Calendar No. 668

117TH CONGRESS *2d Session*	SENATE	REPORT 117–269

MAKE PPE IN AMERICA ACT

R E P O R T

OF THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS UNITED STATES SENATE

TO ACCOMPANY

S. 1306

TO PROVIDE FOR DOMESTIC SOURCING OF PERSONAL PROTECTIVE EQUIPMENT, AND FOR OTHER PURPOSES

DECEMBER 19, 2022.—Ordered to be printed

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DECEMBER 19, 2022.—Ordered to be printed

Mr. PETERS, from the Committee on Homeland Security and Governmental Affairs, submitted the following

R E P O R T

[To accompany S. 1306]

The Committee on Homeland Security and Governmental Affairs, to which was referred the bill (S. 1306) to provide for domestic sourcing of personal protective equipment, and for other purposes, having considered the same, reports favorably thereon with an amendment, in the nature of a subsitute, and recommends that the bill, as amended, do pass.

CONTENTS

I. PURPOSE AND SUMMARY

S. 1306, the "Make PPE in America Act," requires certain departments that procure personal protective equipment (PPE) to ensure that any contracts those agencies issue for PPE are at least two years in length, and are for PPE that is grown, reprocessed, reused, or produced in the United States. Covered departments include the Departments of Homeland Security (DHS), Health and Human Services (HHS), Veterans Affairs, and Defense (DoD). The bill provides exceptions to the two-year minimum duration of PPE contracts and the domestic production requirement for non-availability and for alternatives to domestic production that the departmental secretary certifies as necessary to meet the immediate needs of a

public health emergency. The need for use of such exceptions must be re-certified by the departmental secretary every 120 days.

S. 1306 requires the Director of the Office of Management and Budget (OMB), in consultation with the covered secretaries, to submit to Congress a report on the procurement of PPE not later than 180 days after the date of the bill's enactment. The report must address the United States' long-term domestic procurement strategy for PPE, including strategies to incentivize investment in and maintenance of domestic supply chains for PPE needed during a public health emergency. The report must include an estimate of long-term demand for all PPE items procured by the United States, recommendations for congressional action needed to implement the procurement strategy outlined in the report, and a determination as to whether any necessary action has been completed to bring existing United States international obligations into conformity with the requirements of the Act.

S. 1306 authorizes a covered secretary to transfer to the Strategic National Stockpile any excess PPE acquired under a contract executed under the Act. The bill also allows DHS to transfer to HHS excess PPE or medically necessary equipment during a public health emergency, provided Congress is notified and a determination is made that the items are excess and that the transfer will not adversely impact DHS. The bill also requires DHS to maintain an inventory of the Department's PPE and make it available to HHS and Congress. The bill provides transfer authority for the Secretary of HHS, in coordination with the Secretary of Homeland Security, to sell drugs, vaccines, and other biological products, medical devices, and supplies maintained in the Stockpile, provided the items are no longer needed and within one year of their expiration date.

II. BACKGROUND AND NEED FOR THE LEGISLATION

When confronted with the COVID–19 pandemic, the United States quickly faced a PPE supply chain crisis. For supplies such as gowns and gloves, domestic production was limited and supplies were scarce.[1] In response to this situation, the Defense Logistics Agency (DLA) and the Joint Acquisition Task Force (JATF) made a domestic non-availability determination (DNAD) for PPE. The DNAD waives the normal domestic content requirements, such as the Berry Amendment, allowing DLA/JATF to procure PPE from anywhere in the world. While the DNAD was necessary to meet the needs of the country's pandemic response, it underscored a real problem: that the United States should have more control of its PPE supply and production.

Long-term contracts are one option to stimulate re-shoring and expansion of domestic PPE production. Long-term contracts send a powerful demand signal to industry, providing confidence that there will be an assured buyer if businesses make investments in the United States to re-shore or expand existing production.[2]

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[1] Congressional Research Service, *COVID–19 and Domestic PPE Production and Distribution: Issues and Policy Options* (Dec. 7, 2020) (https://crsreports.congress.gov/product/pdf/R/R46628); See also Government Accountability Office, *COVID–19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions* (GAO–20–701) (Sep. 21, 2020).

[2] Brookings Institution Report, *Reshoring Advanced Manufacturing Supply Chains to Generate Good Jobs* (Jul. 23, 2020) (https://www.brookings.edu/research/reshoring-advanced-manufacturing-supply-chains-to-generate-good-jobs/).

III. LEGISLATIVE HISTORY

Ranking Member Rob Portman (R–OH) introduced S. 1306, the Make PPE in America Act, on April 22, 2021, with Chairman Peters (D–MI) as cosponsor. The bill was referred to the Senate Committee on Homeland Security and Governmental Affairs.

The Committee considered S. 1306 at a business meeting on May 12, 2021. During the business meeting, a substitute amendment was offered by Ranking Member Portman and Chairman Peters. The substitute amendment reduced the required contract length from 3 years to 2 years and provided for exceptions to domestic production for nonavailability, cost, and where necessary, as certified by the relevant Secretary, to respond to the immediate needs of a public health emergency. A modification to the substitute amendment to provide for transfer of PPE to the Strategic National Stockpile during a public health emergency was adopted by voice vote *en bloc*. The modified substitute amendment was then adopted by voice vote *en bloc*. An amendment to the modified substitute amendment to add the text of Senator Johnson's Securing Healthcare and Response Equipment Act of 2020, which allows HHS and DHS to effectuate the transfer and sale of excess PPE, medical equipment, and supplies in the event of a public health emergency, to the bill was then offered by Senator Johnson (R–WI) and adopted by voice vote *en bloc*.

The Committee ordered the bill reported favorably by voice vote *en bloc* as amended with Senators Peters, Carper, Hassan, Sinema, Rosen, Padilla, Ossoff, Portman, Johnson, Paul, Lankford, Romney, Scott, and Hawley present.

IV. SECTION-BY-SECTION ANALYSIS OF THE BILL, AS REPORTED

Section 1. Short title

This section provides that the bill may be cited as the "Make PPE in America Act."

Sec. 2. Findings

Section 2 provides that Congress makes the following findings:

(1) The COVID–19 pandemic has exposed the vulnerability of the United States PPE supply chain as well as a lack of domestic production of PPE.

(2) The United States requires a robust, secure, and wholly domestic PPE supply chain to safeguard public health and national security.

(3) Issuing a strategy that provides the government's anticipated PPE needs over the next 3 years will enable suppliers to assess necessary changes to their manufacturing capacity to meet expected demands.

(4) Industry needs a strong and consistent demand signal from the Federal Government to provide the certainty needed for industry to expand production capacity investment in the United States.

(5) Long-term contracts must be no shorter than 3 years in duration in order to effectively incentivize the investment in the United States and re-shoring of manufacturing of PPE.

(6) The United States should seek to ensure compliance with international obligations such as its commitments under the World Trade Organization's Agreement on Government Procurement and

its free trade agreements, including by invoking relevant exceptions to these agreements, especially those related to national security and public health.

(7) The United States needs a long-term investment strategy for domestic production of PPE critical to national response to a public health crisis, including the COVID–19 pandemic.

Sec. 3. Requirement of long-term contracts for domestically manufactured personal protective equipment

Subsection (a) defines "appropriate congressional committees," "covered Secretary," "personal protective equipment," and "United States."

Subsection (b) requires that beginning 90 days after date of enactment, the covered Secretaries of Homeland Security, Health and Human Services, Veterans Affairs, and Defense must issue any contract for the procurement of PPE for a duration of at least 2 years, plus all options necessary, and that the PPE and its materials and components be grown, reprocessed, reused or produced in the United States.

Subsection (c) allows a covered Secretary to certify the need to use alternatives to domestic production after maximizing sources consistent with subsection (b) and maximizing sources for PPE assembled outside the United States containing materials and components that are grown, reprocessed, reused, or produced in the United States. This certification for use of alternative procedures to respond to the immediate needs of a public health emergency must be made every 120 days.

Subsection (d) provides an exception to the domestic sourcing requirements for PPE that includes a material listed in section 25.104 of the Federal Acquisition Regulation as one for which a non-availability determination has been made, or PPE for which a covered Secretary determines that a sufficient quantity of a satisfactory quality cannot be procured when needed at United States market prices. The covered Secretary shall certify every 120 days that the exception is needed to meet the immediate needs of a public health emergency.

Subsection (e) requires the Director of OMB, in consultation with the covered Secretaries, to submit a report to Congress within 180 days after the bill's enactment on the procurement of PPE. The report shall include the long-term domestic procurement strategy of the United States for PPE, including strategies to incentivize investment in and maintenance of domestic supply chains for PPE needed during a public health emergency. The report shall also include an estimate of long-term demand for all PPE items procured by the United States, recommendations for congressional action needed to implement the procurement strategy outlined in the report, and a determination as to whether any necessary action has been completed to bring existing United States international obligations into conformity with the requirements of the Act.

Subsection (f) allows a covered Secretary to transfer to the Strategic National Stockpile any excess PPE acquired under a contract executed pursuant to subsection (b). The subsection amends the Homeland Security Act of 2002 to allow the Secretary of Homeland Security, at the request of the Secretary of Health and Human Services, to transfer to HHS excess PPE or medically necessary

equipment during a public health emergency, provided Congress is notified and the Secretary determines the items are excess and certifies that the transfer will not adversely impact the health or safety of officers, employees, or contractors of DHS. The Secretary of Homeland Security, acting through the Chief Medical Officer, shall maintain a required inventory of PPE and make it available to the Secretary of Health and Human Services and Congress.[3] The subsection also amends the Public Health Service Act to allow the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security, to sell drugs, vaccines, and other biological products, medical devices, and supplies maintained in the Strategic National Stockpile, provided the items are no longer needed and are within 1 year of their expiration date.[4]

Subsection (g) requires the President or President's designee to take all necessary steps, including invoking the rights of the United States under the World Trade Organization's Agreement on Government Procurement and relevant exceptions under other relevant agreements, to ensure that the international obligations of the United States are consistent with the provisions of the Act.

V. EVALUATION OF REGULATORY IMPACT

Pursuant to the requirements of paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee has considered the regulatory impact of this bill and determined that the bill will have no regulatory impact within the meaning of the rules. The Committee agrees with the Congressional Budget Office's statement that the bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

The changes in law set forth in this bill were included in the Infrastructure Investment and Jobs Act of 2021 (Pub. L. 117–58, Sec. 70953(f)), which became law before this bill was reported out of committee. These changes in law are now moot and therefore are not reflected in this section. The bill as enacted did not include the Secretary of Defense in the definition of the term "covered Secretary" set forth in Section 3(a) of the substitute amendment reported out of Committee; the inclusion of the Secretary of Defense in the definition will not be enacted.

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[3] The change to the Homeland Security Act of 2002 set forth in subsection (f) of the bill was included in the Infrastructure Investment and Jobs Act of 2021 (Pub. L. 117–58, Sec. 70953(f)(2), which became law before this bill was reported out of committee. This change in law is now moot and is not reflected in Section VII of this report.

[4] The change to the Public Health Service Act set forth in subsection (f) of the bill was included in the Infrastructure Investment and Jobs Act of 2021 (Pub. L. 117–58, Sec. 70953(f)(3), which became law before this bill was reported out of committee. This change in law is now moot and is not reflected in Section VII of this report.