professional in my district. Recently, Dr. Stuart Weinstein, the Ignacio V. Ponseti chair and professor of orthopaedic surgery and professor of pediatrics at the University of Iowa, was awarded the Lifetime Achievement Award from the Scoliosis Research Society for his incredible work studying pediatric spinal deformity.

Since joining the Department of Orthopaedic Surgery at the University of Iowa in 1976, Stu has worked to make our community and the whole world a better place.

Stu has published over 250 scientific articles in some of the most well-known and prestigious peer-reviewed journals. His research has focused on spinal deformity in children and the natural history and long-term outcome of pediatric musculoskeletal disorders.

Listing and discussing all of Stu's accomplishments would take much longer than one minute, so I will close by saying how grateful I am to have people like Stu living in Iowa's Second District. I also tell anyone I meet that Iowa is the best place to live, work, and raise a family. With outstanding citizens like Stu, we will continue to hold that title.

Mr. Speaker, I would also like to extend my enthusiasm with a happy birthday to our colleague from California, the Honorable YOUNG KIM. Happy birthday to YOUNG.

□ 1415

REMEMBERING KENNETH BAKER

(Ms. TENNEY asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Ms. TENNEY. Mr. Speaker, I rise today to honor the life of Lee Center Fire Chief Kenny Baker, who passed away recently after a long-fought battle due to complications of a brain tumor.

Ken was known by all as a noble, caring, and loving man. He joined the Lee Center Volunteer Fire Department at the age of 30 and served for 48 years straight. For 28 of those years, Ken was the chief, the longest tenure in the department's history.

Ken also served in the U.S. Navy and was the former president of the Oneida County Fire Chiefs Association.

But most importantly, Ken was known for his tremendous family and his love for his family, particularly his wife, Patti, who was his guiding light. His son, Joseph Baker, succeeded him as the fire chief, and Ken's granddaughter, Ashley, and grandson, Tyler, followed their grandfather into the fire service with the Lee Center Fire Department.

I considered Ken a great friend. He was a courageous, principled, and tenacious man. He was a hometown hero and a role model for many, including me. And, boy, was he fun.

Ken, I just want to say thank you to you for your friendship and your profound legacy of service to our community. May you rest in peace.

God bless his family.

$5 TRILLION SPENDING-PALOOZA

(Mr. MOOLENAAR asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. MOOLENAAR. Mr. Speaker, I rise today to oppose the nearly $5 trillion spending package the Democrats have tied together.

This package would massively expand the role of the Federal Government into the lives of every American, and it would significantly raise taxes on people and businesses in Michigan.

There is no doubt we need to invest in roads, bridges, runways, harbors, and rural broadband, but tax increases in this package will make America less competitive.

We need a tax structure that attracts businesses so that there are more jobs in America, more products are made here, and our supply chains are more secure.

This $5 trillion spending package will do just the opposite. It will raise taxes, make our country less competitive, and increase the overall cost of living and doing business in America.

These costs will be passed on to all of us, increasing inflation and hurting families and seniors across the country. I urge my colleagues to vote ''no.''

JOHN FARR'S 898-MILE FUNDRAISER

(Mr. THOMPSON of Pennsylvania asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. THOMPSON of Pennsylvania. Mr. Speaker, I rise today to recognize John Farr of DuBois, Pennsylvania.

John recently completed a 16-day, 898-mile bike ride to raise awareness and support for Habitat for Humanity of Clearfield County.

On October 4, he arrived in Washington, D.C., for a much-needed rest day before completing the final leg of his journey to Clearfield.

John started his cycling fundraising in 2001 when he signed up for a 2-day, 150-mile fundraiser sponsored by Habitat for Humanity New York. Since then, he has completed 20 excursions.

John has always been involved in his community, from tutoring students when he was in college to coaching sports. He enjoys giving back.

He joined Habitat for Humanity in 1994, originally donating monthly, to eventually joining the board and serving as president.

His cycling fundraisers have taken him across the United States and even across the Canadian border. His rides have led him to raise more than $150,000 for Habitat for Humanity.

Mr. Speaker, John's passion for helping others is admirable. Congratulations on completing this journey.

COMMUNICATION FROM THE CLERK OF THE HOUSE

The SPEAKER pro tempore laid before the House the following communication from the Clerk of the House of Representatives:

OFFICE OF THE CLERK,
HOUSE OF REPRESENTATIVES,
Washington, DC, October 19, 2021.

Hon. NANCY PELOSI,
Speaker, House of Representatives,
Washington, DC.

DEAR MADAM SPEAKER: Pursuant to the permission granted in Clause 2(h) of Rule II of the Rules of the U.S. House of Representatives, the Clerk received the following message from the Secretary of the Senate on October 19, 2021, at 12:02 p.m.:

That the Senate agreed to Relative to the death of the Honorable Adlai Ewing Stevenson III, former United States Senator for the State of Illinois S. Res. 420.

With best wishes, I am

Sincerely,

KEVIN F. MCCUMBER,
Deputy Clerk.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12(a) of rule I, the Chair declares the House in recess subject to the call of the Chair.

Accordingly (at 2 o'clock and 20 minutes p.m.), the House stood in recess.

□ 1600

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Ms. MANNING) at 4 p.m.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on motions to suspend the rules on which the yeas and nays are ordered.

The House will resume proceedings on postponed questions at a later time.

NATIONAL CENTERS OF EXCELLENCE IN ADVANCED AND CONTINUOUS PHARMACEUTICAL MANUFACTURING ACT OF 2021

Mr. PALLONE. Madam Speaker, I move to suspend the rules and pass the bill (H.R. 4369) 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. 4369

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 Advanced and Continuous Pharmaceutical Manufacturing Act of 2021''.

SEC. 2. NATIONAL CENTERS OF EXCELLENCE IN ADVANCED AND 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 ADVANCED AND 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 Advanced and Continuous Pharmaceutical Manufacturing Act of 2021, receive requests from institutions of higher education, or consortia of institutions of higher education, to be designated as a National Center of Excellence in Advanced and Continuous Pharmaceutical Manufacturing (in this section referred to as a 'National Center of Excellence') to support the advancement, development, and implementation of advanced and continuous pharmaceutical manufacturing; and

''(2) shall so designate not more than 5 institutions of higher education or consortia of such institutions that—

''(A) request such designation; and

''(B) meet 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, or consortium of institutions 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, or consortium of institutions of higher education, are that the institution or consortium has, as of the date of the submission of a request under subsection (a) by such institution or consortium—

''(1) physical and technical capacity for research, development, implementation, and demonstration of advanced and continuous pharmaceutical 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 relevant entities;

''(3) proven capacity to design, develop, implement, and demonstrate new, highly effective technologies for use in advanced and continuous pharmaceutical manufacturing;

''(4) a track record for creating, preserving, and transferring knowledge with respect to advanced and continuous pharmaceutical manufacturing;

''(5) the proven ability to facilitate training of an adequate future workforce for research on, and implementation of, advanced and continuous pharmaceutical manufacturing; and

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

''(A) to support companies seeking to implement advanced and continuous pharmaceutical manufacturing in the United States;

''(B) to support Federal agencies with technical assistance and employee training, which may include regulatory and quality metric guidance as applicable, and hands-on training, for advanced and continuous pharmaceutical manufacturing;

''(C) with respect to advanced and continuous pharmaceutical manufacturing, to organize and conduct research and development activities needed to create new and more effective technology, develop and share knowledge, create intellectual property, and maintain technological leadership;

''(D) to develop best practices for designing and implementing advanced and continuous pharmaceutical manufacturing processes; and

''(E) to assess and respond to the national workforce needs for advanced and continuous pharmaceutical manufacturing, including the development and implementing of training programs.

''(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 90 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 or consortium of institutions of higher education enter into an agreement with the Secretary under which the institution or consortium 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 research organizations or contract manufacturers that carry out drug development and manufacturing activities) and another institution or consortium designated under this section, if any, a roadmap for developing an advanced and continuous pharmaceutical manufacturing workforce;

''(4) to develop, along with industry partners and other institutions or consortia of such institutions designated under this section, a roadmap for strengthening existing, and developing new, relationships with other institutions of higher education or consortia thereof; and

''(5) to provide an annual report to the Food and Drug Administration regarding the institution's or consortium's activities under this section, including a description of how the institution or consortium continues to meet and make progress on the criteria specified 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 advanced and continuous pharmaceutical manufacturing, including such improvements as may enable the Centers—

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

''(B) to expand capacity for research on, and development of, advanced and continuous pharmaceutical manufacturing; and

''(C) to implement research infrastructure in advanced and continuous pharmaceutical manufacturing suitable for accelerating the development of drug products needed to respond to emerging medical threats, such as emerging drug shortages, quality issues disrupting the supply chain, epidemics and pandemics, and other such situations requiring the rapid development of new products or new manufacturing processes.

''(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 advanced and continuous pharmaceutical manufacturing through the National Center of Excellence; and

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

''(3) 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;

''(B) include in such report an accounting of the Federal administrative expenses described in subsection (i)(2) over the reporting period; and

''(C) 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 advanced and continuous pharmaceutical manufacturing, including—

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

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

''(C) a plan for development of Federal regulations or guidance for how advanced and continuous pharmaceutical manufacturing will be reviewed by the Food and Drug Administration; and

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

''(h) DEFINITIONS.—In this section:

''(1) ADVANCED.—The term 'advanced', with respect to pharmaceutical manufacturing, refers to an approach that incorporates novel technology, or uses an established technique or technology in a new or innovative way, that enhances drug quality or improves the performance of a manufacturing process.

''(2) CONTINUOUS.—The term 'continuous', with respect to pharmaceutical manufacturing, refers to a process—

''(A) 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) that consists of an integrated process that consists of a series of two or more simultaneous 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.

''(i) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—There is authorized to be appropriated to carry out this section $100,000,000 for the period of fiscal years 2022 through 2026.

''(2) FEDERAL ADMINISTRATIVE EXPENSES.—Of the amounts made available to carry out this section for a fiscal year, the Secretary shall not use more than eight percent for Federal administrative expenses, including training, technical assistance, reporting, and evaluation.''.

(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.

(c) CLERICAL AMENDMENT.—The item relating to section 3016 in the table of contents in section 1(b) of the 21st Century Cures Act (Public Law 114-255) is amended to read as follows:

''Sec. 3016. National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Kentucky (Mr. GUTHRIE) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. Madam 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. 4369.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New Jersey?

There was no objection.

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

Madam Speaker, my colleagues and I on the Energy and Commerce Committee have been working on legislation to invest in and support American pharmaceutical manufacturing to reduce our dependence on items produced abroad, such as active ingredients and raw materials. As the COVID–19 pandemic has made clear, domestic pharmaceutical manufacturing is critical to our Nation's public health and global economic competitiveness.

The bill before us now, H.R. 4369, would leverage the expertise and ingenuity of academic institutions in the United States to help support and develop advanced manufacturing technologies right here at home. The legislation will improve the quality of our pharmaceuticals, reduce drug shortages, and help to produce more nimble and efficient manufacturing processes that could be replicated throughout the Nation.

Specifically, H.R. 4369 would direct the Food and Drug Administration to designate a number of American academic institutions as national centers of excellence. It then provides funding to these centers to develop advanced and continuous manufacturing.

Now, continuous manufacturing is an emerging technology whereby a finished product is produced in a continuous stream, making it more efficient than the current so-called batch model that can be slow and may be subject to the risk of defects or errors during the manufacturing process.

The centers would be required to work closely with the FDA and industry to support regulatory guidance and expertise, catalyze research and development in advanced and continuous manufacturing technologies, and cultivate an advanced pharmaceutical manufacturing workforce here in the United States.

The legislation requires that the majority of the $100 million in funding be awarded directly to the designated centers of excellence, while also providing resources for FDA technical assistance, guidance, or training.

H.R. 4369 sets us on the right track for advanced manufacturing here at home.

This legislation passed the House last Congress but was not taken up in the Senate. If we are to meet the goal and demand for uninterrupted access and supply of critical drugs and active pharmaceutical ingredients, the time to act is now.

I want to thank our Health Subcommittee Ranking Member GUTHRIE for working with me on this legislation, as well as full committee Ranking Member RODGERS and Health Subcommittee Chairwoman ANNA ESHOO.

I urge my colleagues to support H.R. 4369, and I hope the Senate will follow suit so that we can finally expand advanced and continuous manufacturing technology here in the United States.

Madam Speaker, I reserve the balance of my time.

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

Madam Speaker, I rise today in support of H.R. 4369, the National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing Act, a bill I introduced with my colleague, Energy and Commerce Committee Chairman FRANK PALLONE. I enjoyed working with him on this bill.

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. 4369, which we are considering today, builds on this partnership established in the Cures Act. Advanced and 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.

I urge my colleagues to support H.R. 4369, and I reserve the balance of my time.

Mr. PALLONE. Madam Speaker, I have no additional speakers. I am prepared to close, and I reserve the balance of my time.

Mr. GUTHRIE. Madam Speaker, this is an important bill. We have all seen what happened with COVID–19, our dependence on the global supply chain, particularly in pharmaceuticals. It is a national security issue that we have our own production here.

As we saw, we have had shortages during the height of the pandemic, and we are still experiencing other supply chain issues. As we know, those will work themselves out.

Having access to our own pharmaceuticals is not a luxury that we have time for them to work out themselves. We are hopeful that we will get things moving again in a normal supply chain, but we absolutely must take the action necessary to make sure that we make it in America, and we don't depend on countries such as China.

Madam Speaker, I urge the passage of this bill. I yield back the balance of my time.

Mr. PALLONE. Madam Speaker, I, too, would say this is an important bill, both from the point of view of moving toward more domestic manufacturing and addressing the supply chain shortages that we saw during COVID–19 for drugs.

Madam Speaker, I ask for Members to support this bill, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 4369, 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. PALLONE. Madam Speaker, on that I demand the yeas and nays.

The SPEAKER pro tempore. Pursuant to section 3(s) of House Resolution 8, the yeas and nays are ordered.

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

STATE OPIOID RESPONSE GRANT AUTHORIZATION ACT OF 2021

Mr. PALLONE. Madam Speaker, I move to suspend the rules and pass the bill (H.R. 2379) to amend the 21st Century Cures Act to reauthorize and expand a grant program for State response to the opioid use disorders crisis, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 2379

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