

116TH CONGRESS
2D SESSION

S. 4368

To prepare the Strategic National Stockpile for a public health emergency and require the maintenance of a domestic supply chain for countermeasures in the stockpile, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 29, 2020

Mr. BROWN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To prepare the Strategic National Stockpile for a public health emergency and require the maintenance of a domestic supply chain for countermeasures in the stockpile, 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 “Protecting American
5 Heroes Act of 2020”.

1 **SEC. 2. STRATEGIC NATIONAL STOCKPILE.**

2 (a) ADDITIONAL PROVISIONS TO PREPARE THE
3 STRATEGIC NATIONAL STOCKPILE FOR PUBLIC HEALTH
4 EMERGENCIES.—

5 (1) IN GENERAL.—Section 319F–2 of the Pub-
6 lic Health Service Act (42 U.S.C. 247d–6b) is
7 amended—

8 (A) by redesignating subsection (h) as sub-
9 section (i); and

10 (B) by inserting after subsection (g) the
11 following:

12 “(h) ADDITIONAL PROVISIONS TO PREPARE THE
13 STRATEGIC NATIONAL STOCKPILE FOR PUBLIC HEALTH
14 EMERGENCIES.—

15 “(1) PREPARING FOR EMERGENCIES AFFECT-
16 ING ALL STATES.—

17 “(A) IN GENERAL.—The Public Health
18 Emergency Medical Countermeasures Enter-
19 prise established under section 2811–1 shall de-
20 velop a model to enable the stockpile under sub-
21 section (a)(1) to be prepared to effectively re-
22 spond to a public health emergency, including
23 one that simultaneously affects all States.

24 “(B) MODEL.—The model under subpara-
25 graph (A) shall include—

1 “(i)(I) requirements with respect to
2 the number, types, and amounts of coun-
3 termeasures that are necessary to prepare
4 the stockpile under subsection (a)(1) to re-
5 spond to a public health emergency de-
6 scribed in subparagraph (A); and

7 “(II) the cost necessary to meet such
8 requirements;

9 “(ii) an assessment of the domestic
10 supply chain for all countermeasures that
11 are needed for the stockpile to be prepared
12 for a public health emergency described in
13 subparagraph (A), including—

14 “(I) an identification of any
15 known domestic suppliers of such
16 countermeasures;

17 “(II) an identification of any
18 gaps in the domestic supply chain for
19 such countermeasures;

20 “(III) steps needed to address
21 the gaps in the domestic supply chain
22 for such countermeasures;

23 “(IV) an identification of any
24 countermeasure in the stockpile that

1 only has one source, domestic or for-
2 eign, for procurement; and

3 “(V) steps needed to diversify
4 sources for any countermeasure in the
5 stockpile that has only one source, do-
6 mestic or foreign, for procurement.

7 “(C) SUBMISSION TO CONGRESS.—Not
8 later than 120 days after the date of enactment
9 of the Protecting American Heroes Act of 2020,
10 the Public Health Emergency Medical Counter-
11 measures Enterprise established under section
12 2811–1 shall submit the assessment required
13 under subparagraph (B)(ii) to each Committee
14 described in subsection (a)(2)(A).

15 “(2) REQUIREMENT TO IDENTIFY AND MAIN-
16 TAIN DOMESTIC SUPPLY CHAIN.—

17 “(A) IN GENERAL.—The Executive Deputy
18 Assistant Secretary of the Strategic National
19 Stockpile appointed under paragraph (3) (re-
20 ferred to in this paragraph as the ‘Executive
21 Deputy Assistant Secretary’) shall, in accord-
22 ance with this paragraph, identify and maintain
23 a domestic source (which may be multiple
24 sources) for all countermeasures in the stockpile
25 under subsection (a)(1).

1 “(B) REQUIREMENT FOR ITEMS IN STOCK-
2 PILE.—

3 “(i) IN GENERAL.—Except as pro-
4 vided under clause (ii), the Executive Dep-
5 uty Assistant Secretary shall require all
6 countermeasures in the stockpile under
7 subsection (a)(1), and any component part
8 of such countermeasures, to be grown, re-
9 processed, reused, or produced in the
10 United States.

11 “(ii) WAIVERS.—The Executive Dep-
12 uty Assistant Secretary may, on a case-by-
13 case basis, waive the requirement under
14 clause (i) in the case of a contract for a
15 countermeasure in the stockpile under sub-
16 section (a)(1)—

17 “(I) for which the Executive
18 Deputy Assistant Secretary deter-
19 mines that a satisfactory quality and
20 sufficient quantity of such counter-
21 measure that is grown, reprocessed,
22 reused, or produced in the United
23 States cannot be procured as and
24 when needed at United States market
25 prices; or

1 “(II) that is, or includes, any
2 material determined to be a nonavail-
3 able article under section 25.104 of
4 the Federal Acquisition Regulation for
5 purposes of subpart I of part 25 of
6 the Federal Acquisition Regulation.

7 “(iii) NOTIFICATION OF WAIVERS.—In
8 the case of any contract for the procure-
9 ment of a countermeasure in the stockpile
10 under subsection (a)(1), if the Executive
11 Deputy Assistant Secretary applies a waiv-
12 er under clause (ii) with respect to that
13 contract, the Executive Deputy Assistant
14 Secretary shall, not later than 7 days after
15 the award of the contract, submit to each
16 Committee described in subsection
17 (a)(2)(A) a notification that the waiver has
18 been applied.

19 “(C) NOTICE OF DISCONTINUANCE OR
20 INTERRUPTION IN DOMESTIC SUPPLY CHAIN.—

21 “(i) TIMING.—The Executive Deputy
22 Assistant Secretary shall require any man-
23 ufacturer of a countermeasure in the
24 stockpile under subsection (a)(1) (other
25 than a countermeasure to which a waiver

has been applied under subparagraph (B)(ii)) to provide notice to the Executive Deputy Assistant Secretary of any discontinuance or interruption in the manufacture of such countermeasure. Such notice shall be submitted to the Executive Deputy Assistant Secretary—

“(I) at least 6 months prior to the date of the discontinuance or interruption; or

“(II) if compliance with subclause (I) is not possible, as soon as practicable.

“(ii) CONTENTS.—The notice required under clause (i) shall include disclosure of—

“(I) reasons for the discontinuation or interruption of the countermeasure;

“(II) if applicable, and without disclosing proprietary information, if an active pharmaceutical ingredient is a reason for, or risk factor in, such discontinuation or interruption, the source of the active pharmaceutical

1 ingredient, and any alternative
 2 sources for the active pharmaceutical
 3 ingredient known by the manufac-
 4 turer;

5 “(III) if applicable, whether any
 6 associated device used for preparation
 7 or administration included in the
 8 countermeasure is a reason for, or a
 9 risk factor in, such discontinuation or
 10 interruption;

11 “(IV) if applicable, the expected
 12 duration of the interruption; and

13 “(V) any such other information
 14 as the Executive Deputy Assistant
 15 Secretary may require.

16 “(3) EXECUTIVE DEPUTY ASSISTANT SEC-
 17 RETARY OF THE STRATEGIC NATIONAL STOCK-
 18 PILE.—

19 “(A) IN GENERAL.—The Assistant Sec-
 20 retary for Preparedness and Response shall ap-
 21 point an Executive Deputy Assistant Secretary
 22 of the Strategic National Stockpile (referred to
 23 in this paragraph as the ‘Executive Deputy As-
 24 sistant Secretary’), who shall report directly to
 25 the Assistant Secretary for Preparedness and

1 Response and serve in a career reserved posi-
2 tion, as defined in section 3132(a) of title 5,
3 United States Code.

4 “(B) QUALIFICATIONS.—Any individual
5 appointed as the Executive Deputy Assistant
6 Secretary under subparagraph (A) shall be se-
7 lected from individuals who, on the day before
8 the date of enactment of the Protecting Amer-
9 ican Heroes Act of 2020—

10 “(i) are career appointees, as defined
11 in section 3132(a) of title 5, United States
12 Code; or

13 “(ii) are former such career ap-
14 pointees and are eligible for reinstatement
15 as such career appointees.

16 “(C) FUNCTIONS.—The Executive Deputy
17 Assistant Secretary appointed under subpara-
18 graph (A) shall—

19 “(i) notwithstanding the functions of
20 the Assistant Secretary for Preparedness
21 and Response under section 2811–1, have
22 authority to make decisions with respect to
23 the stockpile under subsection (a)(1);

24 “(ii) establish and maintain a domes-
25 tic supply chain for countermeasures in

1 such stockpile to the greatest extent pos-
2 sible;

3 “(iii) consult with States and relevant
4 stakeholders, including public health orga-
5 nizations, about the procurement and dis-
6 tribution of countermeasures in the stock-
7 pile; and

8 “(iv) carry out all other duties of any
9 individual serving as the Director of the
10 Strategic National Stockpile prior to the
11 date of enactment of the Protecting Amer-
12 ican Heroes Act of 2020.

13 “(D) QUARTERLY REPORT.—Not later
14 than 180 days after the date of enactment of
15 the Protecting American Heroes Act of 2020,
16 and each calendar quarter thereafter, the Exec-
17 utive Deputy Assistant Secretary shall submit
18 to the Assistant Secretary for Preparedness and
19 Response and each Committee described in sub-
20 section (a)(2)(A) a report that includes—

21 “(i) the number, types, and amounts
22 of countermeasures in the stockpile under
23 subsection (a)(1);

24 “(ii) whether such number, types, and
25 amounts are sufficient to meet a public

1 health emergency that simultaneously af-
2 fects all States;

3 “(iii) whether any countermeasures in
4 the stockpile have expired or failed to re-
5 ceive necessary maintenance in a timely
6 fashion;

7 “(iv) the status of the domestic supply
8 chain with respect to countermeasures in
9 such stockpile, including—

10 “(I) whether there are gaps in
11 the supply chain, including the domes-
12 tic supply chain, for such counter-
13 measures; and

14 “(II) any instance in which the
15 Executive Deputy Assistant Secretary
16 applies a waiver under paragraph
17 (2)(B)(ii) to a countermeasure;

18 “(v) recommended steps necessary to
19 address any gap described in clause (iv)(I);
20 and

21 “(vi)(I) whether any countermeasures
22 in such stockpile are obtained from a sole
23 source; and

1 “(II) whether any steps should be
2 taken to diversify sourcing of such counter-
3 measures.

4 “(E) FIRST APPOINTMENT.—With respect
5 to the first individual to serve as the Executive
6 Deputy Assistant Secretary after the date of
7 enactment of the Protecting American Heroes
8 Act of 2020, the Assistant Secretary for Pre-
9 paredness and Response shall appoint such in-
10 dividual under subparagraph (A) not later than
11 90 days after such date of enactment.

12 “(4) DEFINITION OF COUNTERMEASURE.—In
13 this subsection, the term ‘countermeasure’ includes a
14 drug, vaccine or other biological product, medical de-
15 vice, or other supplies (including personal protective
16 equipment, ancillary medical supplies, and other ap-
17 plicable supplies required for the administration of
18 drugs, vaccines and other biological products, med-
19 ical devices, and diagnostic tests in the stockpile) de-
20 scribed in subsection (a)(1).”.

21 (2) APPROPRIATIONS.—Section 319F–2(f) of
22 the Public Health Service Act (42 U.S.C. 247d–
23 6b(f)) is amended—

24 (A) in the subsection heading, by striking
25 “AUTHORIZATION OF APPROPRIATIONS” and

1 inserting “APPROPRIATIONS; AUTHORIZATION
2 OF APPROPRIATIONS”; and

3 (B) by amending paragraph (1) to read as
4 follows:

5 “(1) STRATEGIC NATIONAL STOCKPILE.—There
6 are appropriated, out of any money in the Treasury
7 not otherwise appropriated, such sums as necessary,
8 to remain available until expended, to carry out sub-
9 sections (a) and (h). Such amounts are in addition
10 to any amounts in the special reserve fund under
11 subsection (g).”.

12 (3) CONFORMING AMENDMENTS.—

13 (A) Section 319F–2 of the Public Health
14 Service Act (42 U.S.C. 247d–6b) is amended—

15 (i) in subsection (c), by striking “as
16 defined in subsection (h)” each place it ap-
17 pears; and

18 (ii) in subsection (f), by striking as
19 “referred to in subsection (h)”.

20 (B) Section 2811(d)(2)(G) of the Public
21 Health Service Act (42 U.S.C. 300hh–
22 10(d)(2)(G)) is amended by striking “as de-
23 fined in section 319F–2(h)” and inserting “as
24 defined in section 319F–2(i)”.

1 (b) DOMESTIC SUPPLY CHAIN EVALUATIONS IN
2 THREAT ASSESSMENT AND GAO REPORT; FUNCTIONS OF
3 SECRETARY.—Section 319F–2(a) of the Public Health
4 Service Act (42 U.S.C. 247d–6b(a)) is amended—

5 (1) in paragraph (2)—

6 (A) in subparagraph (A), by inserting “,
7 including the domestic supply chain for such
8 contents,” after “within the stockpile”; and

9 (B) in subparagraph (B)(i)(II), by insert-
10 ing “, including domestic manufacturing capac-
11 ity,” after “appropriate manufacturing capac-
12 ity”;

13 (2) in paragraph (3)—

14 (A) by redesignating subparagraphs (E)
15 through (J) as subparagraphs (F) through (K),
16 respectively;

17 (B) by inserting after subparagraph (D)
18 the following:

19 “(E) acting through the Executive Deputy
20 Assistant Secretary of the Strategic National
21 Stockpile appointed under subsection (h)(3), in
22 accordance with subsection (h)(2), establish,
23 maintain, and (when necessary) expand a sup-
24 ply chain based in the United States for coun-

1 termesures (as defined in subsection (h)(4)) in
2 the stockpile;”; and

3 (C) in subparagraph (F), as so redesign-
4 nated, by inserting “to ensure a robust supply
5 chain for the production in the United States of
6 countermeasures (as defined in subsection
7 (h)(4)),” before “in consultation with”; and
8 (3) in paragraph (5)(A)—

9 (A) by redesignating clauses (iii) through
10 (ix) as clauses (iv) through (x), respectively;
11 and

12 (B) by inserting after clause (ii) the fol-
13 lowing:

14 “(iii) an assessment of the plans de-
15 veloped by the Executive Deputy Assistant
16 Secretary of the Strategic National Stock-
17 pile appointed under subsection (h)(3) to,
18 in accordance with subsection (h)(2), es-
19 tablish, maintain, and (when necessary) ex-
20 pand a supply chain based in the United
21 States for countermeasures (as defined in
22 subsection (h)(4)) procured for the stock-
23 pile;”.

1 (c) ENHANCING THREAT-BASED REVIEWS.—Section
 2 319F–2(a) of the Public Health Service Act (42 U.S.C.
 3 247d–6b(a)) is amended—

4 (1) in paragraph (1), by striking “based on the
 5 review conducted under paragraph (2)” and insert-
 6 ing “based on any review conducted under para-
 7 graph (2)”; and

8 (2) in paragraph (2), by adding at the end the
 9 following:

10 “(C) IN-PERSON OR VIRTUAL BRIEF-
 11 INGS.—

12 “(i) IN GENERAL.—Not later than 30
 13 days after submitting each annual threat-
 14 based review under subparagraph (A) to
 15 the Committees described in such subpara-
 16 graph, the Executive Deputy Assistant
 17 Secretary of the Strategic National Stock-
 18 pile, appointed under subsection (h)(3),
 19 shall provide an in-person, or virtual, brief-
 20 ing on such review to the members of such
 21 Committees.

22 “(ii) PUBLIC HEALTH EMER-
 23 GENCIES.—

24 “(I) MONTHLY REVIEWS.—Dur-
 25 ing the period of any public health

1 emergency, the Executive Deputy As-
2 sistant Secretary of the Strategic Na-
3 tional Stockpile, appointed under sub-
4 section (h)(3), shall, on a monthly
5 basis, provide an in-person, or virtual,
6 briefing to all members of Congress
7 on—

8 “(aa) the countermeasures
9 (as defined in subsection (h)4))
10 in the stockpile under paragraph
11 (1);

12 “(bb) the status of the sup-
13 ply chain, including the domestic
14 supply chain, for such counter-
15 measures;

16 “(cc) how such counter-
17 measures are being distributed;
18 and

19 “(dd) communication with
20 State and local governments on
21 their needs with respect to ac-
22 quiring such countermeasures in
23 the stockpile and on the status of
24 countermeasures that are avail-
25 able in the stockpile.

1 “(II) BASELINE REVIEW.—Not
2 later than 15 days after the date of
3 enactment of the Protecting American
4 Heroes Act of 2020, the Secretary
5 shall conduct a baseline review of the
6 stockpile under paragraph (1) and
7 provide an in-person, or virtual, brief-
8 ing to all members of Congress on
9 each issue described in items (aa)
10 through (dd) of subclause (I).

11 “(D) SUPPLEMENTAL REVIEWS.—In the
12 event that the Executive Deputy Assistant Sec-
13 retary of the Strategic National Stockpile, ap-
14 pointed under subsection (h)(3), determines
15 there is a significant depletion of any counter-
16 measure (as defined in subsection (h)(4)) in the
17 stockpile under paragraph (1), the Executive
18 Deputy Assistant Secretary of the Strategic
19 National Stockpile shall, not later than 30 days
20 after making such determination—

21 “(i) conduct a supplemental threat-
22 based review on each issue described in
23 items (aa) through (dd) of subparagraph
24 (C)(I); and

1 “(ii) provide such review in writing to
2 the Committees described in subparagraph
3 (A).”.

4 **SEC. 3. ENHANCEMENTS TO THE DEFENSE PRODUCTION**
5 **ACT OF 1950.**

6 Section 107 of the Defense Production Act of 1950
7 (50 U.S.C. 4517) is amended by adding at the end the
8 following:

9 “(c) HEALTH EMERGENCY AUTHORITY.—With re-
10 spect to a public health emergency declared under section
11 319 of the Public Health Service Act (42 U.S.C. 247d),
12 or preparations for such a public health emergency, the
13 Secretary of Health and Human Services and the Admin-
14 istrator of the Federal Emergency Management Agency
15 may carry out the authorities provided under this section
16 to the same extent as the President.”.

○