

116TH CONGRESS
2D SESSION

S. 4439

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 SENATE OF THE UNITED STATES

AUGUST 5, 2020

Ms. SMITH (for herself, Mr. MERKLEY, Ms. BALDWIN, Mrs. GILLIBRAND, and Ms. HARRIS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 “Make Medications Af-
5 fordable by Preventing Pandemic Price-gouging Act of
6 2020” or the “MMAPPP Act of 2020”.

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
15 Government 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) the holder of an application approved
25 under section 505 of the Federal Food, Drug,
26 and Cosmetic Act (21 U.S.C. 355) or section

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

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

12 (3) REQUIREMENTS.—

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

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

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

7 (d) DEFINITIONS.—In this section:

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

13 (A) section 207 of title 35, United States
 14 Code; and

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

18 (2) COVERED TRANSACTION.—The term “cov-
 19 ered transaction” means any contract, funding
 20 agreement, license, other transaction, or other ar-
 21 rangement entered into between a party and the
 22 Federal Government on or after the date of enact-
 23 ment of this Act with respect to research and devel-
 24 opment regarding a drug that—

1 (A) is intended or anticipated to be used to
2 diagnose, mitigate, prevent, or treat COVID—
3 19; and

4 (B) consists of—

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

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

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

16 (iv) any other transaction entered into
17 pursuant to—

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

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

24 (III) section 2371 of title 10,
25 United States Code.

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

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

13 (A) Clauses (ii) through (v) of section
14 505(c)(3)(E) of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 355(c)(3)(E)).

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

19 (C) Section 505A of such Act (21 U.S.C.
20 355a).

21 (D) Section 505E of such Act (21 U.S.C.
22 355f).

23 (E) Section 527 of such Act (21 U.S.C.
24 360cc).

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

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

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

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

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

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

22 **SEC. 3. REQUIREMENTS FOR REASONABLE PRICING OF**
23 **FEDERALLY SUPPORTED COVID-19 DRUGS.**

24 (a) REASONABLE PRICING REQUIREMENTS.—Any
25 covered transaction shall include terms and conditions re-

1 quiring that the pricing of the drug by the party referred
 2 to in section 2(d)(2) be fair and reasonable, and facilitate
 3 global access, taking into consideration—

4 (1) the impact of the price on access to the
 5 drug in the United States, taking into consideration
 6 racial disparities in COVID–19 cases and fatalities
 7 and other socioeconomic disparities;

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

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

12 (4) the costs associated with development and
 13 manufacturing of the drug;

14 (5) the size of the affected patient population in
 15 the United States and globally; and

16 (6) the therapeutic efficacy of the drug.

17 (b) DEFINITIONS.—In this section:

18 (1) COVERED TRANSACTION.—The term “cov-
 19 ered transaction” has the meaning given to such
 20 term in section 2.

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

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

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

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

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

14 (2) investigational use of the drug under section
15 505(i) of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 355(i)) or section 351(a)(3) of the Public
17 Health Service Act (42 U.S.C. 262(a)(3));

18 (3) the submission of an application for licens-
19 ing the drug under subsection (a) or (k) of section
20 351 of the Public Health Service Act (42 U.S.C.
21 262);

22 (4) the issuance of an authorization for emer-
23 gency use of the drug under section 564 of the Fed-
24 eral Food, Drug, and Cosmetic Act (21 U.S.C.
25 360bbb-3); or

26 (5) the marketing of the drug.

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

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

8 (2) the current wholesale acquisition cost of the
 9 covered drug when applicable;

10 (3) the total expenditures of the manufacturer,
 11 specified by individual costs, on—

12 (A) materials and manufacturing for the
 13 covered drug; and

14 (B) acquiring patents and licensing for the
 15 covered drug;

16 (4) the total amount and percentage of research
 17 and development expenditures for the covered drug
 18 that was derived from Federal funds;

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

22 (A) the specific amounts and periods of
 23 impact for each such benefit;

1 (B) the specific value of any tax credits,
2 including benefits from patient assistance pro-
3 grams and donated samples;

4 (C) clinical and preclinical investments;

5 (D) any Federal benefit toward manufac-
6 turing costs, including building or retrofitting
7 facilities;

8 (E) Federal grants, including from the Na-
9 tional Institutes of Health, the Centers for Dis-
10 ease Control and Prevention, the Department of
11 Defense, the Department of Energy, or other
12 Federal departments or agencies;

13 (F) patent applications that benefitted
14 from such grants;

15 (G) patent extensions;

16 (H) exclusivity periods; and

17 (I) waivers of fees;

18 (6) the total expenditures of the manufacturer
19 on research and development, itemized by basic and
20 preclinical research and by clinical research, re-
21 ported separately for each clinical trial, for the cov-
22 ered drug to demonstrate that the covered drug
23 meets applicable statutory standards for approval
24 under section 505 of the Federal Food, Drug, and
25 Cosmetic Act (21 U.S.C. 355), licensure under sec-

1 tion 351 of the Public Health Service Act (42
2 U.S.C. 262), an exemption for investigational use
3 under section 505(i) of the Federal Food, Drug, or
4 Cosmetic Act (21 U.S.C. 355(i)) or section
5 351(a)(3) of the Public Health Service Act (42
6 U.S.C. 262(a)(3)), or authorization under section
7 564 of the Federal Food, Drug, and Cosmetic Act
8 (21 U.S.C. 360bbb-3), as applicable;

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

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

20 (9) the specific expenditures associated with
21 marketing and advertising costs for the covered
22 drug;

23 (10) any anticipated royalty fees from licensing
24 to other manufacturers; and

25 (11) with respect to the manufacturer—

1 (A) all stock-based performance metrics
 2 used by the manufacturer to determine execu-
 3 tive compensation over the preceding 12
 4 months; and

5 (B) any additional information the manu-
 6 facturer chooses to provide related to drug pric-
 7 ing decisions.

8 (d) CIVIL MONETARY PENALTIES.—

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

16 (2) FALSE INFORMATION.—Any manufacturer
 17 of a covered drug that knowingly provides false in-
 18 formation in a report under this section is subject to
 19 a civil monetary penalty in an amount not to exceed
 20 \$100,000 for each item of false information.

21 (e) PUBLIC POSTING.—

22 (1) IN GENERAL.—Subject to paragraph (3),
 23 the Secretary shall post each report submitted under
 24 subsection (b) on the public website of the Depart-

1 ment of Health and Human Services no later than
2 30 days after the submission of the report.

3 (2) **FORMAT.**—The Secretary shall ensure that
4 such reports are—

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

6 (B) written in plain language that con-
7 sumers can readily understand.

8 (3) **PROTECTED INFORMATION.**—Nothing in
9 this section shall be construed to authorize the pub-
10 lic disclosure of information submitted by a manu-
11 facturer that is prohibited from disclosure by any
12 applicable law concerning the protection of trade se-
13 crets, commercial information, and other informa-
14 tion.

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

18 **SEC. 5. PRICING REQUIREMENTS FOR EXISTING TREAT-**
19 **MENTS AND VACCINES IN A PUBLIC HEALTH**
20 **EMERGENCY.**

21 Title III of the Public Health Service Act is amended
22 by inserting after section 319A (42 U.S.C. 247d–1) the
23 following new section:

1 **“SEC. 319B. PRICING REQUIREMENTS FOR TREATMENTS**
2 **AND VACCINES IN A PUBLIC HEALTH EMER-**
3 **GENCY.**

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

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

10 “(2) The term ‘covered period’ means the pe-
11 riod ending if and when the circumstances which led
12 to an applicable public health emergency cease to
13 exist and are unlikely to recur.

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

17 “(A) Clauses (ii) through (v) of section
18 505(c)(3)(E) of the Federal Food, Drug, and
19 Cosmetic Act.

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

22 “(C) Section 505A of such Act.

23 “(D) Section 505E of such Act.

24 “(E) Section 527 of such Act.

25 “(F) Section 351(k)(7) of this Act.

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

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

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

14 “(1) the impact of the price on access to the
 15 covered drug in the United States, taking into con-
 16 sideration racial disparities and other socioeconomic
 17 disparities;

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

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

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

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

1 “(6) the therapeutic efficacy of the covered
2 drug.

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

6 “(1) shall waive or void any FDA-granted
7 exclusivities with respect to the covered drug, effective
8 on the date that the excessive price determination
9 is made; and

10 “(2) shall grant open, nonexclusive licenses allowing
11 any person to make, use, offer to sell, or sell,
12 or import into the United States such drug, and to
13 rely upon the regulatory test data of such drug, and
14 to access and use otherwise confidential information,
15 including know-how, related to the manufacture of
16 such drug in accordance with subsection (d).

17 “(d) REASONABLE ROYALTY.—

18 “(1) IN GENERAL.—An entity accepting an
19 open, nonexclusive license under subsection (c)(2)
20 shall pay a reasonable royalty with respect to sales
21 within the United States to the holder of a patent
22 that claims the covered drug or that claims a use of
23 the covered drug or to the holder of an application
24 approved under section 505 of the Federal Food,
25 Drug, and Cosmetic Act or section 351 of the Public

1 Health Service Act for which any FDA-granted ex-
2 clusivity with respect to the covered drug was termi-
3 nated under subsection (c)(1).

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

6 “(A) a percentage of sales, where the per-
7 centage rate is no higher than the average roy-
8 alty rate estimated from the data provided by
9 the Internal Revenue Service for pharma-
10 ceutical manufacturer Federal income tax re-
11 turns; or

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

14 “(i) the therapeutic efficacy of the
15 covered drug;

16 “(ii) the size of the affected patient
17 population in the United States and glob-
18 ally;

19 “(iii) the risk adjusted value of Fed-
20 eral subsidies and investments related to
21 the covered drug;

22 “(iv) the extent to which the manufac-
23 turer of the covered drug has recovered
24 risk adjusted investments related to the
25 covered drug, including the investments re-

lated to the invention, regulatory test data,
and any other relevant research and devel-
opment costs; and

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

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

“(e) REQUIREMENTS.—

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

1 to be sold at an excessive price, as determined under
 2 subsection (b).

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 covered
 6 drug, the royalty rate shall be divided among the
 7 holders or investors (including such manufacturer)
 8 in a manner agreed upon by the manufacturer and
 9 other holders or investors, or, in the absence of such
 10 an agreement, in a manner the Secretary determines
 11 to be appropriate.

12 “(3) PRICE.—An entity accepting an open, non-
 13 exclusive license under subsection (c)(2) shall sell
 14 the covered drug at a price not higher than the ex-
 15 cessive price determined for the covered drug under
 16 subsection (b).

17 “(f) CLARIFICATION.—An open, nonexclusive license
 18 under subsection (c)(2) shall be liable, subject to adequate
 19 protection of the legitimate interests of any party utilizing
 20 the license, to be terminated only if the circumstances
 21 which led to the granting of the open, nonexclusive license
 22 cease to exist and are unlikely to recur. The Secretary may
 23 review, upon request, the continued existence of these cir-
 24 cumstances.”.

○