

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

A BILL

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

4 This Act may be cited as the “Secure America’s Med-
5 icine Act of 2020”.

1 **SEC. 2. ENSURING THE AVAILABILITY OF CRITICAL MEDI-**
2 **CATIONS IN THE EVENT OF PUBLIC HEALTH**
3 **EMERGENCIES.**

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

7 **“SEC. 319F–5. ENSURING THE AVAILABILITY OF CRITICAL**
8 **MEDICATIONS IN THE EVENT OF PUBLIC**
9 **HEALTH EMERGENCIES.**

10 “(a) LIST OF CRITICAL MEDICATIONS.—

11 “(1) IN GENERAL.—The Secretary shall main-
12 tain a list of medications (in this section referred to
13 as ‘critical medications’) with respect to which it is
14 critical that the Federal Government ensure avail-
15 ability in the event of a public health emergency.

16 “(2) COLLABORATION.—The Secretary shall
17 carry out this subsection and subsection (b) in col-
18 laboration with the Assistant Secretary for Pre-
19 paredness and Response, the Commissioner of Food
20 and Drugs, the Director of the Centers for Disease
21 Control and Prevention, and the Secretary of Home-
22 land Security.

23 “(3) TIMING OF LIST; REPORTING.—The Sec-
24 retary shall—

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

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

3 “(ii) submit a report, in a manner
4 that does not compromise national secu-
5 rity, to the Committee on Appropriations
6 and the Committee on Energy and Com-
7 merce of the House of Representatives and
8 the Committee on Appropriations and the
9 Committee on Health, Education, Labor,
10 and Pensions of the Senate, setting
11 forth—

12 “(I) the list in effect under para-
13 graph (1);

14 “(II) the reasons why each crit-
15 ical medication is included on the list;

16 “(III) the reasons why other
17 medications described in paragraph
18 (4) were not included; and

19 “(IV) which critical medications
20 are designated critical medications
21 under subsection (b) and the reasons
22 for each such designation; and

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

1 any redactions or edits necessary to re-
2 move classified information or otherwise
3 ensure that national security is not com-
4 promised; and

5 “(B) not later than March 15 of each year
6 following the year in which the first list of crit-
7 ical medications is required by paragraph (1)—

8 “(i) update the list required by para-
9 graph (1);

10 “(ii) submit an updated report under
11 subparagraph (A)(ii); and

12 “(iii) make publicly available such up-
13 dated list and report in accordance with
14 subparagraph (A)(iii).

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

18 “(A) Commonly-used medications likely to
19 be needed in order to prevent, mitigate, or treat
20 the adverse health effects which frequently re-
21 sult from a public health emergency, including
22 medications routinely needed to effectively man-
23 age patients in hospital emergency rooms or in-
24 tensive care units, and medications needed dur-

1 ing surgical procedures often required during a
2 public health emergency.

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

10 “(C) Commonly-used medications which
11 are life-supporting, life-sustaining, or intended
12 for the use in the prevention or treatment of a
13 debilitating disease or condition, as such terms
14 are defined in section 506C of the Federal
15 Food, Drug, and Cosmetics Act and the regula-
16 tions thereunder.

17 “(5) LIMITATIONS ON INCLUSION ON LIST.—

18 The Secretary—

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

22 “(B) shall prioritize the inclusion on the
23 list under paragraph (1) of 300 to 400 medica-
24 tions meeting such criteria—

25 “(i) that are most commonly used; or

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

4 “(C) in applying subparagraph (B), shall
5 count as a single medication—

6 “(i) all strengths, dosage forms, and
7 package forms of a given medication;

8 “(ii) medications that are therapeuti-
9 cally equivalent (under the Food and Drug
10 Administration’s most recent publication of
11 ‘Approved Drug Products with Therapeutic
12 Equivalence Evaluations’); and

13 “(iii) a biological product licensed
14 under section 351(a) and all biosimilar bio-
15 logical products that are licensed under
16 section 351(k) using the biological product
17 as the reference product; and

18 “(D) in applying subparagraph (B), shall
19 not prioritize the inclusion of any medication
20 that is a qualified countermeasure (as defined
21 in section 319F–1(a)(2)), a security counter-
22 measure (as defined in section 319F–
23 2(c)(1)(B)), or a qualified pandemic and epi-
24 demic product (as defined in section 319F–
25 3(i)).

1 “(6) PUBLIC INPUT AND COMMENT.—In devel-
2 oping and updating the list under paragraph (1), the
3 Secretary shall solicit public input, including by—

4 “(A) consulting (through public meetings
5 or other forms of engagement) with relevant
6 stakeholders, including health care providers,
7 medical professional societies, public health ex-
8 perts, State and local public health depart-
9 ments, patient groups, and drug manufacturers
10 and distributors;

11 “(B) publishing in the Federal Register,
12 for public review and comment, the Secretary’s
13 proposed list of critical medications, together
14 with the Secretary’s reasons why each medica-
15 tion included on such proposed list was included
16 and the reasons why other medications were not
17 included;

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

21 “(D) taking such comments into account
22 in determining the final list under paragraph
23 (1); and

24 “(E) addressing such comments in report-
25 ing under paragraph (3).

1 “(7) ADDITIONAL CONSIDERATIONS.—In devel-
2 oping and updating the list under paragraph (1), the
3 Secretary shall consider—

4 “(A) the most recent annual threat-based
5 review conducted by the Secretary under section
6 319F–2(a)(2), the most recent report of the
7 Comptroller General of the United States under
8 section 319F–2(a)(5), and the most recent rec-
9 ommendations of the Public Health Emergency
10 Countermeasures Enterprise established under
11 section 2811–1;

12 “(B) input from each member of the Pub-
13 lic Health Emergency Countermeasures Enter-
14 prise (or a designee thereof); and

15 “(C) if available, the report of the National
16 Academies of Sciences, Engineering, and Medi-
17 cine prepared pursuant to section 3101 of the
18 Coronavirus Aid, Relief, and Economic Stability
19 Act (Public Law 116–136).

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

23 “(1) IN GENERAL.—The Secretary shall—

24 “(A) evaluate each critical medication to
25 determine whether there is adequate assurance

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

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

8 “(2) FACTORS TO BE TAKEN INTO ACCOUNT.—

9 In carrying out paragraph (1), the Secretary shall
10 take into account factors including—

11 “(A) volume inventories of each critical
12 medication that are normally available for use
13 in the United States, in the public and private
14 sector, in the absence of a public health emer-
15 gency;

16 “(B) current and expected production ca-
17 pacity, in the United States and in foreign
18 countries, of each critical medication, including
19 the domestic and foreign capacity to surge pro-
20 duction of each critical medication and the time
21 required to do so, taking into account, among
22 other things, current marketplace trends and
23 factors and the economic viability of creating
24 and maintaining such surge capacity in the ab-
25 sence of nonemergency commercial demand;

1 “(C) the potential demand and historic de-
2 mand trends for each critical medication in the
3 event of a public health emergency, including
4 demand in the United States and in foreign
5 countries; and

6 “(D) potential constraints on the timely
7 manufacture and distribution of each critical
8 medication in sufficient quantities for each por-
9 tion of the United States where it is needed in
10 the event of public health emergency, including
11 constraints due to the unavailability or limited
12 availability of such critical medication or any
13 key ingredients thereof (including active phar-
14 maceutical ingredients) from one or more for-
15 eign countries.

16 “(3) CONDUCT OF EVALUATION.—In carrying
17 out paragraph (1), the Secretary may consider such
18 other factors as the Secretary considers relevant to
19 determining the supply chain vulnerability of each
20 critical medication and each key ingredient thereof
21 (including active pharmaceutical ingredients) in the
22 event of a public health emergency, which may in-
23 clude—

24 “(A) whether and to what extent the exist-
25 ing sources of such supply for the United

1 States are domestic or foreign, the specific for-
2 eign countries from which any such foreign sup-
3 ply is obtained and in what quantities, and the
4 extent of the risk of a disruption in supply from
5 each such foreign country in the event of a pub-
6 lic health emergency;

7 “(B) the location of each domestic and for-
8 eign establishment registered under section 510
9 of the Federal Food, Drug, and Cosmetic Act
10 and identified in such registration as manufac-
11 turing, preparing, propagating, or compounding
12 such critical medication or a key ingredient
13 thereof, as well as, for each such establishment,
14 the current and historical production thereof
15 and the current production capacity thereof;

16 “(C) the likelihood of continued or in-
17 creased production from each domestic and for-
18 eign establishment referenced in subparagraph
19 (B), and the timeframe necessary for any in-
20 crease in production, taking into account regu-
21 latory, logistical, economic, and other relevant
22 factors; and

23 “(D) any economic, regulatory, or other
24 impediments to domestic production thereof.

1 “(4) TIMEFRAME FOR DESIGNATION AND RE-
2 EVALUATION.—The Secretary shall—

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

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

11 “(ii) the date that such medication be-
12 came a critical medication pursuant to the
13 final determination of the Secretary in ac-
14 cordance with subsection (a)(1)(A); or

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

19 “(5) PUBLIC INPUT AND FACTORS TO BE CON-
20 sidered.—In carrying out paragraph (1), the Sec-
21 retary shall—

22 “(A) consult with relevant stakeholders, in-
23 cluding those described in subsection (a)(6)(A);

1 “(B) consider the annual threat-based re-
2 view and reports referenced in and input re-
3 ceived under subsection (a)(7); and

4 “(C) consult with experts in medication
5 production, distribution, and demand, including
6 economists or other analysts with expertise in
7 the economic factors affecting domestic and for-
8 eign production and distribution of critical
9 medications.

10 “(6) INCORPORATION OF FINDINGS AND DE-
11 TERMINATIONS IN SUBMISSIONS TO CONGRESS.—
12 With respect to each designated critical medication,
13 the Assistant Secretary for Preparedness and Re-
14 sponse shall include in the annual coordinated 5-year
15 budget plan required to be submitted under section
16 2811(b)(7) such amounts as are determined to be
17 necessary or appropriate to fund the procurement or
18 contracting required under subsection (c) for such
19 designated critical medications.

20 “(c) PROCUREMENT OR CONTRACTING FOR DES-
21 IGNATED CRITICAL MEDICATIONS TO ENSURE AVAIL-
22 ABILITY IN THE EVENT OF A PUBLIC HEALTH EMER-
23 GENCY.—Subject to the availability of appropriations, the
24 Secretary shall procure for the Strategic National Stock-
25 pile pursuant to section 319F–2(a)(1)(A)(ii), or otherwise

1 enter into contracts under such section, as necessary to
2 ensure the availability of each designated critical medica-
3 tion, in the quantities and at the times needed, in the
4 event of a public health emergency.

5 “(d) EVALUATING IMPEDIMENTS TO DOMESTIC PRO-
6 Duction OF CRITICAL MEDICATIONS, AND RELATED
7 RECOMMENDATIONS.—

8 “(1) REPORT TO CONGRESS.—Not later than
9 one year after the date of enactment of this section,
10 the Secretary shall make available to the Committee
11 on Appropriations and the Committee on Energy
12 and Commerce of the House of Representatives and
13 the Committee on Appropriations and the Com-
14 mittee on Health, Education, Labor, and Pensions
15 of the Senate, a report containing—

16 “(A) findings on—

17 “(i) the domestic and foreign produc-
18 tion of critical medications and their key
19 ingredients; and

20 “(ii) impediments to the domestic pro-
21 duction of critical medications and their
22 key ingredients; and

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

1 ments or otherwise promote such domestic pro-
2 duction (which may include measures to ensure
3 the economic viability of such domestic produc-
4 tion or to address policies that competitively
5 disadvantage such domestic production).

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

10 “(e) DEFINITIONS.—In this section:

11 “(1) The term ‘designated critical medication’
12 means a critical medication for which a designation
13 is in effect under subsection (b).

14 “(2) The term ‘medication’ means a drug (as
15 defined in section 201(g)(1) of the Federal Food,
16 Drug, and Cosmetic Act), a biological product (as
17 defined in section 351 of this Act), or a combination
18 product (as described in section 503(g) of the Fed-
19 eral Food, Drug, and Cosmetic Act) that is ap-
20 proved, licensed, or cleared, as applicable, under
21 chapter V of the Federal Food, Drug, and Cosmetic
22 Act or section 351 of this Act.

23 “(3) The term ‘public health emergency’ means
24 a disease or disorder, including pandemics and other
25 significant outbreaks of infectious diseases, bioter-

1 rorist attacks, the effects of chemical, biological, ra-
2 diological, or nuclear agents or toxins, or the effects
3 of extreme weather, earthquakes, or other natural
4 disasters, that the Secretary has declared or may de-
5 clare to be a public health emergency pursuant to
6 section 319.

7 “(4) The term ‘United States’ include the terri-
8 tories of the United States.”.

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

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

15 “(1) IN GENERAL.—

16 “(A) MAINTAINING STOCKPILE OR STOCK-
17 PILES.—The Secretary, in collaboration with
18 the Assistant Secretary for Preparedness and
19 Response, the Commissioner of Food and
20 Drugs, and the Director of the Centers for Dis-
21 ease Control and Prevention, and in coordina-
22 tion with the Secretary of Homeland Security
23 (referred to in this section as the ‘Homeland
24 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-

1 pile or stockpiles based on the review con-
2 ducted under paragraph (2); and

3 “(ii) enter into multiyear contracts
4 (each of which shall have a term of no less
5 than 5 years) with private entities to en-
6 sure the availability, in the event of a pub-
7 lic health emergency, of adequate domestic
8 supplies of each designated critical medica-
9 tion, as determined by the Secretary under
10 section 319F–5, in lieu of or as a supple-
11 ment to procuring and maintaining in such
12 stockpile or stockpiles a physical accumula-
13 tion of such designated critical medica-
14 tions, through measures which may in-
15 clude—

16 “(I) one or more private entities’
17 agreement to maintain specified in-
18 ventory levels, in specified domestic lo-
19 cations, of one or more such des-
20 ignated critical medications, or of one
21 or more key ingredients thereof (in-
22 cluding active pharmaceutical ingredi-
23 ents), under specified conditions (in-
24 cluding maintenance and inventory re-
25 placement prior to expiration), and to

1 make specified quantities of such des-
2 ignated critical medications or key in-
3 gredients thereof available when di-
4 rected by the Secretary, on predeter-
5 mined terms and conditions;

6 “(II) one or more private enti-
7 ties’ agreement to commence or main-
8 tain production of one or more such
9 designated critical medications, in
10 specified locations, or to build or
11 maintain specified surge capacity for
12 such production, and to manufacture
13 or otherwise make specified quantities
14 of such designated critical medications
15 available, when directed, on predeter-
16 mined terms and conditions; and

17 “(III) compensation for mainte-
18 nance of such inventory, production,
19 or production capacity and associated
20 overhead, as necessary or appropriate.

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

1 “(i) whether the designated critical
2 medication would be produced in the
3 United States;

4 “(ii) the track record and dem-
5 onstrated ability of the given manufacturer
6 to produce the designated critical medica-
7 tion in the required quantities when needed
8 (in domestic or foreign locations, after con-
9 sideration of whether supply from such for-
10 eign locations is at significant risk of dis-
11 ruption in the event of a public health
12 emergency); and

13 “(iii) the United States regulatory
14 compliance history of the given manufac-
15 turer.

16 “(C) PREFERENCE.—In entering into con-
17 tracts under subparagraph (A)(ii), the Sec-
18 retary may give preference to contracting with
19 manufacturers of medications which are based
20 in the United States.

21 “(D) REFERENCES.—References in this
22 paragraph to the United States include any ter-
23 ritory of the United States.”;

24 (2) in subsection (a)(2)(B)—

1 (A) in the matter preceding clause (i), by
2 inserting “and each new or modified contract
3 with a private entity under paragraph
4 (1)(A)(ii)” after “for each new or modified
5 countermeasure procurement or replenish-
6 ment”;

7 (B) in clause (i)(III), by inserting “or con-
8 tracting for procurement” after “procurement”;

9 (C) in clause (i)(IV), by inserting “or con-
10 tracting for procurement” after “whether such
11 procurement”;

12 (D) in clause (i)(V), by inserting “(includ-
13 ing through one or more contracts under para-
14 graph (1)(A)(ii))” after “stockpile”; and

15 (E) in clause (ii), by inserting “or for
16 which the Secretary entered into a contract
17 with a private entity under paragraph
18 (1)(A)(ii),” after “for each countermeasure pro-
19 cured or replenished under this subsection,”;

20 (3) in subsection (a)(3)(E) by inserting “the
21 Commissioner of Food and Drugs,” after “Assistant
22 Secretary for Preparedness and Response,”;

23 (4) in subsection (a)(5)(A)—

24 (A) in the matter preceding clause (i), by
25 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

1 requirements set forth in this clause
 2 (ii) shall apply to contracts entered
 3 into under subsection (a)(1)(A)(ii),
 4 other than contracts for procurement
 5 of security countermeasures from the
 6 special reserve fund, except that the
 7 Secretary may, at the Secretary's dis-
 8 cretion, include any of the terms de-
 9 scribed in this clause, or similar
 10 terms, in any contract entered into
 11 under subsection (a)(1)(A)(ii)."; and

12 (6) by amending subsection (e) to read as fol-
 13 lows:

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

15 "(1) The terms 'critical medication', 'designated
 16 critical medication', and 'medication' have the mean-
 17 ings given to such terms in section 319F–5.

18 "(2) The term 'stockpile' includes—

19 "(A) a physical accumulation (at one or
 20 more locations) of the supplies described in sub-
 21 section (a) (including any maintained in inven-
 22 tory under a contract with a private entity
 23 under subsection (a)(1)(A)(ii) under a contract
 24 with a private entity entered into under sub-
 25 section (a)(1)(A)(ii)); and

1 “(B) any supplies described in subsection
2 (a)(1)(A)(i) which a vendor or vendors agree to
3 provide to the Secretary under a contractual
4 agreement between the Secretary and such ven-
5 dor or vendors, and any designated critical
6 medications which a private entity is required
7 to manufacture or otherwise supply under an
8 agreement between the Secretary and such pri-
9 vate entity entered into pursuant to subsection
10 (a)(1)(A)(ii).”.

○