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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—119th Cong., 2d Sess.

S. 3014

To amend the Federal Food, Drug, and Cosmetic Act with respect to citizen petitions.

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 appropriate place, insert the following:

2 **TITLE II—PRESCRIPTION DRUG**
3 **PRICE RELIEF**

4 **SEC. 201. SHORT TITLE.**

5 This title may be cited as the “Prescription Drug
6 Price Relief Act of 2026”.

7 **SEC. 202. IDENTIFICATION OF EXCESSIVELY PRICED**
8 **DRUGS.**

9 (a) IN GENERAL.—Not later than 30 days after the
10 date of enactment of this Act, the Secretary shall establish

1 a process to conduct a review of all brand name drugs,
2 not less frequently than once per calendar year, under
3 which the Secretary determines under subsection (b)
4 whether the price of each such drug is excessive.

5 (b) EXCESSIVE PRICE DETERMINATIONS.—

6 (1) INTERNATIONAL REFERENCE PRICE.—

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

15 (B) REFERENCE COUNTRIES.—In this
16 title, the term “reference countries” means
17 Canada, the United Kingdom, Germany,
18 France, and Japan.

19 (C) REQUIREMENT WITH RESPECT TO
20 DRUGS FOR WHICH CERTAIN REFERENCE COUN-
21 TRY INFORMATION IS NOT AVAILABLE.—The
22 Secretary shall make a determination under
23 paragraph (1) for every brand name drug for
24 which pricing information is available for at
25 least 3 of the 5 reference countries.

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

10 (A) The size of the affected patient popu-
11 lation.

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

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

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

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

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

3 (G) 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 (H) 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 205.

12 **SEC. 203. ENDING GOVERNMENT-GRANTED MONOPOLIES**
13 **FOR EXCESSIVELY PRICED DRUGS.**

14 (a) EXCESSIVE DRUG PRICE AUTHORITY.—With re-
15 spect to any brand name drug, if the Secretary determines
16 under section 202 that the price of the drug is excessive,
17 the Secretary—

18 (1) shall waive or void any government-granted
19 exclusivities with respect to such drug, effective on
20 the date that the excessive price determination under
21 section 202 is made for such drug; and

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

1 rely upon the regulatory test data of such drug, in
2 accordance with section 204.

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

8 (c) CIVIL ACTIONS.—If the Secretary determines that
9 the manufacturer of an excessively priced drug (as deter-
10 mined under section 202(a)) has increased the price of
11 such drug during the period beginning on the date on
12 which such price determination is made and ending on the
13 date on which an entity begins manufacturing the drug
14 under an open, non-exclusive license under subsection
15 (a)(2), the Secretary may file a civil action in the United
16 States district court for the district in which the manufac-
17 turer is located, or in the United States district court for
18 the District of Columbia, to recover damages in an amount
19 equal to not less than the total amount of revenue derived
20 by the manufacturer as a result of any such price increase
21 during such period. In actions brought under this sub-
22 section, the district courts shall have jurisdiction to grant
23 all appropriate relief including injunctive relief and com-
24 pensatory damages.

1 **SEC. 204. EXCESSIVE DRUG PRICE LICENSE.**

2 (a) **REASONABLE ROYALTY.**—

3 (1) **IN GENERAL.**—An entity accepting an open,
4 non-exclusive license under section 203(a)(2) shall
5 pay a reasonable royalty to the holder of a patent
6 that claims the drug or that claims a use of the drug
7 or to the holder of an application approved under
8 subsection 505(c) of the Federal Food, Drug, and
9 Cosmetic Act (21 U.S.C. 355(c)) or section 351(a)
10 of the Public Health Service Act (42 U.S.C. 262(a))
11 for which any government-granted exclusivity with
12 respect to the drug was terminated under section
13 203(a)(1).

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

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

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

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

25 (ii) the size of the affected patient
26 population;

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

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

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

15 (vi) any other information the Sec-
16 retary determines appropriate.

17 (b) REQUIREMENTS.—

18 (1) IN GENERAL.—A royalty rate under sub-
19 section (a) shall be consistent with making drugs
20 available to purchasers, including Federal, State,
21 local, and nongovernmental purchasers and individ-
22 uals, at prices that are affordable and reasonable.
23 Under no condition shall a royalty be set at a rate
24 that would cause a product for which an open, non-
25 exclusive license was issued under section 203 to be

1 sold at an excessive price, as determined under sec-
2 tion 202.

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

13 (3) PRICE.—An entity accepting an open, non-
14 exclusive license under section 203(a)(2) shall sell
15 the drug at a price below the excessive price deter-
16 mined for that drug under section 202(b).

17 **SEC. 205. PUBLIC EXCESSIVE DRUG PRICE DATABASE.**

18 (a) EXCESSIVE DRUG PRICE DATABASE.—

19 (1) IN GENERAL.—The Secretary shall establish
20 and maintain a comprehensive, up-to-date database
21 of brand name drugs and the excessive price deter-
22 minations for such drugs under section 202.

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

1 (A) the name of the drug;

2 (B) the manufacturer;

3 (C) whether the drug was determined
4 under section 202(b) to have an excessive price;

5 (D) the number of petitions the Secretary
6 received under section 202(c) to make an exces-
7 sive price determination for the drug, together
8 with the information described in section
9 202(c)(3);

10 (E) the number of open, non-exclusive li-
11 censes the Secretary has granted under section
12 203(a)(2) for generic drug or biosimilar biologi-
13 cal product versions of the drug; and

14 (F) the number of applications under sub-
15 section (b)(2) or (j) of section 505 of the Fed-
16 eral Food, Drug, and Cosmetic Act (21 U.S.C.
17 355) or under section 351(k) of the Public
18 Health Service Act (42 U.S.C. 262(k)) sub-
19 mitted to the Secretary, pursuant to such a li-
20 cense granted under section 203(a)(2), and the
21 number of such applications that have been ap-
22 proved.

23 (3) CERTAIN DETERMINATIONS.—With respect
24 to a determination made under section 202(b)(1),
25 the Secretary shall publish on the database such de-

1 termination in accordance with paragraph (1) within
2 30 days of receiving domestic and international pric-
3 ing information from manufacturers under section
4 206.

5 (b) ANNUAL REPORTS TO CONGRESS.—Not later
6 than 60 days after the first excessive price review under
7 section 202 is complete, and annually thereafter, the Sec-
8 retary shall submit to Congress a report describing the
9 excessive drug price review for the preceding year. The
10 report shall contain summary data regarding—

11 (1) the total number of drugs that were re-
12 viewed;

13 (2) the total number of drugs determined to be
14 excessively priced under each of paragraphs (1) and
15 (2) of section 202(b), and the name and manufac-
16 turer of each such drug;

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

19 (4) the extent to which the prices of the drugs
20 identified under section 202 were higher than rea-
21 sonable, on average;

22 (5) the total number of drugs for which an
23 open, non-exclusive license has been granted under
24 section 203(a)(2);

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

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

7 (8) the total number of petitions the Secretary
8 received under section 202(c) to make excessive
9 price determinations for drugs;

10 (9) a list of any manufacturers who failed to re-
11 port information as required under section 206; and

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

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

20 **SEC. 206. DRUG MANUFACTURER REPORTING.**

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

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

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

9 (3) Cumulative global revenues generated by
10 the drug.

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

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

18 (A) basic and preclinical research;

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

21 (C) development of alternative dosage
22 forms and strengths for the drug molecule or
23 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 (21 U.S.C. 355); 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 (21 U.S.C. 355(o)(3)).

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 title, includ-
5 ing 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. 207. PROHIBITION OF ANTICOMPETITIVE BEHAVIOR.**

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

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

3 **SEC. 208. DEFINITIONS.**

4 For the purposes of this title:

5 (1) AVERAGE MANUFACTURER PRICE.—

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

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

23 (2) BIOSIMILAR BIOLOGICAL PRODUCT.—The
24 term “biosimilar biological product” means a biologi-
25 cal product licensed pursuant to an application

1 under section 351(k) of the Public Health Service
2 Act (42 U.S.C. 262(k)).

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

5 (A) that is approved pursuant to an appli-
6 cation under section 505(b)(1) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C.
8 355(b)(1)) or that is licensed under section
9 351(a) of the Public Health Service Act (42
10 U.S.C. 262(a));

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

14 (C) that is claimed in a patent, or a use
15 of which 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 section 505 of the Fed-
19 eral Food, 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.