other cases States use these fees for other public safety-type expenses that do not directly support 911 services. Those States are currently classified by the FCC as 911 fee diverters.

To clarify what is considered a diversion, and what is considered to support 911 services, the bill directs the FCC to clarify its rules of what obligations or expenditures are acceptable. These rules would be crafted with input from States to ensure that appropriate 911 uses are included.

Additionally, if a State has expenditures that don't fit squarely within the eligible uses determined by the Commission, but can provide documentation and receipts to show how those expenditures support public safety answering point functions and operations or the ability to dispatch emergency responders, then the States ought to have an opportunity to challenge the acceptable nature of those expenses, and this bill provides for that as well.

For the States that are truly bad actors, I think we can all agree that those States should be held accountable for their shameful practice of diverting 911 fees for programs completely unrelated to 911 services. Misleading the public on something this important to public safety is unacceptable.

To that end, this bill sets up a strike force of State law enforcement officers, public safety officials, and others to consider potential criminal penalties to end fee diversion at its source. This strike force would also study jurisdictional, budgetary, and other barriers to ending diversion.

Mr. Speaker, I want to thank Mr. ENGEL and Chairman PALLONE for working with us to add this important language to the bill. I would also like to thank FCC Commissioner Michael O'Rielly, for his work on the issue. He has been a steadfast champion on trying to address this issue and hold States accountable to the fullest extent of the law.

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

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

Mr. Speaker, I want to thank the minority manager, Mr. GIANFORTE, for his work this afternoon in managing the floor.

The T-Band is what our first responders and public safety personnel are used to. They don't want to lose it. And letting them continue in that band saves the taxpayers up to $4 billion. That is why we must pass H.R. 451.

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 gentleman from California (Mr. MCNERNEY) that the House suspend the rules and pass the bill, H.R. 451, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. MCNERNEY. Mr. Speaker, on that I demand the yeas and nays.

The SPEAKER pro tempore. Pursuant to section 3 of House Resolution 965, the yeas and nays are ordered.

Pursuant to clause 8 of rule XX, further proceedings on this motion are postponed.

## NATIONAL CENTERS OF EXCELLENCE IN CONTINUOUS PHARMACEUTICAL MANUFACTURING ACT OF 2020

Mrs. DINGELL. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4866) to amend the 21st Century Cures Act to provide for designation of institutions of higher education that provide research, data, and leadership on continuous manufacturing as National Centers of Excellence in Continuous Pharmaceutical Manufacturing, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 4866

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

***SECTION 1. SHORT TITLE.***

*This Act may be cited as the ''National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act of 2020''.*

***SEC. 2. NATIONAL CENTERS OF EXCELLENCE IN CONTINUOUS PHARMACEUTICAL MANUFACTURING.***

*(a) IN GENERAL.—Section 3016 of the 21st Century Cures Act (21 U.S.C. 399h) is amended to read as follows:*

***''SEC. 3016. NATIONAL CENTERS OF EXCELLENCE IN CONTINUOUS PHARMACEUTICAL MANUFACTURING.***

*''(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs—*

*''(1) shall solicit and, beginning not later than one year after the date of enactment of the National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act of 2020, receive requests from institutions of higher education to be designated as a National Center of Excellence in Continuous Pharmaceutical Manufacturing (in this section referred to as a 'National Center of Excellence') to support the advancement and development of continuous manufacturing; and*

*''(2) shall so designate any institution of higher education that—*

*''(A) requests such designation; and*

*''(B) meets the criteria specified in subsection (c).*

*''(b) REQUEST FOR DESIGNATION.—A request for designation under subsection (a) shall be made to the Secretary at such time, in such manner, and containing such information as the Secretary may require. Any such request shall include a description of how the institution of higher education meets or plans to meet each of the criteria specified in subsection (c).*

*''(c) CRITERIA FOR DESIGNATION DESCRIBED.—The criteria specified in this subsection with respect to an institution of higher education are that the institution has, as of the date of the submission of a request under subsection (a) by such institution—*

*''(1) physical and technical capacity for research and development of continuous manufacturing;*

*''(2) manufacturing knowledge-sharing networks with other institutions of higher education, large and small pharmaceutical manufacturers, generic and nonprescription manufacturers, contract manufacturers, and other entities;*

*''(3) proven capacity to design and demonstrate new, highly effective technology for use in continuous manufacturing;*

*''(4) a track record for creating and transferring knowledge with respect to continuous manufacturing;*

*''(5) the potential to train a future workforce for research on and implementation of advanced manufacturing and continuous manufacturing; and*

*''(6) experience in participating in and leading a continuous manufacturing technology partnership with other institutions of higher education, large and small pharmaceutical manufacturers, generic and nonprescription manufacturers, contract manufacturers, and other entities—*

*''(A) to support companies with continuous manufacturing in the United States;*

*''(B) to support Federal agencies with technical assistance, which may include regulatory and quality metric guidance as applicable, for advanced manufacturing and continuous manufacturing;*

*''(C) with respect to continuous manufacturing, to organize and conduct research and development activities needed to create new and more effective technology, capture and disseminate expertise, create intellectual property, and maintain technological leadership;*

*''(D) to develop best practices for designing continuous manufacturing; and*

*''(E) to assess and respond to the workforce needs for continuous manufacturing, including the development of training programs if needed.*

*''(d) TERMINATION OF DESIGNATION.—The Secretary may terminate the designation of any National Center of Excellence designated under this section if the Secretary determines such National Center of Excellence no longer meets the criteria specified in subsection (c). Not later than 60 days before the effective date of such a termination, the Secretary shall provide written notice to the National Center of Excellence, including the rationale for such termination.*

*''(e) CONDITIONS FOR DESIGNATION.—As a condition of designation as a National Center of Excellence under this section, the Secretary shall require that an institution of higher education enter into an agreement with the Secretary under which the institution agrees—*

*''(1) to collaborate directly with the Food and Drug Administration to publish the reports required by subsection (g);*

*''(2) to share data with the Food and Drug Administration regarding best practices and research generated through the funding under subsection (f);*

*''(3) to develop, along with industry partners (which may include large and small biopharmaceutical manufacturers, generic and nonprescription manufacturers, and contract manufacturers) and another institution or institutions designated under this section, if any, a roadmap for developing a continuous manufacturing workforce;*

*''(4) to develop, along with industry partners and other institutions designated under this section, a roadmap for strengthening existing, and developing new, relationships with other institutions; and*

*''(5) to provide an annual report to the Food and Drug Administration regarding the institution's activities under this section, including a description of how the institution continues to meet and make progress on the criteria listed in subsection (c).*

*''(f) FUNDING.—*

*''(1) IN GENERAL.—The Secretary shall award funding, through grants, contracts, or cooperative agreements, to the National Centers of Excellence designated under this section for the purpose of studying and recommending improvements to continuous manufacturing, including such improvements as may enable the Centers—*

*''(A) to continue to meet the conditions specified in subsection (e); and*

*''(B) to expand capacity for research on, and development of, continuing manufacturing.*

*''(2) CONSISTENCY WITH FDA MISSION.—As a condition on receipt of funding under this subsection, a National Center of Excellence shall agree to consider any input from the Secretary regarding the use of funding that would—*

*''(A) help to further the advancement of continuous manufacturing through the National Center of Excellence; and*

*''(B) be relevant to the mission of the Food and Drug Administration.*

*''(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $80,000,000 for the period of fiscal years 2021 through 2025.*

*''(4) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as precluding a National Center for Excellence designated under this section from receiving funds under any other provision of this Act or any other Federal law.*

*''(g) ANNUAL REVIEW AND REPORTS.—*

*''(1) ANNUAL REPORT.—Beginning not later than one year after the date on which the first designation is made under subsection (a), and annually thereafter, the Secretary shall—*

*''(A) submit to Congress a report describing the activities, partnerships and collaborations, Federal policy recommendations, previous and continuing funding, and findings of, and any other applicable information from, the National Centers of Excellence designated under this section; and*

*''(B) make such report available to the public in an easily accessible electronic format on the website of the Food and Drug Administration.*

*''(2) REVIEW OF NATIONAL CENTERS OF EXCELLENCE AND POTENTIAL DESIGNEES.—The Secretary shall periodically review the National Centers of Excellence designated under this section to ensure that such National Centers of Excellence continue to meet the criteria for designation under this section.*

*''(3) REPORT ON LONG-TERM VISION OF FDA ROLE.—Not later than 2 years after the date on which the first designation is made under subsection (a), the Secretary, in consultation with the National Centers of Excellence designated under this section, shall submit a report to the Congress on the long-term vision of the Department of Health and Human Services on the role of the Food and Drug Administration in supporting continuous manufacturing, including—*

*''(A) a national framework of principles related to the implementation and regulation of continuous manufacturing;*

*''(B) a plan for the development of Federal regulations and guidance for how advanced manufacturing and continuous manufacturing can be incorporated into the development of pharmaceuticals and regulatory responsibilities of the Food and Drug Administration; and*

*''(C) appropriate feedback solicited from the public, which may include other institutions, large and small biopharmaceutical manufacturers, generic and nonprescription manufacturers, and contract manufacturers.*

*''(h) DEFINITIONS.—In this section:*

*''(1) ADVANCED MANUFACTURING.—The term 'advanced manufacturing' means an approach for the manufacturing of pharmaceuticals that incorporates novel technology, or uses an established technique or technology in a new or innovative way (such as continuous manufacturing where the input materials are continuously transformed within the process by two or more unit operations) that enhances drug quality or improves the manufacturing process.*

*''(2) CONTINUOUS MANUFACTURING.—The term 'continuous manufacturing'—*

*''(A) means a process where the input materials are continuously fed into and transformed within the process, and the processed output materials are continuously removed from the system; and*

*''(B) consists of an integrated process that consists of a series of two or more unit operations.*

*''(3) INSTITUTION OF HIGHER EDUCATION.—The term 'institution of higher education' has the meaning given such term in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)).*

*''(4) SECRETARY.—The term 'Secretary' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.''.*

*(b) TRANSITION RULE.—Section 3016 of the 21st Century Cures Act (21 U.S.C. 399h), as in effect on the day before the date of the enactment of this section, shall apply with respect to grants awarded under such section before such date of enactment.*

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. 4866.

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, before I begin, I want to thank Chairman PALLONE and Ranking Member WALDEN for their bipartisan leadership on all of the legislation before us today. During this unprecedented public health crisis, and in spite of significant logistical challenges, the Energy and Commerce Committee has come together on a bipartisan basis on legislation to meaningfully address many public health issues we continue to face.

I would also like to commend many of my fellow committee members for their advocacy and efforts on the legislation before us today.

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

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COVID–19 has made clear that the United States is overly reliant on foreign manufacturers for critical products like personal protective equipment and pharmaceuticals. For far too long, we have relied on China and India to provide our necessary medicines and the ingredients needed to make them. In times of crisis like COVID–19, access to critical medicines is even more critical.

While there are many things we must do to encourage drug manufacturing to come back to the United States, investing and supporting the use of efficient, innovative technologies like continuous manufacturing hold promise.

Continuous manufacturing allows manufacturers to make drugs more efficiently, thereby improving the quality of drugs while also reducing waste and the footprint needs that traditional drug manufacturing requires.

FDA has been working to support increased utilization of this technology because, as we have heard from the head of FDA's drug center, Dr. Janet Woodcock, continuous manufacturing can help ''increase the resilience of our domestic manufacturing base and reduce quality issues that trigger drug shortages or recalls.''

H.R. 4866 will help support this work by investing in centers of excellence at universities that can help us to further improve this technology, transfer it to drug manufacturers, and increase its use and capability in the United States. These centers of excellence would also be charged with helping to develop a domestic workforce that would be able to help manufacturers with the adoption of continuous manufacturing.

For States like mine, Michigan, centers of excellence supported by H.R. 4866 could help to leverage our manufacturing expertise to support the growth of a new generation of drug manufacturers in our own backyard.

Now more than ever, we must work to bring drug manufacturing home to ensure that our critical medicines are available without interruption in public health emergencies or crises.

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

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

Mr. Speaker, I rise today in support of H.R. 4866, the National Centers of Excellence and Continuous Pharmaceutical Manufacturing Act introduced by Chairman PALLONE and Representative GUTHRIE.

This legislation would direct the FDA to designate higher education institutions as national centers of excellence, allowing the FDA to work with the centers and industry to create a national framework for implementation of continuous manufacturing technology.

Last October, the Committee on Energy and Commerce held a hearing on safeguarding the pharmaceutical supply chain. At this hearing, Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research at the FDA, spoke at length about the advantages of advanced manufacturing technology, such as continuous manufacturing.

This included the potential to reduce our dependence on foreign sources of active pharmaceutical ingredients, increase our manufacturing resiliency, and reduce quality issues that often trigger drug shortages. Increased adoption of these technologies could open the door to a revived U.S. manufacturing base and lower production costs, resulting in lower drug prices and a more stable drug supply.

Given the potential this technology holds, I am pleased we are moving forward with this bipartisan legislation to further advance this development. I

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 gentlewoman 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. 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''; 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