

116TH CONGRESS  
2D SESSION

# S. 3780

To encourage domestic advanced manufacturing of critical drugs and devices in order to address economic, health, and security concerns, combat shortages of critical drugs and devices, and promote increased domestic diversification of, and independence from foreign reliance on, pharmaceutical and medical device supply chains.

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IN THE SENATE OF THE UNITED STATES

MAY 20, 2020

Mr. PETERS 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 encourage domestic advanced manufacturing of critical drugs and devices in order to address economic, health, and security concerns, combat shortages of critical drugs and devices, and promote increased domestic diversification of, and independence from foreign reliance on, pharmaceutical and medical device supply chains.

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 “Help Onshore Manu-  
5       facturing Efficiencies for Drugs and Devices Act” or the  
6       “HOME Act”.

1 **SEC. 2. INVESTMENTS IN DOMESTIC ADVANCED MANUFAC-**  
2 **TURING AND PREPAREDNESS.**

3 Part A of title III of the Public Health Service Act  
4 (42 U.S.C. 241 et seq.) is amended by adding at the end  
5 the following:

6 **“SEC. 310B. INVESTMENTS IN DOMESTIC ADVANCED MANU-**  
7 **FACTURING FOR CRITICAL DRUGS AND DE-**  
8 **VICES.**

9 “(a) ESTABLISHMENT.—There is established within  
10 the Office of the Assistant Secretary for Preparedness and  
11 Response of the Department of Health and Human Serv-  
12 ices, the ‘Center for Domestic Advanced Manufacturing  
13 of Critical Drugs and Devices’ (referred to in this section  
14 as the ‘Center’).

15 “(b) PURPOSE.—The purpose of the Center for Do-  
16 mestic Advanced Manufacturing of Critical Drugs and De-  
17 vices shall be to implement a program to invest in the ad-  
18 vanced manufacturing for critical drugs and devices, and  
19 to increase domestic production of critical drugs and de-  
20 vices, throughout the United States.

21 “(c) DIRECTOR.—The Center shall be headed by a  
22 Director (referred to in this section as the ‘Director’) who  
23 shall be appointed by the Secretary and to whom the Sec-  
24 retary shall delegate such functions and authorities as  
25 may be necessary to implement this section.

26 “(d) PROGRAM.—

1           “(1) IN GENERAL.—The Center for Domestic  
2       Advanced Manufacturing of Critical Drugs and De-  
3       vices shall—

4                   “(A) not later than 18 months after the  
5       date of enactment of this section—

6                           “(i) establish an advisory board of ex-  
7                           perts from governmental entities, manufac-  
8                           turers, other private industry entities, non-  
9                           profit entities, and institutions of higher  
10                          education, and any other entity as deter-  
11                          mined by the Center; and

12                           “(ii) compile a list of critical drugs  
13                           and devices that should be prioritized for  
14                           domestic advanced manufacturing and in-  
15                           creased domestic production under the pro-  
16                           gram described in paragraph (2), based on  
17                           reports to the Secretary under sections  
18                           506C and 506J of the Federal Food,  
19                           Drug, and Cosmetic Act, the drug shortage  
20                           list under section 506E of such Act, the  
21                           device shortage list under section 506J(g)  
22                           of such Act, and the annual risk assess-  
23                           ments described in section 5 of the HOME  
24                           Act, if available, and update such list quar-  
25                           terly;

“(B) establish and oversee the grant and forgivable loan program described in paragraph (2), including by establishing requirements for participation in such program, including—

“(i) target goals to substantially increase advanced manufacturing production for critical drugs and devices within the United States; and

“(ii) conditioning the receipt of funding under such program on an entity’s agreement to commercially distribute the drug or device in the United States; and

“(C) review the effects of the program described in paragraph (2) on the percentage change in domestic manufacturing of critical drugs, devices, and active pharmaceutical ingredients.

“(2) GRANT AND FORGIVABLE LOAN PROGRAM.—

“(A) IN GENERAL.—The Center for Domestic Advanced Manufacturing of Critical Drugs and Devices shall establish a grant and forgivable loan program in order to support investment in—

1 “(i) advanced manufacturing and fa-  
2 cilities upgrades for the domestic produc-  
3 tion of critical drugs, devices, and active  
4 pharmaceutical ingredients; and

5 “(ii) increased domestic production  
6 and diversification of critical drugs, de-  
7 vices, and active pharmaceutical ingredi-  
8 ents.

9 “(B) ELIGIBLE ENTITIES.—

10 “(i) IN GENERAL.—To be eligible to  
11 receive a grant or forgivable loan under  
12 this paragraph, an entity shall meet the re-  
13 quirements established under paragraphs  
14 (1)(A)(ii) and (1)(B) and such criteria as  
15 the Center shall develop and, as applica-  
16 ble—

17 “(I) with respect to a critical  
18 drug, shall be the holder of an appli-  
19 cation approved under section 505 of  
20 the Federal Food, Drug, and Cos-  
21 metic Act or section 351 of this Act,  
22 or a contract manufacturer of the  
23 drug for such holder of an approved  
24 application;

1           “(II) with respect to an active  
2           pharmaceutical ingredient, shall be  
3           the manufacturer of an active phar-  
4           maceutical ingredient of a drug ap-  
5           proved under section 505 of the Fed-  
6           eral Food, Drug, and Cosmetic Act or  
7           section 351 of this Act;

8           “(III) with respect to a critical  
9           device, shall have received approval  
10          under section 515 of the Federal  
11          Food, Drug, and Cosmetic Act, clear-  
12          ance under section 510(k) of such Act  
13          (or be exempt from the requirements  
14          of such section 510(k)), or authoriza-  
15          tion under section 513(f)(2) of such  
16          Act, or shall be a contract manufac-  
17          turer of the device for such an entity;  
18          or

19          “(IV) with respect to a drug or  
20          device, shall have submitted an appli-  
21          cation under section 505 or 515 of the  
22          Federal Food, Drug, and Cosmetic  
23          Act or under section 351 of this Act,  
24          a report under section 510(k), or a re-  
25          quest under section 513(f)(2).

1                   “(ii) PRIORITY.—In awarding grants  
2                   and forgivable loans under this paragraph  
3                   the Center for Domestic Advanced Manu-  
4                   facturing of Critical Drugs and Devices  
5                   shall give priority—

6                   “(I) in the case of manufacturers  
7                   of drugs or active pharmaceutical in-  
8                   gredients, to entities—

9                   “(aa) described in sub-  
10                  clauses (I) and (II) of clause (i);  
11                  and

12                  “(bb) whose application for  
13                  an award under this paragraph  
14                  relates to a drug that was ap-  
15                  proved under section 505(j) of  
16                  the Federal Food, Drug, and  
17                  Cosmetic Act; and

18                  “(II) in the case of manufactur-  
19                  ers of devices, to entities described in  
20                  clause (i)(III).

21                  “(C) USE OF FUNDS.—Awards received  
22                  under this paragraph shall be used for the ad-  
23                  vanced manufacturing and increased production  
24                  of critical drugs and devices in the United  
25                  States.

1           “(D) FORGIVABLE LOANS.—The Center  
2           may award forgivable loans under this para-  
3           graph under which a recipient shall receive a  
4           loan and be eligible for forgiveness of indebted-  
5           ness on such loan, under such conditions for re-  
6           ceipt and forgiveness as the Center may estab-  
7           lish.

8           “(E) GRANTS.—The Center may award  
9           grants under this section, which shall be condi-  
10          tioned upon the recipient matching Federal  
11          funds so awarded.

12          “(F) FUNDING.—Out of amounts made  
13          available to carry out this section, the Secretary  
14          shall allocate \$500,000,000 toward awards of  
15          forgivable loans and grants under this para-  
16          graph.

17          “(e) ANNUAL REPORTING.—The Secretary shall sub-  
18          mit to the relevant committees of Congress annual reports  
19          on the program under this section. At a minimum, each  
20          such report shall—

21                 “(1) identify the list of critical drugs and de-  
22          vices under subsection (d)(1)(A)(ii) and account for  
23          any alterations in the list;



1           “(2) describe the participants in the program  
2           under subsection (d)(2) and criteria for eligibility for  
3           such participation;

4           “(3) address target goals for substantially in-  
5           creased advanced manufacturing production for crit-  
6           ical drugs and devices; and

7           “(4) review the percentage change in domestic  
8           manufacturing of critical drugs, devices, and active  
9           pharmaceutical ingredients since the most recent re-  
10          port.

11         “(f) INTERAGENCY COOPERATION.—

12           “(1) IN GENERAL.—In carrying out activities  
13           under this section, the Center is authorized, subject  
14           to paragraph (2), to enter into interagency agree-  
15           ments and other collaborative undertakings with  
16           other Federal agencies.

17           “(2) LIMITATION.—An agreement or under-  
18           taking under this subsection shall not authorize an-  
19           other agency to exercise the authorities provided by  
20           this section.

21         “(g) AUTHORIZATION OF APPROPRIATIONS.—To  
22         carry out this section, there is authorized to be appro-  
23         priated such funds as may be necessary, for each of fiscal  
24         years 2021 through 2031.

25         “(h) DEFINITIONS.—In this section—

1 “(1) the terms ‘drug’ and ‘device’ have the  
2 meanings given such terms in section 201 of the  
3 Federal Food, Drug, and Cosmetic Act;

4 “(2) the term ‘institution of higher education’  
5 has the meaning given such term in section 101(a)  
6 of the Higher Education Act of 1965; and

7 “(3) the term ‘relevant committees of Congress’  
8 means the Committee on Homeland Security and  
9 Governmental Affairs, the Committee on Health,  
10 Education, Labor, and Pensions, and the Committee  
11 on Armed Services of the Senate and the Committee  
12 on Homeland Security, the Committee on Energy  
13 and Commerce, and the Committee on Armed Serv-  
14 ices of the House of Representatives.”.

15 **SEC. 3. EXPEDITED REVIEW OF CERTAIN SUPPLEMENTAL**  
16 **APPLICATIONS.**

17 Section 506 of the Federal Food, Drug, and Cosmetic  
18 Act (21 U.S.C. 356) is amended by adding at the end the  
19 following:

20 “(i) EXPEDITED REVIEW OF CERTAIN SUPPLE-  
21 MENTAL APPLICATIONS.—

22 “(1) IN GENERAL.—The holder of an applica-  
23 tion approved under section 505 of this Act or li-  
24 cense under section 351 of the Public Health Service  
25 Act who submits a supplemental application with re-

1       spect to such application or license may request an  
2       expedited review of such supplemental application  
3       under this subsection.

4           “(2) APPLICATION.—To be eligible for expedited review under this subsection, the holder of the  
5       approved application or license with respect to a  
6       drug included on the most recent list of critical  
7       drugs and devices compiled under section  
8       310B(d)(1)(A)(ii) of the Public Health Service Act,  
9       shall demonstrate in the supplemental application  
10      that—  
11      that—

12           “(A) approval of such supplemental appli-  
13       cation would enable the incorporation of a man-  
14       ufacturing change that is intended to enhance  
15       drug quality, increase domestic manufacturing  
16       of the drug, or incorporate the use of advanced  
17       manufacturing; and

18           “(B) the applicant’s plan for producing the  
19       drug domestically after approval of the supple-  
20       mental application.

21           “(3) REVIEW BY SECRETARY.—If the Secretary  
22       determines, after preliminary evaluation of a supple-  
23       mental application, that the application dem-  
24       onstrates that the manufacturing change would en-  
25       hance the ability of the holder of the application to

1       domestically manufacture a drug on the list of crit-  
 2       ical drugs and devices described in paragraph (2),  
 3       the Secretary shall evaluate for filing, and may com-  
 4       mence review of portions of, such supplemental ap-  
 5       plication before the sponsor submits a complete ap-  
 6       plication. The Secretary shall commence such review  
 7       only if the applicant provides a schedule for submis-  
 8       sion of information necessary to make the applica-  
 9       tion complete.”.

10   **SEC. 4. LONG-TERM, HIGH-VOLUME CONTRACTS TO PUR-**  
 11       **CHASE CRITICAL DRUGS AND DEVICES.**

12       (a) CONTRACTING GOALS.— In order to further the  
 13       needs of the Department of Health and Human Services  
 14       and the Department of Defense, invest in preparedness  
 15       and the strategic national stockpile, and mitigate drug and  
 16       device shortages, each of the Secretary of Health and  
 17       Human Services and the Assistant Secretary of Defense  
 18       for Health Affairs may enter into contracts to purchase  
 19       a drug or device included on the list of critical drugs and  
 20       devices compiled under section 310B(d)(1)(A)(ii) of the  
 21       Public Health Service Act (as added by section 2), includ-  
 22       ing multi-year, high-volume contracts, as set forth in sub-  
 23       section (b), and otherwise in accordance with procurement  
 24       laws and regulations.

1 (b) RESPONSIBILITY DETERMINATIONS.—For pur-  
2 poses of meeting the goals under subsection (a), a con-  
3 tracting officer of the Department of Health and Human  
4 Services or the Department of Defense may give pref-  
5 erence and award a contract to a program participant  
6 under section 310B(d)(2) of the Public Health Service Act  
7 (as added by section 2), if—

8 (1) the program participant is determined by  
9 the contracting officer, in consultation with the Cen-  
10 ter for Domestic Advanced Manufacturing of Critical  
11 Drugs and Devices with respect to the participant’s  
12 performance in the program under section  
13 310B(d)(2) of the Public Health Service Act, to be  
14 a responsible source with respect to performance of  
15 the contract; and

16 (2) in the estimation of the contracting officer,  
17 the contract award can be made at a fair and rea-  
18 sonable price that offers best value to the United  
19 States.

20 **SEC. 5. ANNUAL RISK ASSESSMENT.**

21 (a) IN GENERAL.—Not later than 1 year after the  
22 date of enactment of this Act, and annually thereafter,  
23 the Secretary of Homeland Security, the Secretary of  
24 Health and Human Services, and the Secretary of Defense  
25 shall each conduct separate independent risk assessments

1 of the medical supply chain and report to the relevant  
2 committees of Congress on the findings of such assess-  
3 ments. At a minimum, each risk assessment shall—

4           (1) identify drugs and devices critical to each  
5           agency in responding to a public health emergency,  
6           biological or chemical threat, or other national secu-  
7           rity threat;

8           (2) identify the drugs and devices identified  
9           under paragraph (1) for which there is a single man-  
10          ufacturer or distributor in the United States;

11          (3) list the drugs and devices identified under  
12          paragraph (1) that are sourced exclusively from for-  
13          eign sources;

14          (4) assess current domestic manufacturing ca-  
15          pability with respect to drugs and devices identified  
16          under paragraph (1), including advanced manufac-  
17          turing capabilities; and

18          (5) identify critical vulnerabilities and establish  
19          contingency plans in the event of a public health  
20          emergency, biological or chemical threat, or other  
21          national security threat.

22          (b) RISK ASSESSMENT REPORT CONCLUSIONS.—  
23          Each risk assessment of each secretary under subsection  
24          (a) shall indicate, at a minimum—

1           (1) the existing statutory authorities the de-  
2           partment has to address public health or national se-  
3           curity risks that may arise as a result of vulnerabili-  
4           ties in the medical supply chain;

5           (2) any deficiencies, lack of authorities, or limi-  
6           tations in policy or process that limit the depart-  
7           ment’s ability to address vulnerabilities identified in  
8           the applicable risk assessment; and

9           (3) the secretary’s plans to address drug and  
10          device shortages, control costs, and prepare for pub-  
11          lic health emergencies, biological or chemical threats,  
12          and other national security threats.

13       (c) REVIEW BY SECRETARIES.—The Secretary of  
14       Homeland Security, the Secretary of Health and Human  
15       Services, and the Secretary of Defense, in providing the  
16       risk assessments under subsection (a) may consult with  
17       each other, as appropriate, regarding any similarities in  
18       vulnerabilities experienced by each such secretary and any  
19       coordination among the secretaries that may address such  
20       vulnerabilities.

21       (d) DEFINITIONS.—In this section—

22           (1) the terms “device” and “drug” have the  
23           meanings given such terms in section 201 of the  
24           Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
25           321); and

1           (2) the term “relevant committees of Congress”  
2       means the Committee on Homeland Security and  
3       Governmental Affairs, the Committee on Health,  
4       Education, Labor, and Pensions, and the Committee  
5       on Armed Services of the Senate and the Committee  
6       on Homeland Security, the Committee on Energy  
7       and Commerce, and the Committee on Armed Serv-  
8       ices of the House of Representatives.

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