I

116TH CONGRESS
2D SESSION

H. R. 8644

To ensure the availability of critical medications in the event of public health emergencies, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 20, 2020

Mr. SMITH of Missouri (for himself and Mr. SCHNEIDER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To ensure the availability of critical medications in the event of public health emergencies, 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; SENSE OF CONGRESS.

This Act may be cited as the ''Secure America's Medicine Act of 2020''.

SEC. 2. ENSURING THE AVAILABILITY OF CRITICAL MEDICATIONS IN THE EVENT OF PUBLIC HEALTH EMERGENCIES.

(a) IN GENERAL.—The Public Health Service Act is amended by inserting after section 319F–4 of such Act (42 U.S.C. 247d–6e) the following new section:

"SEC. 319F–5. ENSURING THE AVAILABILITY OF CRITICAL MEDICATIONS IN THE EVENT OF PUBLIC HEALTH EMERGENCIES.

''(a) LIST OF CRITICAL MEDICATIONS.—

''(1) IN GENERAL.—The Secretary shall maintain a list of medications (in this section referred to as 'critical medications') with respect to which it is critical that the Federal Government ensure availability in the event of a public health emergency.

''(2) COLLABORATION.—The Secretary shall carry out this subsection and subsection (b) in collaboration with the Assistant Secretary for Preparedness and Response, the Commissioner of Food and Drugs, the Director of the Centers for Disease Control and Prevention, and the Secretary of Homeland Security.

''(3) TIMING OF LIST; REPORTING.—The Secretary shall—

''(A) not later than 180 days after the date of the enactment of the this section—

"(i) establish the initial list required by paragraph (1);

"(ii) submit a report, in a manner that does not compromise national security, to the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives and the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, setting forth—

"(I) the list in effect under paragraph (1);

"(II) the reasons why each critical medication is included on the list;

"(III) the reasons why other medications described in paragraph (4) were not included; and

"(IV) which critical medications are designated critical medications under subsection (b) and the reasons for each such designation; and

"(iii) make publicly available the list in effect under paragraph (1) and the most recent report under clause (ii), subject to

any redactions or edits necessary to remove classified information or otherwise ensure that national security is not compromised; and

''(B) not later than March 15 of each year following the year in which the first list of critical medications is required by paragraph (1)—

''(i) update the list required by paragraph (1);

''(ii) submit an updated report under subparagraph (A)(ii); and

''(iii) make publicly available such updated list and report in accordance with subparagraph (A)(iii).

''(4) REQUIRED INCLUSION ON LIST.—Subject to paragraph (5), the Secretary shall include on the list under paragraph (1) the following medications:

''(A) Commonly-used medications likely to be needed in order to prevent, mitigate, or treat the adverse health effects which frequently result from a public health emergency, including medications routinely needed to effectively manage patients in hospital emergency rooms or intensive care units, and medications needed dur-

ing surgical procedures often required during a public health emergency.

''(B) Anti-infective medications, including antibiotic, antifungal, and antiviral medications, which are either commonly used to treat infectious diseases or have a significant likelihood of being needed to treat an infectious disease that, if not so treated, may result in a public health emergency.

''(C) Commonly-used medications which are life-supporting, life-sustaining, or intended for the use in the prevention or treatment of a debilitating disease or condition, as such terms are defined in section 506C of the Federal Food, Drug, and Cosmetics Act and the regulations thereunder.

''(5) LIMITATIONS ON INCLUSION ON LIST.—The Secretary—

''(A) shall not be required to include on the list under paragraph (1) every medication meeting the criteria described in paragraph (4);

''(B) shall prioritize the inclusion on the list under paragraph (1) of 300 to 400 medications meeting such criteria—

''(i) that are most commonly used; or

"(ii) for which a shortage would be most likely to have the greatest potential adverse health consequences;

"(C) in applying subparagraph (B), shall count as a single medication—

"(i) all strengths, dosage forms, and package forms of a given medication;

"(ii) medications that are therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations'); and

"(iii) a biological product licensed under section 351(a) and all biosimilar biological products that are licensed under section 351(k) using the biological product as the reference product; and

"(D) in applying subparagraph (B), shall not prioritize the inclusion of any medication that is a qualified countermeasure (as defined in section 319F–1(a)(2)), a security countermeasure (as defined in section 319F–2(c)(1)(B)), or a qualified pandemic and epidemic product (as defined in section 319F–3(i)).

"(6) PUBLIC INPUT AND COMMENT.—In developing and updating the list under paragraph (1), the Secretary shall solicit public input, including by—

"(A) consulting (through public meetings or other forms of engagement) with relevant stakeholders, including health care providers, medical professional societies, public health experts, State and local public health departments, patient groups, and drug manufacturers and distributors;

"(B) publishing in the Federal Register, for public review and comment, the Secretary's proposed list of critical medications, together with the Secretary's reasons why each medication included on such proposed list was included and the reasons why other medications were not included;

"(C) accepting public comment on such proposed list and reasons for a period of not less than 60 days;

"(D) taking such comments into account in determining the final list under paragraph (1); and

"(E) addressing such comments in reporting under paragraph (3).

''(7) ADDITIONAL CONSIDERATIONS.—In developing and updating the list under paragraph (1), the Secretary shall consider—

''(A) the most recent annual threat-based review conducted by the Secretary under section 319F–2(a)(2), the most recent report of the Comptroller General of the United States under section 319F–2(a)(5), and the most recent recommendations of the Public Health Emergency Countermeasures Enterprise established under section 2811–1;

''(B) input from each member of the Public Health Emergency Countermeasures Enterprise (or a designee thereof); and

''(C) if available, the report of the National Academies of Sciences, Engineering, and Medicine prepared pursuant to section 3101 of the Coronavirus Aid, Relief, and Economic Stability Act (Public Law 116–136).

''(b) DESIGNATION OF CRITICAL MEDICATIONS FOR WHICH AVAILABILITY IS AT RISK IN THE EVENT OF A PUBLIC HEALTH EMERGENCY.—

''(1) IN GENERAL.—The Secretary shall—

''(A) evaluate each critical medication to determine whether there is adequate assurance

that it will be available in sufficient quantities in the event of a public health emergency, on a timely basis, within each portion of the United States where it is needed; and

''(B) designate each critical medication with respect to which the Secretary determines there is not such an adequate assurance.

''(2) FACTORS TO BE TAKEN INTO ACCOUNT.—In carrying out paragraph (1), the Secretary shall take into account factors including—

''(A) volume inventories of each critical medication that are normally available for use in the United States, in the public and private sector, in the absence of a public health emergency;

''(B) current and expected production capacity, in the United States and in foreign countries, of each critical medication, including the domestic and foreign capacity to surge production of each critical medication and the time required to do so, taking into account, among other things, current marketplace trends and factors and the economic viability of creating and maintaining such surge capacity in the absence of nonemergency commercial demand;

"(C) the potential demand and historic demand trends for each critical medication in the event of a public health emergency, including demand in the United States and in foreign countries; and

"(D) potential constraints on the timely manufacture and distribution of each critical medication in sufficient quantities for each portion of the United States where it is needed in the event of public health emergency, including constraints due to the unavailability or limited availability of such critical medication or any key ingredients thereof (including active pharmaceutical ingredients) from one or more foreign countries.

"(3) CONDUCT OF EVALUATION.—In carrying out paragraph (1), the Secretary may consider such other factors as the Secretary considers relevant to determining the supply chain vulnerability of each critical medication and each key ingredient thereof (including active pharmaceutical ingredients) in the event of a public health emergency, which may include—

"(A) whether and to what extent the existing sources of such supply for the United

States are domestic or foreign, the specific foreign countries from which any such foreign supply is obtained and in what quantities, and the extent of the risk of a disruption in supply from each such foreign country in the event of a public health emergency;

''(B) the location of each domestic and foreign establishment registered under section 510 of the Federal Food, Drug, and Cosmetic Act and identified in such registration as manufacturing, preparing, propagating, or compounding such critical medication or a key ingredient thereof, as well as, for each such establishment, the current and historical production thereof and the current production capacity thereof;

''(C) the likelihood of continued or increased production from each domestic and foreign establishment referenced in subparagraph (B), and the timeframe necessary for any increase in production, taking into account regulatory, logistical, economic, and other relevant factors; and

''(D) any economic, regulatory, or other impediments to domestic production thereof.

''(4) TIMEFRAME FOR DESIGNATION AND REEVALUATION.—The Secretary shall—

''(A) determine whether to designate a critical medication under paragraph (1) not later than 90 days after the earlier of—

''(i) the date that such medication was first proposed by the Secretary to be a critical medication through publication in the Federal Register in accordance with subsection (a)(4)(B); or

''(ii) the date that such medication became a critical medication pursuant to the final determination of the Secretary in accordance with subsection (a)(1)(A); or

''(B) not later than March 15 each year, reevaluate in accordance with paragraph (1)(A) each designation in effect under paragraph (1)(B).

''(5) PUBLIC INPUT AND FACTORS TO BE CONSIDERED.—In carrying out paragraph (1), the Secretary shall—

''(A) consult with relevant stakeholders, including those described in subsection (a)(6)(A);

"(B) consider the annual threat-based review and reports referenced in and input received under subsection (a)(7); and

"(C) consult with experts in medication production, distribution, and demand, including economists or other analysts with expertise in the economic factors affecting domestic and foreign production and distribution of critical medications.

"(6) INCORPORATION OF FINDINGS AND DETERMINATIONS IN SUBMISSIONS TO CONGRESS.—With respect to each designated critical medication, the Assistant Secretary for Preparedness and Response shall include in the annual coordinated 5-year budget plan required to be submitted under section 2811(b)(7) such amounts as are determined to be necessary or appropriate to fund the procurement or contracting required under subsection (c) for such designated critical medications.

"(c) PROCUREMENT OR CONTRACTING FOR DESIGNATED CRITICAL MEDICATIONS TO ENSURE AVAILABILITY IN THE EVENT OF A PUBLIC HEALTH EMERGENCY.—Subject to the availability of appropriations, the Secretary shall procure for the Strategic National Stockpile pursuant to section 319F–2(a)(1)(A)(ii), or otherwise

enter into contracts under such section, as necessary to ensure the availability of each designated critical medication, in the quantities and at the times needed, in the event of a public health emergency.

"(d) EVALUATING IMPEDIMENTS TO DOMESTIC PRODUCTION OF CRITICAL MEDICATIONS, AND RELATED RECOMMENDATIONS.—

"(1) REPORT TO CONGRESS.—Not later than one year after the date of enactment of this section, the Secretary shall make available to the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives and the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, a report containing—

"(A) findings on—

"(i) the domestic and foreign production of critical medications and their key ingredients; and

"(ii) impediments to the domestic production of critical medications and their key ingredients; and

"(B) recommendations for measures (which may include legislative, regulatory, or other policy changes) to remove such impedi-

ments or otherwise promote such domestic production (which may include measures to ensure the economic viability of such domestic production or to address policies that competitively disadvantage such domestic production).

''(2) COORDINATION.—In preparing the report required by paragraph (1), the Secretary shall take into account any information provided to, and any findings and recommendations of, such Commission.

''(e) DEFINITIONS.—In this section:

''(1) The term 'designated critical medication' means a critical medication for which a designation is in effect under subsection (b).

''(2) The term 'medication' means a drug (as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act), a biological product (as defined in section 351 of this Act), or a combination product (as described in section 503(g) of the Federal Food, Drug, and Cosmetic Act) that is approved, licensed, or cleared, as applicable, under chapter V of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act.

''(3) The term 'public health emergency' means a disease or disorder, including pandemics and other significant outbreaks of infectious diseases, bioter-

rorist attacks, the effects of chemical, biological, radiological, or nuclear agents or toxins, or the effects of extreme weather, earthquakes, or other natural disasters, that the Secretary has declared or may declare to be a public health emergency pursuant to section 319.

''(4) The term 'United States' include the territories of the United States.''.

(b) ENSURING THE AVAILABILITY OF DESIGNATED CRITICAL MEDICATIONS THROUGH THE STRATEGIC NATIONAL STOCKPILE.—Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended—

(1) by amending subsection (a)(1) to read as follows:

''(1) IN GENERAL.—

''(A) MAINTAINING STOCKPILE OR STOCKPILES.—The Secretary, in collaboration with the Assistant Secretary for Preparedness and Response, the Commissioner of Food and Drugs, and the Director of the Centers for Disease Control and Prevention, and in coordination with the Secretary of Homeland Security (referred to in this section as the 'Homeland Security Secretary'), shall—

"(i) maintain a stockpile or stockpiles of drugs, vaccines, and other biological products, medical devices, and other supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile) in such numbers, types, and amounts as are determined consistent with section 2811 by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for and optimize the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency and, as informed by existing recommendations of, or consultations with, the Public Health Emergency Medical Countermeasure Enterprise established under section 2811–1, make necessary additions or modifications to the contents of such stock-

pile or stockpiles based on the review conducted under paragraph (2); and

''(ii) enter into multiyear contracts (each of which shall have a term of no less than 5 years) with private entities to ensure the availability, in the event of a public health emergency, of adequate domestic supplies of each designated critical medication, as determined by the Secretary under section 319F–5, in lieu of or as a supplement to procuring and maintaining in such stockpile or stockpiles a physical accumulation of such designated critical medications, through measures which may include—

''(I) one or more private entities' agreement to maintain specified inventory levels, in specified domestic locations, of one or more such designated critical medications, or of one or more key ingredients thereof (including active pharmaceutical ingredients), under specified conditions (including maintenance and inventory replacement prior to expiration), and to

make specified quantities of such designated critical medications or key ingredients thereof available when directed by the Secretary, on predetermined terms and conditions;

''(II) one or more private entities' agreement to commence or maintain production of one or more such designated critical medications, in specified locations, or to build or maintain specified surge capacity for such production, and to manufacture or otherwise make specified quantities of such designated critical medications available, when directed, on predetermined terms and conditions; and

''(III) compensation for maintenance of such inventory, production, or production capacity and associated overhead, as necessary or appropriate.

''(B) FACTORS.—In entering into contracts under subparagraph (A)(ii), the Secretary shall take into account as factors more significant than price—

''(i) whether the designated critical medication would be produced in the United States;

''(ii) the track record and demonstrated ability of the given manufacturer to produce the designated critical medication in the required quantities when needed (in domestic or foreign locations, after consideration of whether supply from such foreign locations is at significant risk of disruption in the event of a public health emergency); and

''(iii) the United States regulatory compliance history of the given manufacturer.

''(C) PREFERENCE.—In entering into contracts under subparagraph (A)(ii), the Secretary may give preference to contracting with manufacturers of medications which are based in the United States.

''(D) REFERENCES.—References in this paragraph to the United States include any territory of the United States.'';

(2) in subsection (a)(2)(B)—

(A) in the matter preceding clause (i), by inserting ''and each new or modified contract with a private entity under paragraph (1)(A)(ii)'' after ''for each new or modified countermeasure procurement or replenishment'';

(B) in clause (i)(III), by inserting ''or contracting for procurement'' after ''procurement'';

(C) in clause (i)(IV), by inserting ''or contracting for procurement'' after ''whether such procurement'';

(D) in clause (i)(V), by inserting ''(including through one or more contracts under paragraph (1)(A)(ii))'' after ''stockpile''; and

(E) in clause (ii), by inserting ''or for which the Secretary entered into a contract with a private entity under paragraph (1)(A)(ii),'' after ''for each countermeasure procured or replenished under this subsection,'';

(3) in subsection (a)(3)(E) by inserting ''the Commissioner of Food and Drugs,'' after ''Assistant Secretary for Preparedness and Response,'';

(4) in subsection (a)(5)(A)—

(A) in the matter preceding clause (i), by inserting ''and any contracts entered into under

paragraph (1)(A)(ii)'' after ''any changes to the contents or management of the stockpile'';

(B) in clause (ii), by striking ''or replenishment'' and inserting ''replenishment, or contracting'';

(C) in clause (iv), by striking ''an accounting of countermeasures procured, modified, or replenished under paragraph (1)'' and inserting ''an accounting of countermeasures procured, modified, or replenished under paragraph (1)(A)(i) or for which contracts with private entities were entered into under paragraph (1)(A)(ii)'';

(D) in clause (v)—

(i) by inserting ''and contracts'' after ''decisions''; and

(ii) by striking ''or replenished'' and inserting ''replenished or contracted''; and

(E) in clause (vii), by inserting ''and new or modified contracts with a private entity'' after ''replenishments'';

(5) in subsection (c)(7)(B)(ii), by adding at the end the following subclause:

''(X) NONAPPLICABILITY TO CERTAIN CONTRACTS.—None of the

requirements set forth in this clause (ii) shall apply to contracts entered into under subsection (a)(1)(A)(ii), other than contracts for procurement of security countermeasures from the special reserve fund, except that the Secretary may, at the Secretary's discretion, include any of the terms described in this clause, or similar terms, in any contract entered into under subsection (a)(1)(A)(ii).''; and

(6) by amending subsection (e) to read as follows:

''(e) DEFINITIONS.—For the purposes of this section:

''(1) The terms 'critical medication', 'designated critical medication', and 'medication' have the meanings given to such terms in section 319F–5.

''(2) The term 'stockpile' includes—

''(A) a physical accumulation (at one or more locations) of the supplies described in subsection (a) (including any maintained in inventory under a contract with a private entity under subsection (a)(1)(A)(ii) under a contract with a private entity entered into under subsection (a)(1)(A)(ii)); and

"(B) any supplies described in subsection (a)(1)(A)(i) which a vendor or vendors agree to provide to the Secretary under a contractual agreement between the Secretary and such vendor or vendors, and any designated critical medications which a private entity is required to manufacture or otherwise supply under an agreement between the Secretary and such private entity entered into pursuant to subsection (a)(1)(A)(ii).".

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