

117TH CONGRESS
1ST SESSION

H. R. 597

To require any COVID–19 drug developed in whole or in part with Federal support to be affordable and accessible by prohibiting monopolies and price gouging, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 28, 2021

Ms. SCHAKOWSKY (for herself, Mr. DOGGETT, Ms. DELAURO, Mr. DEFazio, Mr. GRIJALVA, Mr. KHANNA, Mr. RASKIN, Ms. PINGREE, Mr. WELCH, Mr. POCAN, Mr. BISHOP of Georgia, Ms. NORTON, Ms. MCCOLLUM, Ms. JAYAPAL, and Ms. CHU) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, Science, Space, and Technology, and Armed 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 require any COVID–19 drug developed in whole or in part with Federal support to be affordable and accessible by prohibiting monopolies and price gouging, 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 “Pandemic Treatment
5 Access and Affordability Act of 2021”.

1 **SEC. 2. REQUIREMENTS FOR LICENSING OF NEW COVID-19**
2 **TREATMENT AND PREVENTION TECH-**
3 **NOLOGIES TO MEET DOMESTIC AND GLOBAL**
4 **DEMAND.**

5 (a) **NONEXCLUSIVE LICENSE REQUIRED.**—Any cov-
6 ered license granted by the Federal Government shall be
7 an open, nonexclusive license.

8 (b) **CONTRACTOR, ASSIGNEE, EXCLUSIVE LI-**
9 **CENSEE.**—Notwithstanding any other provision of law,
10 any contractor, assignee, or exclusive licensee to an inven-
11 tion developed in whole or in part in work performed
12 under a covered transaction shall grant an open, non-ex-
13 clusive license. If any such contractor, assignee, or exclu-
14 sive licensee refuses to grant such license, the Federal gov-
15 ernment shall grant the license.

16 (c) **REASONABLE ROYALTY.**—

17 (1) **IN GENERAL.**—Except as provided in para-
18 graph (4), an entity that accepts an open, nonexclu-
19 sive license under this section shall pay a reasonable
20 royalty with respect to sales within the United
21 States to—

22 (A) the holder of a patent that claims the
23 COVID-19 related invention; or

24 (B) to the holder of an application ap-
25 proved under section 505 of the Federal Food,
26 Drug, and Cosmetic Act (21 U.S.C. 355) or

1 section 351 of the Public Health Service Act
2 (42 U.S.C. 262) for which any FDA-granted
3 exclusivity with respect to a drug related to
4 such invention that was terminated under this
5 section.

6 (2) ROYALTY.—The reasonable royalty de-
7 scribed under paragraph (1) shall be a percentage of
8 sales of the entity paying the royalty, where the per-
9 centage rate is no higher than the average royalty
10 rate estimated from the data provided by the Inter-
11 nal Revenue Service for pharmaceutical manufac-
12 turer Federal income tax returns.

13 (3) REQUIREMENTS.—

14 (A) IN GENERAL.—The royalty described
15 under paragraph (2) shall be subject to the ap-
16 plicable royalty rate requirements of section
17 319B of the Public Health Service Act, as
18 added by section 5 of this Act.

19 (B) MULTIPLE AFFECTED PARTIES.—In
20 the case of more than one recipient of a royalty,
21 the royalty shall be divided among each such re-
22 cipient (including any manufacturer) in a man-
23 ner agreed upon by the manufacturer and other
24 recipients, or, in the absence of such an agree-

1 ment, in a manner the Secretary determines to
2 be appropriate.

3 (4) EXCEPTION FOR GOVERNMENT-OWNED IN-
4 VENTIONS.—An entity that accepts an open, non-
5 exclusive license for a federally owned invention de-
6 scribed under section 207 of title 35, United States
7 Code, is not required to pay a royalty under this sec-
8 tion.

9 (d) DEFINITIONS.—In this section:

10 (1) COVERED LICENSE.—The term “covered li-
11 cense” means a license that allows a licensee to
12 make, use, offer to sell, or sell, export, or import
13 into the United States or any other country or terri-
14 tory a COVID–19 related invention pursuant to—

15 (A) section 207 of title 35, United States
16 Code; and

17 (B) section 12 of the Stevenson-Wydler
18 Technology Innovation Act of 1980 (15 U.S.C.
19 3710a).

20 (2) COVERED TRANSACTION.—The term “cov-
21 ered transaction” means any contract, funding
22 agreement, license, other transaction, or other ar-
23 rangement entered into between a party and the
24 Federal Government on or after the date of enact-

1 ment of this Act with respect to research and devel-
2 opment regarding a drug that—

3 (A) is intended or anticipated to be used to
4 diagnose, mitigate, prevent, or treat COVID-
5 19; and

6 (B) consists of—

7 (i) a licensing agreement pursuant to
8 section 207 of title 35, United States
9 Code;

10 (ii) a cooperative research and devel-
11 opment agreement and licensing agreement
12 pursuant to section 12 of the Stevenson-
13 Wydler Technology Innovation Act of 1980
14 (15 U.S.C. 3710a);

15 (iii) a funding agreement, as defined
16 under section 201 of title 35, United
17 States Code; or

18 (iv) any other transaction entered into
19 pursuant to—

20 (I) section 319L, 421, or 480 of
21 the Public Health Service Act (42
22 U.S.C. 247d-7e, 285b-3, 287a);

23 (II) section 105 of the National
24 Institutes of Health Reform Act of
25 2006 (42 U.S.C. 284n); or

1 (III) section 2371 of title 10,
2 United States Code.

3 (3) COVID–19 RELATED INVENTION.—The
4 term “COVID–19 related invention” means any in-
5 vention that claims a drug that is manufactured,
6 used, designed, developed, modified, licensed, or pro-
7 cured to diagnose, mitigate, prevent, treat, or cure
8 COVID–19; a use of such drug; a form of such
9 drug; a method of use of such drug; or a method of
10 manufacturing such drug.

11 (4) FDA-GRANTED EXCLUSIVITY.—The term
12 “FDA-granted exclusivity” means prohibitions on
13 the submission or approval of drug applications
14 granted under any of the following:

15 (A) Clauses (ii) through (v) of section
16 505(c)(3)(E) of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 355(c)(3)(E)).

18 (B) Subsection (j)(5)(B)(iv) or clause (ii),
19 (iii), or (iv) of subsection (j)(5)(F) of such Act
20 (21 U.S.C. 355(c)(3)(E)).

21 (C) Section 505A of such Act (21 U.S.C.
22 355a).

23 (D) Section 505E of such Act (21 U.S.C.
24 355f).

1 (E) Section 527 of such Act (21 U.S.C.
2 360cc).

3 (F) Section 351(k)(7) of this Act (42
4 U.S.C. 262(k)(7)).

5 (G) Any other provision of law that pro-
6 vides for marketing or data exclusivity (or ex-
7 tension of exclusivity) with respect to a drug.

8 (5) OPEN, NONEXCLUSIVE LICENSE.—The term
9 “open, nonexclusive license” means a license that al-
10 lows a qualified licensee, subject to the provisions of
11 the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 301 et seq.) and the Public Health Service
13 Act (42 U.S.C. 201 et seq.)—

14 (A) to make, use, offer to sell, sell, export,
15 or import into the United States and any other
16 country and territory an invention;

17 (B) to reference or rely upon earlier-sub-
18 mitted regulatory test data or the earlier grant
19 of marketing approval of a treatment or vaccine
20 related to such invention; and

21 (C) to access and use otherwise confiden-
22 tial know-how relating to the manufacture of
23 such invention.

1 **SEC. 3. REQUIREMENTS FOR REASONABLE PRICING OF**
2 **FEDERALLY SUPPORTED COVID-19 DRUGS.**

3 (a) **REASONABLE PRICING REQUIREMENTS.**—Any
4 covered transaction shall include terms and conditions re-
5 quiring that the pricing of the drug by the party referred
6 to in subsection (b)(1) be fair and reasonable, and facili-
7 tate global access, taking into consideration—

8 (1) the impact of the price on access to the
9 drug in the United States, taking into consideration
10 racial disparities in COVID-19 cases and fatalities
11 and other socioeconomic disparities;

12 (2) the impact of the price on health program
13 spending and budgets in the United States;

14 (3) the risk adjusted value of Federal subsidies
15 and investments related to the drug;

16 (4) the costs associated with development and
17 manufacturing of the drug;

18 (5) the size of the affected patient population in
19 the United States and globally; and

20 (6) the therapeutic efficacy of the drug.

21 (b) **DEFINITIONS.**—In this section:

22 (1) **COVERED TRANSACTION.**—The term “cov-
23 ered transaction” has the meaning given to such
24 term in section 2.

1 (2) DRUG.—The term “drug” has the meaning
2 given to such term in section 201 of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 321).

4 **SEC. 4. REPORTING ON THE EXPENDITURES OF MANUFAC-**
5 **TURERS WITH RESPECT TO COVID-19 DRUGS.**

6 (a) COVERED DRUG.—For purposes of this section,
7 the term “covered drug” means a drug that is intended
8 or anticipated to be used to diagnose, mitigate, prevent,
9 or treat COVID-19.

10 (b) REPORTING REQUIRED.—The manufacturer of a
11 covered drug shall submit a report described in subsection
12 (c) to the Secretary upon—

13 (1) the submission of an application for ap-
14 proval of the drug under subsection (b) or (j) of sec-
15 tion 505 of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 355);

17 (2) investigational use of the drug under section
18 505(i) of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 355(i)) or section 351 of the Public
20 Health Service Act (42 U.S.C. 262);

21 (3) the submission of an application for licens-
22 ing the drug under subsection (a) or (k) of section
23 351 of the Public Health Service Act (42 U.S.C.
24 262);

1 (4) the issuance of an authorization for emer-
2 gency use of the drug under section 564 of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C.
4 360bbb-3); or

5 (5) the marketing of the drug.

6 (c) CONTENTS.—A report under subsection (a), con-
7 sistent with the standard for disclosures described in sec-
8 tion 213.3(d) of title 12, Code of Federal Regulations (as
9 in effect on the date of enactment of this Act), shall ad-
10 dress the expenditures of the manufacturer with respect
11 to the covered drug and include, at a minimum—

12 (1) the sponsor or sponsors of the covered drug;

13 (2) the current wholesale acquisition cost of the
14 covered drug when applicable;

15 (3) the total expenditures of the manufacturer,
16 specified by individual costs, on—

17 (A) materials and manufacturing for the
18 covered drug; and

19 (B) acquiring patents and licensing for the
20 covered drug;

21 (4) the total amount and percentage of research
22 and development expenditures for the covered drug
23 that was derived from Federal funds;

1 (5) the total amount of any Federal benefits re-
2 ceived by the manufacturer with respect to the cov-
3 ered drug, including—

4 (A) the specific amounts and periods of
5 impact for each such benefit;

6 (B) the specific value of any tax credits,
7 including benefits from patient assistance pro-
8 grams and donated samples;

9 (C) clinical and preclinical investments;

10 (D) any Federal benefit toward manufac-
11 turing costs, including building or retrofitting
12 facilities;

13 (E) Federal grants, including from the Na-
14 tional Institutes of Health, the Centers for Dis-
15 ease Control and Prevention, the Department of
16 Defense, the Department of Energy, or other
17 Federal departments or agencies;

18 (F) patent applications that benefitted
19 from such grants;

20 (G) patent extensions;

21 (H) exclusivity periods; and

22 (I) waivers of fees;

23 (6) the total expenditures of the manufacturer
24 on research and development, itemized by basic and
25 preclinical research and by clinical research, re-

1 reported separately for each clinical trial, for the covered
2 drug to demonstrate that the covered drug
3 meets applicable statutory standards for approval
4 under section 505 of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 355), licensure under section
6 351 of the Public Health Service Act (42
7 U.S.C. 262), an exemption for investigational use
8 under section 505(i) of the Federal Food, Drug, or
9 Cosmetic Act (21 U.S.C. 355(i)) or section 351 of
10 the Public Health Service Act, or approval under
11 section 564 of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 360bbb-3), as applicable;

13 (7) the total expenditures of the manufacturer
14 on pursuing new or expanded indications or dosage
15 changes for the covered drug under section 505 of
16 the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 355) or section 351 of the Public Health
18 Service Act (42 U.S.C. 262);

19 (8) the total expenditures of the manufacturer
20 on carrying out postmarket requirements related to
21 such drug, including under section 505(o)(3) of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 355-1);

1 (9) the specific expenditures associated with
2 marketing and advertising costs for the covered
3 drug;

4 (10) any anticipated royalty fees from licensing
5 to other manufacturers; and

6 (11) with respect to the manufacturer—

7 (A) all stock-based performance metrics
8 used by the manufacturer to determine execu-
9 tive compensation over the preceding 12
10 months; and

11 (B) any additional information the manu-
12 facturer chooses to provide related to drug pric-
13 ing decisions.

14 (d) CIVIL MONETARY PENALTIES.—

15 (1) FAILURE TO SUBMIT.—Any manufacturer
16 of a covered drug that fails to submit a report as
17 required by this section, following notification by the
18 Secretary to the manufacturer that the manufac-
19 turer is not in compliance with this section, shall be
20 subject to a civil monetary penalty of \$100,000 for
21 each day on which the violation continues.

22 (2) FALSE INFORMATION.—Any manufacturer
23 of a covered drug that knowingly provides false in-
24 formation in a report under this section is subject to

1 a civil monetary penalty in an amount not to exceed
2 \$100,000 for each item of false information.

3 (e) PUBLIC POSTING.—

4 (1) IN GENERAL.—Subject to paragraph (3),
5 the Secretary shall post each report submitted under
6 subsection (b) on the public website of the Depart-
7 ment of Health and Human Services no later than
8 30 days after the submission of the report.

9 (2) FORMAT.—The Secretary shall ensure that
10 such reports are—

11 (A) user-friendly to the public; and

12 (B) written in plain language that con-
13 sumers can readily understand.

14 (3) PROTECTED INFORMATION.—Nothing in
15 this section shall be construed to authorize the pub-
16 lic disclosure of information submitted by a manu-
17 facturer that is prohibited from disclosure by appli-
18 cable laws concerning the protection of trade secrets,
19 commercial information, and other information cov-
20 ered under such laws.

21 (f) DEFINITION.—In this section, the term “drug”
22 has the meaning given to such term in section 201 of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

1 **SEC. 5. PRICING REQUIREMENTS FOR EXISTING TREAT-**
2 **MENTS AND VACCINES IN A PUBLIC HEALTH**
3 **EMERGENCY.**

4 Title III of the Public Health Service Act is amended
5 by inserting after section 319A (42 U.S.C. 247d-1a) the
6 following new section:

7 **“SEC. 319B. PRICING REQUIREMENTS FOR TREATMENTS**
8 **AND VACCINES IN A PUBLIC HEALTH EMER-**
9 **GENCY.**

10 “(a) DEFINITIONS.—For purposes of this section:

11 “(1) The term ‘covered drug’ means a drug (in-
12 cluding any vaccine) used to diagnose, mitigate, pre-
13 vent, or treat a disease or disorder with respect to
14 which there is or was in effect a declaration of a
15 public health emergency under section 319.

16 “(2) The term ‘covered period’ means the pe-
17 riod ending if and when the circumstances which led
18 to the public health emergency cease to exist and are
19 unlikely to recur.

20 “(3) The term ‘FDA-granted exclusivity’ means
21 prohibitions on the submission or approval of drug
22 applications granted under any of the following:

23 “(A) Clauses (ii) through (v) of section
24 505(c)(3)(E) of the Federal Food, Drug, and
25 Cosmetic Act.

1 “(B) Subsection (j)(5)(B)(iv) or clause (ii),
2 (iii), or (iv) of subsection (j)(5)(F) of such Act.

3 “(C) Section 505A of such Act.

4 “(D) Section 505E of such Act.

5 “(E) Section 527 of such Act.

6 “(F) Section 351(k)(7) of this Act.

7 “(G) Any other provision of law that pro-
8 vides for marketing or data exclusivity (or ex-
9 tension of exclusivity) with respect to a drug.

10 “(4) The term ‘wholesale acquisition cost’ has
11 the meaning given that term in section
12 1847A(c)(6)(B) of the Social Security Act.

13 “(b) DETERMINATION OF EXCESSIVE PRICE.—Dur-
14 ing any covered period with respect to a covered drug, the
15 Secretary shall determine that the price of a covered drug
16 is excessive if the wholesale acquisition cost (or a more
17 relevant measure of price) of the covered drug is not fair
18 and reasonable, or does not facilitate global access, taking
19 into consideration—

20 “(1) the impact of the price on access to the
21 covered drug in the United States, taking into con-
22 sideration racial disparities and other socioeconomic
23 disparities;

24 “(2) the impact of the price on health program
25 spending and budgets in the United States;

1 “(3) the risk adjusted value of Federal sub-
2 sidies and investments related to the covered drug;

3 “(4) the costs associated with development and
4 manufacturing of the covered drug;

5 “(5) the size of the affected patient population
6 in the United States and globally; and

7 “(6) the therapeutic efficacy of the covered
8 drug.

9 “(c) EXCESSIVE PRICING REMEDY.—If the Secretary
10 determines pursuant to subsection (b) that the price of
11 a covered drug is excessive, the Secretary—

12 “(1) shall waive or void any FDA-granted
13 exclusivities with respect to the covered drug, effec-
14 tive on the date that the excessive price determina-
15 tion is made; and

16 “(2) shall grant open, nonexclusive licenses al-
17 lowing any person to make, use, offer to sell, or sell,
18 or import into the United States such drug, and to
19 rely upon the regulatory test data of such drug, and
20 to access and use otherwise confidential information,
21 including know-how, related to the manufacture of
22 such drug in accordance with subsection (d).

23 “(d) REASONABLE ROYALTY.—

24 “(1) IN GENERAL.—An entity accepting an
25 open, nonexclusive license under subsection (c)(2)

1 shall pay a reasonable royalty with respect to sales
2 within the United States to the holder of a patent
3 that claims the covered drug or that claims a use of
4 the covered drug or to the holder of an application
5 approved under section 505 of the Federal Food,
6 Drug, and Cosmetic Act or section 351 of the Public
7 Health Service Act for which any FDA-granted ex-
8 clusivity with respect to the covered drug was termi-
9 nated under subsection (c)(1).

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

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

18 “(B) an amount as determined by the Sec-
19 retary, taking into account—

20 “(i) the therapeutic efficacy of the
21 covered drug;

22 “(ii) the size of the affected patient
23 population in the United States and glob-
24 ally;

1 “(iii) the risk adjusted value of Fed-
2 eral subsidies and investments related to
3 the covered;

4 “(iv) the extent to which the manufac-
5 turer of the covered drug has recovered
6 risk adjusted investments related to the
7 covered drug, including the investments re-
8 lated to the invention, regulatory test data,
9 and any other relevant research and devel-
10 opment costs; and

11 “(v) any other information the Sec-
12 retary determines appropriate.

13 “(3) SALES WITHIN OTHER COUNTRIES.—An
14 entity accepting an open, nonexclusive license under
15 subsection (c)(2) shall pay a reasonable royalty with
16 respect to sales within other countries based on the
17 royalty rate paid in the United States times the
18 ratio between that country’s gross domestic product
19 per capita divided by the United States gross domes-
20 tic product per capita in the last year such data was
21 available for both countries, but such royalty shall
22 only be due if there are granted patents or data ex-
23 clusivity rights in that country at the time of sale.

24 “(e) REQUIREMENTS.—

1 “(1) IN GENERAL.—A royalty rate under sub-
2 section (d) shall be consistent with making the cov-
3 ered drug available to purchasers, including govern-
4 mental and nongovernmental purchasers and individ-
5 uals, at prices that are affordable and reasonable.
6 Under no condition shall a royalty be set at a rate
7 that would cause a covered drug for which an open,
8 nonexclusive license was issued under subsection (c)
9 to be sold at an excessive price, as determined under
10 subsection (b).

11 “(2) MULTIPLE AFFECTED PARTIES.—In the
12 case that there is one or more holders or investors
13 in the patented inventions related to the covered
14 drug, the royalty rate shall be divided among the
15 holders or investors (including such manufacturer)
16 in a manner agreed upon by the manufacturer and
17 other holders or investors, or, in the absence of such
18 an agreement, in a manner the Secretary determines
19 to be appropriate.

20 “(3) PRICE.—An entity accepting an open, non-
21 exclusive license under subsection (c)(2) shall sell
22 the covered drug at a price not higher than the ex-
23 cessive price determined for the covered drug under
24 subsection (b).

1 “(f) CLARIFICATION.—An open, nonexclusive license
2 under subsection (c)(2) shall be liable, subject to adequate
3 protection of the legitimate interests of any party utilizing
4 the license, to be terminated only if the circumstances
5 which led to the granting of the open, nonexclusive license
6 cease to exist and are unlikely to recur. The Secretary may
7 review, upon request, the continued existence of these cir-
8 cumstances.”.

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