

119TH CONGRESS
2D SESSION

H. R. 9040

To establish fair prices for prescription drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 26, 2026

Mr. SHERMAN introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, and Financial Services, 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 establish fair prices for prescription drugs, 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 “Regulate the Price of
5 All Drugs Act”.

1 **SEC. 2. ESTABLISHING THE PRESCRIPTION DRUG REGU-**
2 **LATORY COMMISSION.**

3 (a) IN GENERAL.—There is established the Prescrip-
4 tion Drug Price Regulatory Commission (in this section
5 referred to as the “Commission”).

6 (b) DUTIES OF COMMISSION.—

7 (1) IN GENERAL.—Not later than the fair price
8 recommendation date with respect to a fair price ap-
9 plicability year, the Commission shall, with respect
10 to each approved prescription drug, submit to the
11 Secretary of Health and Human Services (in this
12 section referred to as the “Secretary”) a rec-
13 ommendation regarding the price that the Commis-
14 sion determines to be a fair price for such drug in
15 order for the manufacturer of such drug to provide
16 access to such price—

17 (A) to any fair price eligible individual who
18 is dispensed such drug during such fair price
19 applicability year (and to pharmacies, mail
20 order services, and other dispensers, with re-
21 spect to such individuals who are dispensed
22 such drugs); and

23 (B) to any hospital, physician, or other
24 provider of services or supplier that furnishes or
25 administers such drug to such an individual
26 during such year.

1 (2) FAIR PRICE REVISIONS AND WAIVERS.—At
2 any time during a fair price applicability year, the
3 Commission may submit to the Secretary a rec-
4 ommendation—

5 (A) that the Secretary revise the fair price
6 established for an approved prescription drug
7 for such year under section 3(b); or

8 (B) that the Secretary authorize a tem-
9 porary waiver of such fair price under section
10 3(c).

11 (3) REQUIRED FACTORS FOR CONSIDER-
12 ATION.—In making a recommendation under para-
13 graph (1) with respect to the fair price of an ap-
14 proved prescription drug, or a recommendation
15 under paragraph (2) with respect to a revision or
16 waiver of such fair price, the Commission shall take
17 into account the following factors with respect to
18 such drug:

19 (A) The costs to the manufacturer of pro-
20 ducing and distributing of such drug.

21 (B) The cost-effectiveness of the drug and
22 its therapeutic benefit (which may be deter-
23 mined on the basis of quality-adjusted life
24 years, equal value of life years gained, or such
25 other measure as the Commission may specify).

1 (C) The anticipated demand for the drug
2 during the fair price applicability year.

3 (D) The costs and risks to the manufac-
4 turer involved in researching and developing
5 such drug, and the return on investment that
6 would provide adequate incentive to the manu-
7 facturer to continue research.

8 (E) In the case that such drug is available
9 for purchase in 1 or more comparable reference
10 countries, the average price of such drug in
11 such country.

12 (F) Such other factors as the Secretary of
13 Health and Human Services may specify
14 through rulemaking.

15 (c) MEMBERS OF COMMISSION.—

16 (1) IN GENERAL.—The Commission shall be
17 composed of 13 members as follows:

18 (A) Seven members appointed by the
19 President from individuals who are not officers
20 or employees of any government.

21 (B) Six ex officio members appointed by
22 the Secretary of Health and Human Services
23 from each of the following agencies:

24 (i) The Veterans Health Administra-
25 tion.

1 (ii) The Defense Health Agency.

2 (iii) The Centers for Medicare & Med-
3 icaid Services.

4 (iv) The Food and Drug Administra-
5 tion.

6 (v) The Centers for Disease Control
7 and Prevention.

8 (vi) The Federal Trade Commission.

9 (2) TERMS.—Each member shall be appointed
10 for a term of 4 years, except that the Secretary may
11 extend the term of any member for 1 additional year
12 if the Secretary determines such extension appro-
13 priate.

14 (d) OPERATION.—In carrying out the duties under
15 subsection (b), the Commission is not subject to the provi-
16 sions of chapter 10 of title 5, United States Code.

17 (e) AUTHORIZATION OF APPROPRIATIONS.—There
18 are authorized to be appropriated such sums as may be
19 necessary for each fiscal year to carry out the activities
20 of the Commission.

21 **SEC. 3. PUBLICATION OF FAIR PRICES.**

22 (a) IN GENERAL.—Not later than the fair price pub-
23 lication date with respect to a fair price applicability year,
24 the Secretary of Health and Human Services (in this sec-
25 tion referred to as the “Secretary”) shall, with respect to

1 each approved prescription drug, establish and publish the
2 price that the Secretary determines to be a fair price for
3 such drug in order for the manufacturer of such drug to
4 provide access to such price—

5 (1) to any fair price eligible individual who is
6 dispensed such drug during such fair price applica-
7 bility year (and to pharmacies, mail order services,
8 and other dispensers, with respect to such individ-
9 uals who are dispensed such drugs); and

10 (2) to hospitals, physicians, and other providers
11 of services and suppliers that furnish or administer
12 such drug to such an individual during such year.

13 In establishing the fair price for each such drug, the Sec-
14 retary shall take into account the recommendations made
15 by the Prescription Drug Price Regulatory Commission
16 (in this section referred to as the “Commission”) under
17 section 2(b)(1) for such drug and such year.

18 (b) REVISIONS.—The Secretary may revise the fair
19 price applicable to an approved prescription drug for a fair
20 price applicability year after the fair price publication date
21 with respect to such year has passed if—

22 (1) the Secretary has received a recommenda-
23 tion from the Commission that the fair price be so
24 revised;

1 (2) in the judgment of the Secretary, revising
2 such fair price is necessary to account for significant
3 changes to—

4 (A) supply (or projected supply) or de-
5 mand (or projected demand) for such drug; or

6 (B) any of the other factors described in
7 section 2(b)(3) with respect to such drug; and

8 (3) the Secretary notifies the manufacturer of
9 such drug not less than 30 days before such revised
10 fair price goes into effect.

11 (c) TEMPORARY FAIR PRICE WAIVER.—

12 (1) IN GENERAL.—The Secretary may author-
13 ize a manufacturer of an approved prescription drug
14 to provide access to such drug to a fair price eligible
15 individual described in paragraph (1) of subsection
16 (a) (or to a hospital, physician, or other provider of
17 services or supplier described in paragraph (2) of
18 such subsection with respect to such individual) at
19 a price in excess of a fair price if, in the judgment
20 of the Secretary, such authorization is necessary to
21 maintain access to such drug for all fair price eligi-
22 ble individuals.

23 (2) DURATION OF WAIVER.—An authorization
24 under this subsection shall last for a period of 90
25 days. The Secretary may extend such authorization

1 for 1 or more additional 90-day periods if the Sec-
2 retary determines such extension is necessary.

3 (d) PENALTIES FOR NONCOMPLIANCE BY A MANU-
4 FACTURER.—

5 (1) IN GENERAL.—In addition to any other
6 penalties prescribed by law, any manufacturer of an
7 approved prescription drug that does not provide ac-
8 cess during a fair price applicability year to a price
9 that is equal to or less than the fair price for such
10 drug for such year (or, in the case that an author-
11 ization under subsection (c) is in effect with respect
12 to such manufacturer and drug, a price that is equal
13 to or less than the price authorized under such sub-
14 section)—

15 (A) to a fair price eligible individual who
16 is dispensed such drug during such fair price
17 applicability year (and to pharmacies, mail
18 order services, and other dispensers, with re-
19 spect to such individuals who are dispensed
20 such drugs); or

21 (B) to a hospital, physician, or other pro-
22 vider of services or supplier that furnished or
23 administered such drug to such an individual
24 during such year;

1 shall be subject to a civil penalty, for each year and
2 for each drug for which the violation occurs, equal
3 to 10 times the amount equal to the product of the
4 number of units of such drug so furnished, dis-
5 pensed, or administered during such year and the
6 difference between the price for such drug made
7 available for such year by such manufacturer with
8 respect to such individual or hospital, physician, pro-
9 vider of services, or supplier and the fair price for
10 such drug for such year (or the price authorized
11 under subsection (c), as applicable).

12 (2) APPLICATION.—The provisions of section
13 1128A of the Social Security Act (42 U.S.C. 1320a–
14 7) (other than subsections (a) and (b)) shall apply
15 to a civil monetary penalty under this section in the
16 same manner as such provisions apply to a penalty
17 or proceeding under section 1128A(a).

18 **SEC. 4. FAIR PRICES FOR PRESCRIPTION DRUGS RE-**
19 **QUIRED.**

20 (a) PROHIBITION.—Section 301 of the Federal Food,
21 Drug, and Cosmetic Act is amended by adding at the end
22 the following:

23 “(jjj) Selling, or offering for sale, a drug (or biologi-
24 cal product) at a price that exceeds the fair price published

1 under section 3 of the Regulate the Price of All Drugs
2 Act.”.

3 (b) ENFORCEMENT BY FEDERAL TRADE COMMIS-
4 SION.—

5 (1) UNFAIR OR DECEPTIVE ACTS OR PRAC-
6 TICES.—A violation of section 301(jjj) of the Fed-
7 eral Food, Drug, and Cosmetic Act or a regulation
8 promulgated under such subsection shall be treated
9 as a violation of a regulation under section
10 18(a)(1)(B) of the Federal Trade Commission Act
11 (15 U.S.C. 57a(a)(1)(B)) regarding unfair or decep-
12 tive acts or practices.

13 (2) POWERS OF COMMISSION.—The Federal
14 Trade Commission shall enforce subsection (jjj) of
15 such section 301 and any regulation promulgated
16 under such subsection in the same manner, by the
17 same means, and with the same jurisdiction, powers,
18 and duties as though all applicable terms and provi-
19 sions of the Federal Trade Commission Act (15
20 U.S.C. 41 et seq.) were incorporated into and made
21 a part of this section. Any person who violates such
22 subsection or a regulation promulgated under such
23 subsection shall be subject to the penalties and enti-
24 tled to the privileges and immunities provided in the
25 Federal Trade Commission Act.

1 (c) ACTIONS BY STATES.—

2 (1) IN GENERAL.—In any case in which the at-
3 torney general of a State, or an official or agency of
4 a State, has reason to believe that an interest of the
5 residents of such State has been or is threatened or
6 adversely affected by an act or practice in violation
7 of subsection (jjj) of such section 301 or a regula-
8 tion promulgated under such subsection, the State,
9 as *parens patriae*, may bring a civil action on behalf
10 of the residents of the State in an appropriate dis-
11 trict court of the United States to—

12 (A) enjoin such act or practice;

13 (B) enforce compliance with such sub-
14 section or such regulation;

15 (C) obtain damages, restitution, or other
16 compensation on behalf of residents of the
17 State; or

18 (D) obtain such other legal and equitable
19 relief as the court may consider to be appro-
20 priate.

21 (2) NOTICE.—Before filing an action under this
22 subsection, the attorney general, official, or agency
23 of the State involved shall provide to the Federal
24 Trade Commission a written notice of such action
25 and a copy of the complaint for such action. If the

1 attorney general, official, or agency determines that
2 it is not feasible to provide the notice described in
3 this paragraph before the filing of the action, the at-
4 torney general, official, or agency shall provide writ-
5 ten notice of the action and a copy of the complaint
6 to the Federal Trade Commission immediately upon
7 the filing of the action.

8 (3) AUTHORITY OF FEDERAL TRADE COMMIS-
9 SION.—

10 (A) IN GENERAL.—On receiving notice
11 under paragraph (2) of an action under this
12 subsection, the Federal Trade Commission shall
13 have the right—

14 (i) to intervene in the action;

15 (ii) upon so intervening, to be heard
16 on all matters arising therein; and

17 (iii) to file petitions for appeal.

18 (B) LIMITATION ON STATE ACTION WHILE
19 FEDERAL ACTION IS PENDING.—If the Federal
20 Trade Commission or the Attorney General of
21 the United States has instituted a civil action
22 for violation of subsection (jjj) of such section
23 301 or a regulation promulgated under such
24 subsection (referred to in this subparagraph as
25 the “Federal action”), no State attorney gen-

1 eral, official, or agency may bring an action
2 under this subsection during the pendency of
3 the Federal action against any defendant
4 named in the complaint in the Federal action
5 for any violation of such subsection or regula-
6 tion alleged in such complaint.

7 (4) RULE OF CONSTRUCTION.—For purposes of
8 bringing a civil action under this subsection, nothing
9 in this Act shall be construed to prevent an attorney
10 general, official, or agency of a State from exercising
11 the powers conferred on the attorney general, offi-
12 cial, or agency by the laws of such State to conduct
13 investigations, administer oaths and affirmations, or
14 compel the attendance of witnesses or the production
15 of documentary and other evidence.

16 (d) PRIVATE RIGHT OF ACTION.—

17 (1) IN GENERAL.—A person injured by an act
18 or practice in violation of subsection (jjj) of such
19 section 301 or a regulation promulgated under such
20 subsection may bring in an appropriate district court
21 of the United States—

22 (A) an action to enjoin the violation;

23 (B) an action to recover three times the
24 amount of damages for actual monetary loss
25 from the violation, or to receive up to \$50,000

1 in damages for each such violation, whichever is
2 greater; or

3 (C) both such actions.

4 (2) WILLFUL OR KNOWING VIOLATIONS.—If the
5 court finds that the defendant acted willfully or
6 knowingly in committing a violation described in
7 paragraph (1), the court may, in its discretion, in-
8 crease the amount of the award to an amount equal
9 to not more than 3 times the amount available
10 under paragraph (1)(B).

11 (3) COSTS AND ATTORNEY'S FEES.—The court
12 shall award to a prevailing plaintiff in an action
13 under this subsection the costs of such action and
14 reasonable attorney's fees, as determined by the
15 court.

16 (4) LIMITATION.—An action may be com-
17 menced under this subsection not later than 5 years
18 after the date on which the person first discovered
19 or had a reasonable opportunity to discover the vio-
20 lation.

21 (5) NONEXCLUSIVE REMEDY.—The remedy pro-
22 vided by this subsection shall be in addition to any
23 other remedies available to the person.

1 **SEC. 5. MARCH-IN RIGHTS FOR PATENT.**

2 If the owner of a patent sells a drug in the United
3 States above the fair price published pursuant to section
4 3 or does not sell an adequate quantity to meet patient
5 demand of a drug in the United States at the fair price
6 published pursuant to section 3, the Secretary of Health
7 and Human Services may assert the right to claim from
8 the owner of any patent for such drug a nonexclusive, par-
9 tially exclusive, or exclusive license in any field of use,
10 upon terms that are reasonable under the circumstances.

11 **SEC. 6. USE OF THE DEFENSE PRODUCTION ACT.**

12 The President may use the authorities under title I,
13 title III, and title VII of the Defense Production Act of
14 1950 to increase the domestic supply of a drug if the Com-
15 mission has determined that—

16 (1) there are inadequate facilities or means of
17 production in the United States to produce an
18 amount of such drug that would satisfy patient de-
19 mand for such drug; and

20 (2) foreign supplies of such drug cannot be reli-
21 ably and sustainably imported into the United
22 States in such quantities as are necessary for such
23 drug to be purchased at the fair price established for
24 such drug under section 3.

25 **SEC. 7. DEFINITIONS.**

26 In this Act, the following definitions apply:

1 (1) APPROVED PRESCRIPTION DRUG.—The
2 term “approved prescription drug” means—

3 (A) a drug which may be dispensed only
4 upon prescription and that is described in sub-
5 paragraph (A)(i), (A)(ii), or (A)(iii) of section
6 1927(k)(2) of the Social Security Act (42
7 U.S.C. 1396r–8(k)(2));

8 (B) a biological product described in
9 clauses (i) through (iii) of subparagraph (B) of
10 such section;

11 (C) insulin described in subparagraph (C)
12 of such section and medical supplies associated
13 with the injection of insulin (as defined in regu-
14 lations of the Secretary); or

15 (D) a vaccine licensed under section 351 of
16 the Public Health Service Act.

17 (2) COMPARABLE REFERENCE COUNTRY.—The
18 term “comparable reference country” means any of
19 the following countries:

20 (A) Canada.

21 (B) France.

22 (C) Germany.

23 (D) Italy.

24 (E) Japan.

25 (F) The United Kingdom.

1 (3) FAIR PRICE APPLICABILITY YEAR.—The
2 term “fair price applicability year” means a year
3 (beginning with 2027).

4 (4) FAIR PRICE ELIGIBLE INDIVIDUAL.—The
5 term “fair price eligible individual” means, with re-
6 spect to an approved prescription drug, an individual
7 who is located in the United States at the time such
8 drug is furnished or administered to such individual.

9 (5) FAIR PRICE PUBLICATION DATE.—The term
10 “fair price publication date” means, with respect to
11 a fair price applicability year, July 1 of the pre-
12 ceding year.

13 (6) FAIR PRICE RECOMMENDATION DATE.—The
14 term “fair price recommendation date” means, with
15 respect to a fair price applicability year, May 1 of
16 the preceding year.

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