

117TH CONGRESS  
2D SESSION

# S. 3588

To amend the Public Health Service Act to improve domestic manufacturing surge capacity and capabilities for biodefense and pandemic preparedness.

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 7 (legislative day, FEBRUARY 3), 2022

Mr. ROMNEY (for himself and Ms. HASSAN) 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 amend the Public Health Service Act to improve domestic manufacturing surge capacity and capabilities for biodefense and pandemic preparedness.

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 “Medical Counter-  
5 measures Surge Capacity Act of 2022”.

6 **SEC. 2. WARM BASE MANUFACTURING CAPACITY FOR MED-**  
7 **ICAL COUNTERMEASURES.**

8 (a) IN GENERAL.—Section 319L of the Public  
9 Health Service Act (42 U.S.C. 247d–7e) is amended—

1 (1) in subsection (a)(6)(B)—

2 (A) by redesignating clauses (iv) and (v) as  
3 clauses (v) and (vi), respectively;

4 (B) by inserting after clause (iii), the fol-  
5 lowing:

6 “(iv) activities to support, maintain,  
7 and improve domestic manufacturing surge  
8 capacity and capabilities, as appropriate,  
9 including through the utilization of ad-  
10 vanced manufacturing and platform tech-  
11 nologies, to increase the availability of  
12 products that are or may become qualified  
13 countermeasures or qualified pandemic or  
14 epidemic products;”; and

15 (C) in clause (vi) (as so redesignated), by  
16 inserting “manufacturing,” after “improve-  
17 ment,”;

18 (2) in subsection (b)—

19 (A) in the first sentence of paragraph (1),  
20 by inserting “support for domestic manufac-  
21 turing surge capacity and capabilities,” after  
22 “initiatives for innovation,”; and

23 (B) in paragraph (2)—

24 (i) in subparagraph (B), by striking  
25 “and” at the end;

1 (ii) by redesignating subparagraph  
2 (C) as subparagraph (D); and

3 (iii) by inserting after subparagraph  
4 (B), the following:

5 “(C) activities to support, maintain, and  
6 improve domestic manufacturing surge capacity  
7 and capabilities, as appropriate, including  
8 through the utilization of advanced manufac-  
9 turing and platform technologies, to increase  
10 the availability of products that are or may be-  
11 come qualified countermeasures or qualified  
12 pandemic or epidemic products; and”;

13 (3) in subsection (c)—

14 (A) in paragraph (2)(B), by inserting be-  
15 fore the semicolon “, including through the es-  
16 tablishment and maintenance of domestic man-  
17 ufacturing surge capacity and capabilities, con-  
18 sistent with subsection (a)(6)(B)(iv)”;

19 (B) in paragraph (4)—

20 (i) in subparagraph (A)—

21 (I) in clause (i)—

22 (aa) in subclause (I), by  
23 striking “and” at the end; and

24 (bb) by adding at the end  
25 the following:

1 “(III) facilitating such commu-  
2 nication, as appropriate, regarding  
3 manufacturing surge capacity and ca-  
4 pabilities with respect to qualified  
5 countermeasures and qualified pan-  
6 demic or epidemic products to prepare  
7 for, or respond to, a public health  
8 emergency or potential public health  
9 emergency; and

10 “(IV) facilitating such commu-  
11 nication, as appropriate and in a man-  
12 ner that does not compromise national  
13 security, with respect to potential eli-  
14 gibility for the material threat medical  
15 countermeasure priority review vouch-  
16 er program under section 565A of the  
17 Federal Food, Drug, and Cosmetic  
18 Act;”;

19 (II) in clause (ii)(III), by striking  
20 “and” at the end;

21 (III) by redesignating clause (iii)  
22 as clause (iv); and

23 (IV) by inserting after clause (ii),  
24 the following:

1 “(iii) communicate regularly with enti-  
 2 ties in receipt of an award pursuant to  
 3 subparagraph (B)(v), and facilitate com-  
 4 munication between such entities and other  
 5 entities in receipt of an award pursuant to  
 6 subparagraph (B)(iv), as appropriate, for  
 7 purposes of planning regarding the avail-  
 8 ability of countermeasures and the mainte-  
 9 nance of domestic manufacturing surge ca-  
 10 pacity and capabilities, including any  
 11 planned uses of such capacity and capabili-  
 12 ties in the near- and mid-term, and identi-  
 13 fication of any significant challenges re-  
 14 lated to the long-term maintenance of such  
 15 capacity and capabilities; and”;

16 (ii) in subparagraph (B)—

17 (I) in clause (iii), by striking  
 18 “and” at the end;

19 (II) in clause (iv), by striking the  
 20 period and inserting “; and”; and

21 (III) by adding at the end the  
 22 following:

23 “(v) award contracts, grants, and co-  
 24 operative agreements and enter into other  
 25 transactions to support, maintain, and im-

1 prove domestic manufacturing surge capac-  
2 ity and capabilities, including through sup-  
3 porting flexible or advanced manufac-  
4 turing, to ensure that additional capacity  
5 is available to rapidly manufacture prod-  
6 ucts that are or may become qualified  
7 countermeasures or qualified pandemic or  
8 epidemic products in the event of a public  
9 health emergency declaration or significant  
10 potential for a public health emergency.”;

11 (iii) in subparagraph (C)—

12 (I) in clause (i), by striking  
13 “and” at the end;

14 (II) in clause (ii), by striking the  
15 period at the end and inserting “;  
16 and”; and

17 (III) by adding at the end the  
18 following:

19 “(iii) consult with the Commissioner  
20 of Food and Drugs, pursuant to section  
21 565(b)(2) of the Federal Food, Drug, and  
22 Cosmetic Act, to ensure that facilities per-  
23 forming manufacturing, pursuant to an  
24 award under subparagraph (B)(v), are in  
25 compliance with applicable requirements

under such Act and this Act, as appropriate, including current good manufacturing practice pursuant to section 501(a)(2)(B) of the Food, Drug, and Cosmetic Act; and”;

(iv) in subparagraph (D)(i), by inserting “, including to improve manufacturing capacities and capabilities for medical countermeasures” before the semicolon;

(v) in subparagraph (E)(ix), by striking “2023” and inserting “2028”; and

(vi) by adding at the end the following:

“(G) ANNUAL REPORTS BY AWARD RECIPIENTS.—As a condition of receiving an award under subparagraph (B)(v), a recipient shall develop and submit to the Secretary annual reports related to the maintenance of such capacity and capabilities, including ensuring that such capacity and capabilities are able to support the rapid manufacture of countermeasures as required by the Secretary.”; and

(C) in paragraph (5), by adding at the end the following:

“(H) SUPPORTING WARM-BASE AND SURGE  
CAPACITY AND CAPABILITIES.—Pursuant to an  
award under subparagraph (B)(v), the Sec-  
retary may make payments for activities nec-  
essary to maintain domestic manufacturing  
surge capacity and capabilities supported under  
such award to ensure that such capacity and  
capabilities are able to support the rapid manu-  
facture of countermeasures as required by the  
Secretary to prepare for, or respond to, an ex-  
isting or potential public health emergency or  
otherwise address threats that pose a signifi-  
cant level of risk to national security. The Sec-  
retary may support the utilization of such ca-  
pacity and capabilities under awards for coun-  
termeasure and product advanced research and  
development, as appropriate, to provide for the  
maintenance of such capacity and capabilities.”;  
and  
(4) in subsection (f)—

(A) in paragraph (1), by striking “Not  
later than 180 days after the date of enactment  
of this subsection” and inserting “Not later  
than 180 days after the date of enactment of

1 the Medical Countermeasures Surge Capacity  
2 Act of 2022”;

3 (B) in paragraph (2)—

4 (i) in the matter preceding subpara-  
5 graph (A), by striking “this subsection”  
6 and inserting “the Medical Counter-  
7 measures Surge Capacity Act of 2022”;

8 (ii) in subparagraph (B), by striking  
9 “and” at the end; and

10 (iii) in subparagraph (C), by striking  
11 the period and inserting “; and”; and

12 (C) by adding at the end the following:

13 “(D) plans for the near-, mid-, and long-  
14 term sustainment of manufacturing activities  
15 carried out under this section, including such  
16 activities pursuant to subsection (c)(5)(H), spe-  
17 cific actions to regularly assess the ability of re-  
18 cipients of an award under subsection  
19 (c)(4)(B)(v) to rapidly manufacture counter-  
20 measures as required by the Secretary, and rec-  
21 ommendations to address challenges, if any, re-  
22 lated to such activities.”.

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