

urge my colleagues to support this legislation, and I reserve the balance of my time.

Mrs. DINGELL. Mr. Speaker, I reserve the balance of my time.

Mr. GIANFORTE. Mr. Speaker, I yield 3 minutes to the gentleman from Kentucky (Mr. GUTHRIE).

Mr. GUTHRIE. Mr. Speaker, I rise today in support of H.R. 4866, the National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act, a bill I introduced with my colleague, Energy and Commerce Committee Chairman FRANK PALLONE.

In 2016, I was proud to work with my fellow committee members on the 21st Century Cures Act, which included legislation to issue grants for institutions of higher education to study the process of continuous pharmaceutical manufacturing. H.R. 4866, which we are considering today, builds on this partnership established in the Cures Act.

Continuous manufacturing for pharmaceuticals is a new technology that allows for drugs to be produced in a continuous stream, helping drugs get into the market faster. This is something that has become increasingly important during the COVID-19 pandemic. We need to ensure that our drug supply chain does not depend too heavily on other countries, such as China.

Mr. Speaker, I urge my colleagues to support H.R. 4866.

Mrs. DINGELL. Mr. Speaker, I reserve the balance of my time.

Mr. GIANFORTE. Mr. Speaker, I urge adoption of this bill, and I yield back the balance of my time.

Mrs. DINGELL. Mr. Speaker, it is time for the United States to focus on bringing the production back home. I urge my colleagues to support this legislation, and I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I rise in support of H.R. 4866, the National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act.

Continuous pharmaceutical manufacturing is the future of medicine. This bipartisan bill, which I introduced with Representative GUTHRIE last year, will foster the development of continuous manufacturing technology, a more nimble and efficient mode of pharmaceutical production. It does this by expanding opportunities for the Food and Drug Administration (FDA) to partner with universities across the country that are leading these efforts and create Centers of Excellence for Continuous Pharmaceutical Manufacturing. The partnerships created by the legislation will help develop continuous manufacturing technology and standardization, develop a continuous manufacturing workforce here in the United States, and make recommendations for how FDA, industry, and others can expand the use of continuous manufacturing for drugs and biologics.

The COVID-19 pandemic has demonstrated how the outdated batch manufacturing process adds to the potential for supply chain issues. During the initial stages of the outbreak in New Jersey, I heard from health providers in my district about their inability to access commonly used and critically needed

medication, including medication necessary for the use of ventilators, due to surges in demand. H.R. 4866 will help prevent supply chain interruptions like these by increasing domestic manufacturing and allowing manufacturers to more quickly adjust to sudden shifts in demand.

As Dr. Janet Woodcock, the Director for the Center for Drug Evaluation and Research at FDA told the Energy and Commerce Subcommittee on Health last year, advance manufacturing technologies—such as continuous manufacturing—can help to “reduce the Nation’s dependence on foreign sources of [active pharmaceutical ingredients], increase the resilience of our domestic manufacturing base, and reduce quality issues that trigger drug shortages or recalls.”

In other words, by passing this bill and expanding continuous manufacturing technology in the United States, we can avoid future drug shortages and other supply chain interruptions, while bringing jobs back to the United States. This will help those on the frontlines battling COVID-19 and the patients who are depending on them.

I want to thank Representative GUTHRIE for working with me on this bill and demonstrating the collegial and bipartisan spirit of the Energy and Commerce Committee. I urge all members to support this important legislation.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Michigan (Mrs. DINGELL) that the House suspend the rules and pass the bill, H.R. 4866, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

#### STRENGTHENING AMERICA'S STRATEGIC NATIONAL STOCKPILE ACT OF 2020

Mrs. DINGELL. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 7574) to amend the Public Health Service Act with respect to the Strategic National Stockpile, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 7574

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

#### SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Strengthening America’s Strategic National Stockpile Act of 2020”.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Reimbursable transfers.
- Sec. 3. Equipment maintenance.
- Sec. 4. Supply chain flexibility manufacturing pilot.
- Sec. 5. GAO study on the feasibility and benefits of a user fee agreement.
- Sec. 6. Grants for State strategic stockpiles.
- Sec. 7. Action reporting.
- Sec. 8. Improved, transparent processes.
- Sec. 9. Authorization of appropriations.

#### SEC. 2. REIMBURSABLE TRANSFERS.

Section 319F-2(a) of the Public Health Service Act (42 U.S.C. 247d-6b(a)) is amended by adding at the end the following:

“(6) TRANSFERS AND REIMBURSEMENTS.—

“(A) IN GENERAL.—Without regard to chapter 5 of title 40, United States Code, the Secretary may transfer to any Federal department or agency, on a reimbursable basis, any drugs, vaccines and other biological products, medical devices, and other supplies in the stockpile if—

“(i) the transferred supplies are less than one year from expiry;

“(ii) the stockpile is able to replenish the supplies, as appropriate; and

“(iii) the Secretary decides the transfer is in the best interest of the United States Government.

“(B) USE OF REIMBURSEMENT.—Reimbursement derived from the transfer of supplies pursuant to subparagraph (A) may, to the extent and in the amounts made available in advance in appropriations Acts, be used by the Secretary to carry out this section. Funds made available pursuant to the preceding sentence are in addition to any other funds that may be made available for such purpose.

“(C) RULE OF CONSTRUCTION.—This paragraph shall not be construed to preclude transfers of products in the stockpile under other authorities.

“(D) REPORT.—Not later than September 30, 2022, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on each transfer made under this paragraph and the amount received by the Secretary in exchange for that transfer.

“(E) SUNSET.—The authority to make transfers under this paragraph shall cease to be effective on September 30, 2023.”.

#### SEC. 3. EQUIPMENT MAINTENANCE.

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

(1) in subsection (a)(3)—

(A) in subparagraph (I), by striking “; and” and inserting a semicolon;

(B) in subparagraph (J), by striking the period at the end and inserting a semicolon; and

(C) by inserting the following new subparagraph at the end:

“(K) ensure contents of the stockpile remain in good working order and, as appropriate, conduct maintenance services on contents of the stockpile; and”;

(2) in subsection (c)(7)(B), by adding at the end the following new clause:

“(ix) EQUIPMENT MAINTENANCE SERVICE.—In carrying out this section, the Secretary may enter into contracts for the procurement of equipment maintenance services.”.

#### SEC. 4. SUPPLY CHAIN FLEXIBILITY MANUFACTURING PILOT.

(a) IN GENERAL.—Section 319F-2(a)(3) of the Public Health Service Act (42 U.S.C. 247d-6b(a)(3)), as amended by section 3, is further amended by adding at the end the following new subparagraph:

“(L) enhance medical supply chain elasticity and establish and maintain domestic reserves of critical medical supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, and other medical devices (including diagnostic tests)) by—

“(i) increasing emergency stock of critical medical supplies;

“(ii) geographically diversifying domestic production of such medical supplies, as appropriate;

“(iii) entering into cooperative agreements or partnerships with respect to manufacturing lines, facilities, and equipment for the domestic production of such medical supplies; and

“(iv) managing, either directly or through cooperative agreements with manufacturers and distributors, domestic reserves established under this subparagraph by refreshing and replenishing stock of such medical supplies.”.

(b) **REPORTING; SUNSET.**—Section 319F-2(a) of the Public Health Service Act (42 U.S.C. 247d-6b(a)), as amended by section 2, is further amended by adding at the end the following:

“(7) **REPORTING.**—Not later than September 30, 2022, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on the details of each cooperative agreement or partnership entered into under paragraph (3)(L), including the amount expended by the Secretary on each such cooperative agreement or partnership.

“(8) **SUNSET.**—The authority to enter into cooperative agreements or partnerships pursuant to paragraph (3)(L) shall cease to be effective on September 30, 2023.”.

(c) **FUNDING.**—Section 319F-2(f) of the Public Health Service Act (42 U.S.C. 247d-6b(f)) is amended by adding at the end the following:

“(3) **SUPPLY CHAIN ELASTICITY.**—

“(A) **IN GENERAL.**—For the purpose of carrying out subsection (a)(3)(L), there is authorized to be appropriated \$500,000,000 for each of fiscal years 2021 through 2023, to remain available until expended.

“(B) **RELATION TO OTHER AMOUNTS.**—The amount authorized to be appropriated by subparagraph (A) for the purpose of carrying out subsection (a)(3)(L) is in addition to any other amounts available for such purpose.”.

#### **SEC. 5. GAO STUDY ON THE FEASIBILITY AND BENEFITS OF A USER FEE AGREEMENT.**

(a) **IN GENERAL.**—The Comptroller General of the United States shall conduct a study to investigate the feasibility of establishing user fees to offset certain Federal costs attributable to the procurement of single-source materials for the Strategic National Stockpile under section 319F-2 of the Public Health Service Act (42 U.S.C. 247d-6b) and distributions of such materials from the Stockpile. In conducting this study, the Comptroller General shall consider, to the extent information is available—

(1) whether entities receiving such distributions generate profits from those distributions;

(2) any Federal costs attributable to such distributions;

(3) whether such user fees would provide the Secretary with funding to potentially offset procurement costs of such materials for the Strategic National Stockpile; and

(4) any other issues the Comptroller General identifies as relevant.

(b) **REPORT.**—Not later than February 1, 2023, the Comptroller General of the United States shall submit to the Congress a report on the findings and conclusions of the study under subsection (a).

#### **SEC. 6. GRANTS FOR STATE STRATEGIC STOCKPILES.**

Title III of the Public Health Service Act is amended by inserting after section 319F-4 of such Act (42 U.S.C. 247d-6e) the following new section:

##### **“SEC. 319F-5. GRANTS FOR STATE STRATEGIC STOCKPILES.**

“(a) **IN GENERAL.**—The Secretary may establish a pilot program consisting of awarding grants to States to expand or maintain a strategic stockpile of commercially available drugs, devices, personal protective equipment, and other products deemed by the State to be essential in the event of a public health emergency.

“(b) **ALLOWABLE USE OF FUNDS.**—

“(1) **USES.**—A State receiving a grant under this section may use the grant funds to—

“(A) acquire commercially available products listed pursuant to paragraph (2) for inclusion in the State’s strategic stockpile;

“(B) store, maintain, and distribute products in such stockpile; and

“(C) conduct planning in connection with such activities.

“(2) **LIST.**—The Secretary shall develop and publish a list of the products that are eligible, as described in subsection (a), for inclusion in a State’s strategic stockpile using funds received under this section.

“(3) **CONSULTATION.**—In developing the list under paragraph (2) and otherwise determining the allowable uses of grant funds under this section, the Secretary shall consult with States and relevant stakeholders, including public health organizations.

“(c) **FUNDING REQUIREMENT.**—The Secretary may not obligate or expend any funds to award grants or fund any previously awarded grants under this section for a fiscal year unless the total amount made available to carry out section 319F-2 for such fiscal year is equal to or greater than the total amount of funds made available to carry out section 319F-2 for fiscal year 2020.

“(d) **MATCHING FUNDS.**—

“(1) **IN GENERAL.**—With respect to the costs of expanding and maintaining a strategic stockpile through a grant under this section, as a condition on receipt of the grant, a State shall make available (directly) non-Federal contributions in cash toward such costs in an amount that is equal to not less than the amount of Federal funds provided through the grant.

“(2) **WAIVER.**—The Secretary may waive the requirement of paragraph (1) with respect to a State for the first two years of the State receiving a grant under this section if the Secretary determines that such waiver is needed for the State to establish a strategic stockpile described in subsection (a).

“(e) **TECHNICAL ASSISTANCE.**—The Secretary shall provide technical assistance to States in establishing, expanding, and maintaining a stockpile described in subsection (a).

“(f) **DEFINITION.**—In this section, the term ‘drug’ has the meaning given to that term in section 201 of the Federal Food, Drug, and Cosmetic Act.

“(g) **AUTHORIZATION OF APPROPRIATIONS.**—To carry out this section, there is authorized to be appropriated \$3,500,000,000 for each of fiscal years 2021 through 2023, to remain available until expended.

“(h) **SUNSET.**—The authority vested by this section terminates at the end of fiscal year 2023.”.

#### **SEC. 7. ACTION REPORTING.**

(a) **IN GENERAL.**—The Secretary of Health and Human Services or the Assistant Secretary for Preparedness and Response, in consultation with the Administrator of the Federal Emergency Management Agency, shall—

(1) not later than 30 days after the date of enactment of this Act, issue a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate regarding all State, local, Tribal, and territorial requests for supplies from the Strategic National Stockpile related to COVID-19; and

(2) not less than every 30 days thereafter through the end of the emergency period (as such term is defined in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b-5(g)(1)(B))), submit to such committees an updated version of such report.

(b) **REPORTING PERIOD.**—

(1) **INITIAL REPORT.**—The initial report under subsection (a) shall address all requests described in such subsection made during the period—

(A) beginning on January 31, 2020; and

(B) ending on the date that is 30 days before the date of submission of the report.

(2) **UPDATES.**—Each update to the report under subsection (a) shall address all requests described in such subsection made during the period—

(A) beginning at the end of the previous reporting period under this section; and

(B) ending on the date that is 30 days before the date of submission of the updated report.

(c) **CONTENTS OF REPORT.**—The report under subsection (a) (and updates thereto) shall include—

(1) the details of each request described in such subsection, including—

(A) the specific medical countermeasures, devices, personal protective equipment, and other materials requested; and

(B) the amount of such materials requested; and

(2) the outcomes of each request described in subsection (a), including—

(A) whether the request was wholly fulfilled, partially fulfilled, or denied;

(B) if the request was wholly or partially fulfilled, the fulfillment amount; and

(C) if the request was partially fulfilled or denied, a rationale for such outcome.

#### **SEC. 8. IMPROVED, TRANSPARENT PROCESSES.**

(a) **IN GENERAL.**—Not later than January 1, 2021, the Secretary of Health and Human Services shall develop and implement improved, transparent processes for the use and distribution 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 Strategic National Stockpile under section 319F-2 of the Public Health Service Act (42 U.S.C. 247d-6b) (in this section referred to as the “Stockpile”).

(b) **PROCESSES.**—The processes developed under subsection (a) shall include—

(1) the form and manner in which States, localities, Tribes, and territories are required to submit requests for supplies from the Stockpile;

(2) the criteria used by the Secretary of Health and Human Services in responding to such requests, including the reasons for fulfilling or denying such requests;

(3) what circumstances result in prioritization of distribution of supplies from the Stockpile to States, localities, Tribes, or territories;

(4) clear plans for future, urgent communication between the Secretary and States, localities, Tribes, and territories regarding the outcome of such requests; and

(5) any differences in the processes developed under subsection (a) for geographically related emergencies, such as weather events, and national emergencies, such as pandemics.

(c) **CLASSIFICATION.**—The processes developed under subsection (a) shall be unclassified to the greatest extent possible consistent with national security. The Secretary of Health and Human Services may classify portions of such processes as necessary to protect national security.

(d) **REPORT TO CONGRESS.**—Not later than January 1, 2021, the Secretary of Health and Human Services shall—

(1) submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health,

Education, Labor, and Pensions of the Senate regarding the improved, transparent processes developed under this section;

(2) include in such report recommendations for opportunities for communication (by telebriefing, phone calls, or in-person meetings) between the Secretary and States, localities, Tribes, and territories regarding such improved, transparent processes; and

(3) submit such report in unclassified form to the greatest extent possible, except that the Secretary may include a classified appendix if necessary to protect national security.

#### SEC. 9. AUTHORIZATION OF APPROPRIATIONS.

Section 319F-2(f)(1) of the Public Health Service Act (42 U.S.C. 247d-6b(f)(1)) is amended by striking “\$610,000,000 for each of fiscal years 2019 through 2023” and inserting “\$705,000,000 for each of fiscal years 2021 through 2023”.

The SPEAKER pro tempore. Pursuant to the rule, the gentlewoman from Michigan (Mrs. DINGELL) and the gentleman from Montana (Mr. GIANFORTE) each will control 20 minutes.

The Chair recognizes the gentlewoman from Michigan.

GENERAL LEAVE

Mrs. DINGELL. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on H.R. 7574.

The SPEAKER pro tempore. Is there objection to the request of the gentlewoman from Michigan?

There was no objection.

Mrs. DINGELL. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in strong support of the Strengthening America's Strategic National Stockpile Act of 2020.

This legislation incorporates a number of provisions to modernize the Strategic National Stockpile and to ensure that we are adequately prepared for future public health emergencies.

The current COVID-19 pandemic has shown the importance of ensuring that the United States has adequate manufacturing capacity and stockpiles of PPE and other medical equipment so that America's first responders and healthcare workers are prepared for public health emergencies.

In the early days of the pandemic, our frontline healthcare workers were forced to rely on deficient equipment from overseas manufacturers or expired equipment in the existing Strategic National Stockpile.

Even today, after months of efforts at the Federal, State, and local levels, we continue to face concerning deficiencies in PPE and other lifesaving medical equipment.

We must make robust long-term investments in our Nation's Strategic National Stockpile and manufacturing capability to better respond to future public health emergencies.

The Strengthening America's Strategic National Stockpile Act meets this need by increasing the annual authorization of the SNS to \$705 million. This will allow the Federal Government to direct appropriate resources toward future emergencies.

The legislation will also allow the SNS to refresh and replenish stocks of

critical manufacturing supplies before they are expired.

It also includes a provision my colleague Congresswoman JACKIE WALORSKI and I authored to create incentives to geographically diversify production of medical supplies and allow the SNS the flexibility to enter into leasing or joint ventures with manufacturers to quickly scale up production if needed.

The Strengthening America's Strategic National Stockpile Act is the culmination of months of bipartisan work, and I thank Congresswoman SLOTKIN, my colleagues on the Energy and Commerce Committee, as well as both Democrat and Republican committee staff for their efforts.

Mr. Speaker, the Strengthening America's Strategic National Stockpile Act is vital to both our public health and national security. I urge my colleagues to support this legislation, and I reserve the balance of my time.

HOUSE OF REPRESENTATIVES,

COMMITTEE ON ENERGY AND COMMERCE,

Washington, DC, September 21, 2020.

Hon. CAROLYN B. MALONEY,

*Chairwoman, Committee on Oversight and Reform, Washington, DC.*

DEAR CHAIRWOMAN MALONEY: I am writing concerning H.R. 7574, the “Strengthening America's Strategic National Stockpile Act of 2020,” which was referred to the Committee on Energy and Commerce on July 13, 2020.

I appreciate you not seeking a sequential referral of H.R. 7574 so that the bill may be considered expeditiously. I acknowledge that forgoing your referral claim does not waive, reduce, or otherwise affect the jurisdiction of the Committee on Oversight and Reform over this legislation, or any appropriate legislation. I will appropriately consult and involve the Committee on Oversight and Reform as this bill progresses. I would support your effort to seek appointment of an appropriate number of conferees from your committee to any House-Senate conference on this legislation.

I will ensure our letters on H.R. 7574 are entered into the Congressional Record during floor consideration of the bill. I appreciate your cooperation regarding this legislation and look forward to continuing to work together as this measure moves through the legislative process.

Sincerely,

FRANK PALLONE, JR.,

*Chairman.*

HOUSE OF REPRESENTATIVES,

COMMITTEE ON OVERSIGHT AND REFORM,

Washington, DC, September 21, 2020.

Hon. FRANK PALLONE,

*Chairman, Committee on Energy and Commerce, House of Representatives, Washington, DC.*

DEAR CHAIRMAN PALLONE: I am writing to you concerning H.R. 7574, the Strengthening America's Strategic National Stockpile Act of 2020. There are certain provisions in the legislation which fall within the Rule X jurisdiction of the Committee on Oversight and Reform.

In the interest of permitting your Committee to proceed expeditiously on this bill, I am willing to waive this Committee's right to sequential referral. I do so with the understanding that by waiving consideration of the bill, the Committee on Oversight and Reform does not waive any future jurisdictional claim over the subject matters contained in the bill which fall within its Rule X jurisdiction. I request that you urge the

Speaker to name Members of this Committee to any conference committee which is named to consider such provisions.

Please place this letter into the Congressional Record during consideration of the measure on the House floor. Thank you for the cooperative spirit in which you have worked regarding this matter and others between our respective Committees.

Sincerely,

CAROLYN B. MALONEY,

*Chairwoman.*

Mr. GIANFORTE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of H.R. 7574, the Strengthening America's Strategic National Stockpile Act, which was introduced by Representatives SLOTKIN and BROOKS.

The legislation that I cosponsored along with a long bipartisan list of others is a combination of bills to improve the Strategic National Stockpile, or SNS.

This includes allowing the SNS to sell off products in the stockpile before their expiration so that they could be used.

It directs the Secretary of Health and Human Services to examine user fee agreements, improve maintenance of the stockpile, and allowing for agreements with domestic producers of supplies to improve the supply chain to refresh and replenish existing stocks.

It also directs the Federal Emergency Management Agency and the Centers for Disease Control to report on distributions from the stockpile, as well as requests for supplies from State, local, Tribal, and territorial agencies. It would authorize a pilot program for establishing State stockpiles and increase the Strategic National Stockpile funding authorization to \$705 million.

We need to ensure our country is prepared to deal with whatever health crisis it faces, no matter if it is disease, disaster, or terrorism.

I urge my colleagues to support this bipartisan legislation to refill and improve the Strategic National Stockpile.

Mr. Speaker, I urge adoption of this important legislation, and I yield back the balance of my time.

Mrs. DINGELL. Mr. Speaker, I urge my colleagues to support this legislation, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from Michigan (Mrs. DINGELL) that the House suspend the rules and pass the bill, H.R. 7574, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

#### SCARLETT'S SUNSHINE ON SUDDEN UNEXPECTED DEATH ACT

Mrs. DINGELL. Mr. Speaker, I move to suspend the rules and pass the bill