under this title or otherwise
23 run contrary to the public interest in the availability of
24 affordable prescription drugs.

1 **SEC. 1008. DEFINITIONS.**

2 For the purposes of this title:

3 (1) **AVERAGE MANUFACTURER PRICE.**—

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

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

21 (2) **BIOSIMILAR BIOLOGICAL PRODUCT.**—The
22 term “biosimilar biological product” means a biologi-
23 cal product licensed pursuant to an application
24 under section 351(k) of the Public Health Service
25 Act (42 U.S.C. 262(k)).

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

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

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

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

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

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

21 (A) Clauses (ii) through (v) of section
22 505(c)(3)(E) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 355(c)(3)(E)).

24 (B) Section 505(j)(5)(B)(iv) of the Federal
25 Food, Drug, and Cosmetic Act (21 U.S.C.

1 355(j)(5)(B)(iv)) or clause (ii), (iii), or (iv) of
2 section 505(j)(5)(F) of such Act.

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

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

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

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

11 (G) Any other provision of law that pro-
12 vides for exclusivity (or extension of exclusivity)
13 with respect to a drug.

14 (6) 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 (7) OPEN, NON-EXCLUSIVE LICENSE.—The
21 term “open, non-exclusive license” means a license
22 that authorizes any person to use a patent held by
23 a manufacturer that claims a brand name drug or
24 a use of a brand name drug or rely upon regulatory
25 test data for such drug, including patents held in

1 common by the manufacturer and other entities,
2 needed to produce, manufacture, import, export, dis-
3 tribute, offer in liquidation, sell, buy, or use such
4 brand name drug.

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