II

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.

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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

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# 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.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Make Medications Affordable by Preventing Pandemic Price-gouging Act of 2020'' or the ''MMAPPP Act of 2020''.

**SEC. 2. REQUIREMENTS FOR LICENSING OF NEW COVID–19 TREATMENT AND PREVENTION TECHNOLOGIES TO MEET DOMESTIC AND GLOBAL DEMAND.**

(a) NONEXCLUSIVE LICENSE REQUIRED.—Any covered license granted by the Federal Government shall be an open, nonexclusive license.

(b) CONTRACTOR, ASSIGNEE, EXCLUSIVE LICENSEE.—Notwithstanding any other provision of law, any contractor, assignee, or exclusive licensee to an invention developed in whole or in part in work performed under a covered transaction shall grant an open, non-exclusive license. If any such contractor, assignee, or exclusive licensee refuses to grant such license, the Federal Government shall grant the license.

(c) REASONABLE ROYALTY.—

(1) IN GENERAL.—Except as provided in paragraph (4), an entity that accepts an open, nonexclusive license under this section shall pay a reasonable royalty with respect to sales within the United States to—

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

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

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

(2) ROYALTY.—The reasonable royalty described under paragraph (1) shall be a percentage of sales of the entity paying the royalty, where the percentage rate is no higher than the average royalty rate estimated from the data provided by the Internal Revenue Service for pharmaceutical manufacturer Federal income tax returns.

(3) REQUIREMENTS.—

(A) IN GENERAL.—The royalty described under paragraph (2) shall be subject to the applicable royalty rate requirements of section 319B of the Public Health Service Act, as added by section 5 of this Act.

(B) MULTIPLE AFFECTED PARTIES.—In the case of more than one recipient of a royalty, the royalty shall be divided among each such recipient (including any manufacturer) in a manner agreed upon by the manufacturer and other recipients, or, in the absence of such an agreement, in a manner the Secretary determines to be appropriate.

(4) EXCEPTION FOR GOVERNMENT-OWNED INVENTIONS.—An entity that accepts an open, nonexclusive license for a federally owned invention described under section 207 of title 35, United States Code, is not required to pay a royalty under this section.

(d) DEFINITIONS.—In this section:

(1) COVERED LICENSE.—The term ''covered license'' means a license that allows a licensee to make, use, offer to sell, or sell, export, or import into the United States or any other country or territory a COVID–19 related invention pursuant to—

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

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

(2) COVERED TRANSACTION.—The term ''covered transaction'' means any contract, funding agreement, license, other transaction, or other arrangement entered into between a party and the Federal Government on or after the date of enactment of this Act with respect to research and development regarding a drug that—

(A) is intended or anticipated to be used to diagnose, mitigate, prevent, or treat COVID–19; and

(B) consists of—

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

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

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

(iv) any other transaction entered into pursuant to—

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

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

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

(3) COVID–19 RELATED INVENTION.—The term ''COVID–19 related invention'' means any invention that claims a drug that is manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure COVID–19; a use of such drug; a form of such drug; a method of use of such drug; or a method of manufacturing such drug.

(4) FDA-GRANTED EXCLUSIVITY.—The term ''FDA-granted exclusivity'' means prohibitions on the submission or approval of drug applications granted under any of the following:

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

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

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

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

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

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

(G) Any other provision of law that provides for marketing or data exclusivity (or extension of exclusivity) with respect to a drug.

(5) OPEN, NONEXCLUSIVE LICENSE.—The term ''open, nonexclusive license'' means a license that allows a qualified licensee, subject to the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.)—

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

(B) to reference or rely upon earlier-submitted regulatory test data or the earlier grant of marketing approval of a treatment or vaccine related to such invention; and

(C) to access and use otherwise confidential know-how relating to the manufacture of such invention.

**SEC. 3. REQUIREMENTS FOR REASONABLE PRICING OF FEDERALLY SUPPORTED COVID–19 DRUGS.**

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

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

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

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

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

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

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

(6) the therapeutic efficacy of the drug.

(b) DEFINITIONS.—In this section:

(1) COVERED TRANSACTION.—The term ''covered transaction'' has the meaning given to such term in section 2.

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

**SEC. 4. REPORTING ON THE EXPENDITURES OF MANUFACTURERS WITH RESPECT TO COVID–19 DRUGS.**

(a) COVERED DRUG.—For purposes of this section, the term ''covered drug'' means a drug that is intended or anticipated to be used to diagnose, mitigate, prevent, or treat COVID–19.

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

(1) the submission of an application for approval of the drug under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

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

(3) the submission of an application for licensing the drug under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);

(4) the issuance of an authorization for emergency use of the drug under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3); or

(5) the marketing of the drug.

(c) CONTENTS.—A report under subsection (a), consistent with the standard for disclosures described in section 213.3(d) of title 12, Code of Federal Regulations (as in effect on the date of enactment of this Act), shall address the expenditures of the manufacturer with respect to the covered drug and include, at a minimum—

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

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

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

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

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

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

(5) the total amount of any Federal benefits received by the manufacturer with respect to the covered drug, including—

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

(B) the specific value of any tax credits, including benefits from patient assistance programs and donated samples;

(C) clinical and preclinical investments;

(D) any Federal benefit toward manufacturing costs, including building or retrofitting facilities;

(E) Federal grants, including from the National Institutes of Health, the Centers for Disease Control and Prevention, the Department of Defense, the Department of Energy, or other Federal departments or agencies;

(F) patent applications that benefitted from such grants;

(G) patent extensions;

(H) exclusivity periods; and

(I) waivers of fees;

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

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

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

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

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

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

(11) with respect to the manufacturer—

(A) all stock-based performance metrics used by the manufacturer to determine executive compensation over the preceding 12 months; and

(B) any additional information the manufacturer chooses to provide related to drug pricing decisions.

(d) CIVIL MONETARY PENALTIES.—

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

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

(e) PUBLIC POSTING.—

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

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

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

(A) user-friendly to the public; and

(B) written in plain language that consumers can readily understand.

(3) PROTECTED INFORMATION.—Nothing in this section shall be construed to authorize the public disclosure of information submitted by a manufacturer that is prohibited from disclosure by any applicable law concerning the protection of trade secrets, commercial information, and other information.

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

**SEC. 5. PRICING REQUIREMENTS FOR EXISTING TREATMENTS AND VACCINES IN A PUBLIC HEALTH EMERGENCY.**

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

**"SEC. 319B. PRICING REQUIREMENTS FOR TREATMENTS AND VACCINES IN A PUBLIC HEALTH EMERGENCY.**

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

"(1) The term 'covered drug' means a drug (including any vaccine) used to diagnose, mitigate, prevent, or treat a disease or disorder with respect to which there is or was in effect a declaration of a public health emergency under section 319.

"(2) The term 'covered period' means the period ending if and when the circumstances which led to an applicable public health emergency cease to exist and are unlikely to recur.

"(3) The term 'FDA-granted exclusivity' means prohibitions on the submission or approval of drug applications granted under any of the following:

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

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

"(C) Section 505A of such Act.

"(D) Section 505E of such Act.

"(E) Section 527 of such Act.

"(F) Section 351(k)(7) of this Act.

"(G) Any other provision of law that provides for marketing or data exclusivity (or extension of exclusivity) with respect to a drug.

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

"(b) DETERMINATION OF EXCESSIVE PRICE.—During any covered period with respect to a covered drug, the Secretary shall determine that the price of a covered drug is excessive if the wholesale acquisition cost (or a more relevant measure of price) of the covered drug is not fair and reasonable, or does not facilitate global access, taking into consideration—

"(1) the impact of the price on access to the covered drug in the United States, taking into consideration racial disparities and other socioeconomic disparities;

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

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

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

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

''(6) the therapeutic efficacy of the covered drug.

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

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

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

''(d) REASONABLE ROYALTY.—

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

Health Service Act for which any FDA-granted exclusivity with respect to the covered drug was terminated under subsection (c)(1).

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

''(A) a percentage of sales, where the percentage rate is no higher than the average royalty rate estimated from the data provided by the Internal Revenue Service for pharmaceutical manufacturer Federal income tax returns; or

''(B) an amount as determined by the Secretary, taking into account—

''(i) the therapeutic efficacy of the covered drug;

''(ii) the size of the affected patient population in the United States and globally;

''(iii) the risk adjusted value of Federal subsidies and investments related to the covered drug;

''(iv) the extent to which the manufacturer of the covered drug has recovered risk adjusted investments related to the covered drug, including the investments re-

lated to the invention, regulatory test data, and any other relevant research and development costs; and

''(v) any other information the Secretary 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 domestic 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 exclusivity rights in that country at the time of sale.

''(e) REQUIREMENTS.—

''(1) IN GENERAL.—A royalty rate under subsection (d) shall be consistent with making the covered drug available to purchasers, including governmental and nongovernmental purchasers and individuals, 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)

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

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

''(3) PRICE.—An entity accepting an open, nonexclusive license under subsection (c)(2) shall sell the covered drug at a price not higher than the excessive price determined for the covered drug under subsection (b).

''(f) CLARIFICATION.—An open, nonexclusive license under subsection (c)(2) shall be liable, subject to adequate protection of the legitimate interests of any party utilizing the license, to be terminated only if the circumstances which led to the granting of the open, nonexclusive license cease to exist and are unlikely to recur. The Secretary may review, upon request, the continued existence of these circumstances.''.

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