Mr. WALDEN. Mr. Speaker, I yield myself the balance of my time.

I would just conclude my remarks by, again, speaking in favor of the underlying legislation, but also thanking Mike and his team for doing such a great job throughout this Congress and the preceding one to help all of us come together and solve the Nation's problems to the best of our ability. They really are a talented team, and we have been fortunate to have Mike at the helm.

Mr. Speaker, I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I urge support for the 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 New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 3539, 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.

□ 1630

CREATING HOPE REAUTHORIZATION ACT

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4439) to amend the Federal Food, Drug, and Cosmetic Act to make permanent the authority of the Secretary of Health and Human Services to issue priority review vouchers to encourage treatments for rare pediatric diseases, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 4439

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 ''Creating Hope Reauthorization Act''.

SEC. 2. EXTENSION OF AUTHORITY TO ISSUE PRIORITY REVIEW VOUCHERS TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

Section 529(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(b)(5)) is amended—

(1) by striking ''December 11, 2020'' each place it appears and inserting ''September 30, 2024''; and

(2) in subparagraph (B), by striking ''December 11, 2022'' and inserting ''September 30, 2026''.

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

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. 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. 4439.

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

There was no objection.

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

Mr. Speaker, H.R. 4439 would extend the pediatric rare disease priority review voucher program at the Food and Drug Administration. This priority review voucher, or PRV, was originally created in 2012 with the intent to create an incentive for drug manufacturers to develop therapies for rare pediatric diseases that affect neonates, infants, children, and adolescents.

The program requires FDA to award a PRV to the sponsor of an application that receives approval as a drug or biologic to treat a rare pediatric disease. Since the program's creation, 22 of these PRVs have been awarded, with five awards in 2019.

Now, I have long been a supporter of increased research and development of treatments for rare diseases, and I am proud that our committee was able to come to consensus on a reasonable extension of this program. Nevertheless, some observers of this program have shown our committee evidence that the PRV program has not provided the incentive value intended by Congress when it was first enacted.

This program was supposed to incentivize new development of pediatric products that would not otherwise have occurred. However, the Government Accountability Office reviewed the program and concluded that the agency could not find definitive evidence that the program is incentivizing pediatric drug development. Additionally, FDA has said that PRVs drain agency resources away from the agency's public health mission and have a negative impact on the morale of agency staff.

For these reasons, I could not support a permanent reauthorization of the program. But I recognize that many pharmaceutical developers have argued that the PRV provides an incentive for drug development, with one going so far as to say that the PRV was a pivotal consideration for making investments. I worked with Representatives BUTTERFIELD, the bill's sponsor, and Ranking Member WALDEN, as well, to support a reauthorization of the program for 4 years.

Mr. Speaker, the Energy and Commerce Committee will continue to provide oversight to examine the effectiveness of this program and its effect on FDA resources. The committee will also carefully scrutinize it with hopes that it serves its intended purpose and leads to new treatments and cures for rare pediatric diseases.

With this hope, Mr. Speaker, I ask Members to support this bipartisan bill. I urge the Senate to swiftly take action on H.R. 4439, and I reserve the balance of my time.

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

Mr. Speaker, I rise today in support of H.R. 4439, the Creating Hope Reauthorization Act, introduced by our colleagues, Representative BUTTERFIELD and Representative MCCAUL. This bill extends the pediatric priority review voucher program for an additional 4 years.

This program, which has had bipartisan support since it was first created in 2012 with the passage of the Food and Drug Administration Safety and Innovation Act, aims to incentivize the development of therapies to treat rare pediatric diseases.

The pediatric PRV program has already proven successful in encouraging innovation. In fact, 22 therapies have been approved for the treatment of 18 rare pediatric diseases since its inception. However, we still have a long way to go. Nearly 95 percent of all rare diseases do not have an FDA-approved treatment, leaving many patients with no options.

This long-term reauthorization of the program will provide certainty to those currently developing or considering investment in innovative therapies to treat rare pediatric diseases.

Bipartisan bills that encourage biomedical innovation like the one we are considering today mean continued hope for children and their families that, one day, there will be a treatment and that there will be a cure.

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

Mr. PALLONE. I have no additional speakers, and I reserve the balance of my time, Mr. Speaker.

Mr. WALDEN. Mr. Speaker, I yield 3 minutes to the gentleman from Florida (Mr. BILIRAKIS).

Mr. BILIRAKIS. Mr. Speaker, I rise today in support of H.R. 4439, the Creating Hope Reauthorization Act.

Tragically, pediatric cancer remains the number one disease that leads to the death of American children. While survival rates have improved for some types of pediatric cancers, thousands of children are lost to cancer each year, and many more encounter life-threatening complications relating to harsh chemotherapies.

Children have significantly fewer treatment options than adults, Mr. Speaker, and oftentimes must rely on treatment regimens developed for adults because pediatric-specific treatments simply do not exist. Unfortunately, as the popular healthcare adage goes, children are not little adults.

Despite their significant need, pharmaceutical companies have had trouble developing treatments for pediatric cancer and rare diseases because of the small population and high cost of bringing these specific treatments to market.

FDA's priority review voucher program has proven to be a boon to incentivizing the development of therapies to treat rare pediatric diseases. While progress has been made in the development of pediatric therapies—in fact, 22 therapies have been approved

for the treatment of 18 rare pediatric diseases since 2012, which is really great—there is still more work to be done however. Nearly 95 percent of all rare diseases do not have an FDA-approved treatment, leaving many patients without options.

As co-chair of the Rare Disease Caucus, I sincerely appreciate the good work from Ranking Member MCCAUL, of course, the ranking member of the Committee on Energy and Commerce, and the chairman of the Committee on Energy and Commerce for bringing this bill forward, and also Congressman BUTTERFIELD.

So, Mr. Speaker, I urge my colleagues to join us in passing the Creating Hope Reauthorization Act, which will extend this vital innovation lifeline for rare pediatric treatments and cures at FDA.

Mr. PALLONE. Mr. Speaker, I reserve the balance of my time.

Mr. WALDEN. Mr. Speaker, I yield such time as he may consume to the gentleman from Texas (Mr. MCCAUL), who is a serious leader on this issue and has been for a long time.

Mr. MCCAUL. Mr. Speaker, let me thank the ranking member, Mr. WALDEN, from Oregon for his steadfast support on this issue. I want to thank the chairman for getting to this point where we are back on the floor, and the Energy and Commerce Committee, in general, for its support of this bill 4 years ago and, now, a 4-year reauthorization.

As the founder and co-chair of the Childhood Cancer Caucus, I have met with countless cancer patients and advocates who have asked me for one thing: hope. They want meaningful hope, something realistic and something tangible, better cures, safer treatment, and more research dollars.

So, alongside my colleagues, Mr. BUTTERFIELD, Mr. KELLY, and Ms. SPEIER, we have used the Childhood Cancer Caucus to produce that hope. This caucus has yielded tangible results for the hundreds of thousands of patients, advocates, and parents who were just hoping for better results.

When we first started this caucus over a decade ago, there were only two new drugs developed to specifically treat pediatric cancer in the prior 20 years. I would talk to these children and their parents, and they would tell me that the cancer just had no treatment, or if there was a treatment, it was of a drug developed in the 1960s or older.

Many of these drugs were meant to be used by adults, and their intent was to kill the cancer before it killed the person. That is why Mr. BUTTERFIELD and I worked together to pass the original Creating Hope Act in 2011, to try to create a market to get more pediatric cancer and rare disease drugs approved in this country.

Specifically, our bill created a voucher award within the FDA where companies that developed rare pediatric disease drugs have priority on future products that could save kids' lives.

I am happy to report that this program has been very successful. Since 2014 when the first voucher was issued, 22 new drugs for rare diseases in kids have been approved by the FDA, including two drugs for childhood cancers, with more expected on the way.

I have seen, firsthand, the wonders of this program.

In September of 2013, a constituent of mine named Rex Ryan was diagnosed with stage 4 neuroblastoma at just 18 months old. After exhausting all options, Rex was blessed to have received a novel new drug that was developed and approved in part because of the incentive of the Creating Hope Act. Rex is now cancer free and a healthy third grader saved by the drug developed because of this program.

It is for Rex and all the other children who have been saved because of this program and will be saved because of this program that I stand here today in support of the bill.

I think, most remarkably, of a dear friend of mine, Dr. Allison from MD Anderson Cancer Center, who had a childhood cancer clinical trial going and was able to use the voucher program to obtain FDA approval for a treatment now called immunotherapy. Immunotherapy is a breakthrough in cancer treatment not just for children but for all adults. He got the Nobel Prize in medicine for it.

While this bill before us today reauthorizes the program for another 4 years, I would hope to see, when we come back again, that this program will be made permanent. So I look forward to working with my colleagues in the Congress to achieve that goal.

I appreciate the support from the advocates and members of my team, especially my outgoing legislative director, THOMAS RICE, who spent countless hours meeting with the advocates, the brains behind the operation, and Nancy Goodman, who gave us all these great ideas to develop four major pieces of legislation. I can't thank THOMAS enough for all his great work.

Together, we can and will defeat childhood cancer. It is vital that we keep this program alive so that we keep hope alive for the hundreds of thousands of children and their families who are waiting for the big break of a treatment.

Mr. WALDEN. Mr. Speaker, I want to thank my colleague from Texas for his great leadership on this issue. I encourage our colleagues to vote for this bill, and I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I also urge support for the legislation, and I yield back the balance of my time.

Ms. JACKSON LEE. Madam Speaker, I rise in support of H.R. 4439, the "Creating Hope Reauthorization Act," which amends the Federal Food, Drug, and Cosmetic Act to make permanent the authority of the Secretary of Health and Human Services to issue priority review vouchers to encourage treatments for rare pediatric diseases.

Under Section 529 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA will award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria.

By definition, rare diseases do not affect much of the population, so there is little financial gain for pharmaceutical companies.

The U.S. government has created the Orphan Drug Act and the rare pediatric disease priority review voucher programs to add financial incentives for development of medicines, which is making the development of drugs for rare diseases more common.

However, many of the drugs for rare diseases are approved for adults.

Physicians sometimes have no choice but to prescribe offlabel use of such drugs for children.

Drugs for rare diseases, whether approved for pediatric patients or being used off label, often come in formats that are inappropriate for children.

Most young children have trouble swallowing tablets or capsules, and many children are sensitive to bitter-tasting drugs.

Sometimes, however, such formats are all that is available, which can lead to difficulty in effectively treating young patients.

This is why H.R. 4439, the "Creating Hope Reauthorization Act" is needed.

Under this program reinstated by this bill, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product.

Without the passage of this bill, according to the current statutory sunset provisions for the Rare Pediatric Disease Priority Review Voucher Program, after September 30, 2020, which means the FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has rare pediatric disease designation for the drug, and that designation was granted by September 30, 2020.

Further, without this bill after September 30, 2022, FDA may not award any rare pediatric disease priority review vouchers.

Enactment of this bill will mean that requests for rare pediatric disease designation submitted within two weeks of a request for fast track designation or orphan drug designation are entitled to a 60-day review.

Requests for rare pediatric disease designation not submitted with a request for fast track designation or orphan drug designation are reviewed in a timely manner, however, the 60-day response time does not apply.

It is important for us to act today, because Friday, July 31, 2020, is the last business day that is not less than 60 days prior to September 30, 2020.

The Offices of Orphan Products Development and Pediatric. Therapeutics will continue to review all rare pediatric disease designation requests, but they cannot commit to providing a response to requests received after July 31, 2020.

Pediatric rare diseases have received increased attention in recent years due to greater public awareness, significantly improved understanding and treatment.

Rare diseases can be difficult to diagnose in children, and many physicians do not have the proper training and knowledge to diagnose such diseases.

According to a 2014 Medscape Multispecialty article, the average patient with a rare disease sees 7.3 physicians before diagnosis,

and 70 percent of physicians believe additional training in rare diseases would be helpful.

A rare disease can spread and worsen during the lengthy time before diagnosis and the start of the proper treatment.

I ask my colleagues to join me in supporting this bill.

Ms. ESHOO. Madam Speaker, I rise in support of H.R. 4439, the Creating Hope Reauthorization Act. I'm proud to have advanced this bipartisan bill through my Health Subcommittee and I'm pleased to support it on the Floor today.

The Creating Hope Reauthorization Act sponsored by Representative G.K. BUTTERFIELD helps children access pediatric cancer drugs.

Pediatric cancer is the number one disease killer of American children, but pharmaceutical companies often avoid developing pediatric cancer drugs because of the small market and the high risks associated with studying and testing drugs for children.

The Creating Hope Reauthorization Act provides incentives for the research and development of pediatric cancer drugs by providing the developers with the valuable Priority Review Vouchers which allow the recipient to speed up the FDA review of any one of its new drug products.

Since its passage the GAO studied the pediatric priority review vouchers and found that pharmaceutical developers said Priority Review Vouchers were a factor in drug development decisions.

Dr. Crystal Mackall of the Stanford Center for Cancer Cell Therapy said that, ''The voucher program has been remarkedly impactful for childhood cancers. Before the program, I used to go with my hat in hand to beg investors to consider a potential drug. Now people take a second look and are interested in developing drugs. We're just getting started on this new way of thinking about children's drugs. The voucher program required a culture change around how to think of the pediatric drug business model, which in the drug development world could take a while.''

As Dr. Mackall said, this program seeks to shift decision-making early in the lengthy drug development cycle. A lengthy reauthorization of 4 years as offered in the AINS will be beneficial for this decision-making and I urge my colleagues to support this bill.

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. 4439, as amended.

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

The title of the bill was amended so as to read: ''A bill to amend the Federal Food, Drug, and Cosmetic Act to extend the authority of the Secretary of Health and Human Services to issue priority review vouchers to encourage treatments for rare pediatric diseases.''.

A motion to reconsider was laid on the table.

□ 1645

GRID SECURITY RESEARCH AND DEVELOPMENT ACT

Mr. BERA. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5760) to provide for a comprehensive interdisciplinary research, development, and demonstration initiative to strengthen the capacity of the energy sector to prepare for and withstand cyber and physical attacks, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5760

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 ''Grid Security Research and Development Act''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) The Nation, and every critical infrastructure sector, depends on reliable electricity.

(2) Intelligent electronic devices, advanced analytics, and information systems used across the energy sector are essential to maintaining reliable operation of the electric grid.

(3) The cybersecurity threat landscape is constantly changing and attacker capabilities are advancing rapidly, requiring ongoing modifications, advancements, and investments in technologies and procedures to maintain security.

(4) It is in the national interest for Federal agencies to invest in cybersecurity research that informs and facilitates private sector investment and use of advanced cybersecurity tools and procedures to protect information systems.

(5) The number of devices and systems connecting to the electric grid is increasing, and integrating cybersecurity protections into information systems when they are built is more effective than modifying products after installation to meet cybersecurity goals.

(6) An understanding of human factors can be leveraged to understand the behavior of cyber threat actors, develop strategies to counter threat actors, improve cybersecurity training programs, optimize the design of human-machine interfaces and cybersecurity tools, and increase the capacity of the energy sector workforce to prevent unauthorized access to critical systems.

SEC. 3. AMENDMENT TO ENERGY INDEPENDENCE AND SECURITY ACT OF 2007.

Title XIII of the Energy Independence and Security Act of 2007 (42 U.S.C. 17381 et seq.) is amended by adding at the end the following:

''SEC. 1310. ENERGY SECTOR SECURITY RESEARCH, DEVELOPMENT, AND DEMONSTRATION PROGRAM.

''(a) IN GENERAL.—The Secretary, in coordination with appropriate Federal agencies, the Electricity Subsector Coordinating Council, the Electric Reliability Organization, State, tribal, local, and territorial governments, the private sector, and other relevant stakeholders, shall carry out a research, development, and demonstration program to protect the electric grid and energy systems, including assets connected to the distribution grid, from cyber and physical attacks by increasing the cyber and physical security capabilities of the energy sector and accelerating the development of relevant technologies and tools.

''(b) DEPARTMENT OF ENERGY.—As part of the initiative described in subsection (a), the Secretary shall award research, development, and demonstration grants to—

''(1) identify cybersecurity risks to information systems within, and impacting, the electricity sector, energy systems, and energy infrastructure;

''(2) develop methods and tools to rapidly detect cyber intrusions and cyber incidents, including through the use of data and big data analytics techniques, such as intrusion detection, and security information and event management systems, to validate and verify system behavior;

''(3) assess emerging cybersecurity capabilities that could be applied to energy systems and develop technologies that integrate cybersecurity features and procedures into the design and development of existing and emerging grid technologies, including renewable energy, storage, and demand-side management technologies;

''(4) identify existing vulnerabilities in intelligent electronic devices, advanced analytics systems, and information systems;

''(5) work with relevant entities to develop technologies or concepts that build or retrofit cybersecurity features and procedures into—

''(A) information and energy management system devices, components, software, firmware, and hardware, including distributed control and management systems, and building management systems;

''(B) data storage systems, data management systems, and data analysis processes;

''(C) automated- and manually-controlled devices and equipment for monitoring and stabilizing the electric grid;

''(D) technologies used to synchronize time and develop guidance for operational contingency plans when time synchronization technologies, are compromised;

''(E) power system delivery and end user systems and devices that connect to the grid, including—

''(i) meters, phasor measurement units, and other sensors;

''(ii) distribution automation technologies, smart inverters, and other grid control technologies;

''(iii) distributed generation, energy storage, and other distributed energy technologies;

''(iv) demand response technologies;

''(v) home and building energy management and control systems;

''(vi) electric and plug-in hybrid vehicles and electric vehicle charging systems; and

''(vii) other relevant devices, software, firmware, and hardware; and

''(F) the supply chain of electric grid management system components;

''(6) develop technologies that improve the physical security of information systems, including remote assets;

''(7) integrate human factors research into the design and development of advanced tools and processes for dynamic monitoring, detection, protection, mitigation, response, and cyber situational awareness;

''(8) evaluate and understand the potential consequences of practices used to maintain the cybersecurity of information systems and intelligent electronic devices;

''(9) develop or expand the capabilities of existing cybersecurity test beds to simulate impacts of cyber attacks and combined cyber-physical attacks on information systems and electronic devices, including by increasing access to existing and emerging test beds for cooperative utilities, utilities owned by a political subdivision of a State, such as municipally-owned electric utilities, and other relevant stakeholders; and

''(10) develop technologies that reduce the cost of implementing effective cybersecurity technologies and tools, including updates to these technologies and tools, in the energy sector.

''(c) NATIONAL SCIENCE FOUNDATION.—The National Science Foundation, in coordination with other Federal agencies as appropriate, shall through its cybersecurity research and development programs—

''(1) support basic research to advance knowledge, applications, technologies, and tools to strengthen the cybersecurity of information systems, including electric grid and energy systems, including interdisciplinary research in—