that such State applied as of May 31, 2018; or".

The Acting CHAIR. Pursuant to House Resolution 949, the gentleman from Oregon (Mr. WALDEN) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Oregon.

Mr. WALDEN. Mr. Chairman, I appreciate all the work that has been done on this bill up to this point, the great bipartisan work, the biggest effort, I think, Congress has ever undertaken to address this terrible, terrible addiction problem of opioids and everything related to it.

This amendment before us is a bipartisan manager's amendment. It is filed by chairmen and ranking members of the Committees on Energy and Commerce and Ways and Means. This amendment makes simple technical corrections and conforming changes to the underlying H.R. 6 bill that the leaders of our two committees introduced last week.

As has been noted, the policies in H.R. 6 were moved through regular order in our two committees. I appreciate the bipartisan cooperation and teamwork of my colleagues and our terrific staffs who have joined me in introducing H.R. 6.

Mr. Chair, I encourage support of the amendment, and I urge adoption of the amendment.

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

The Acting CHAIR. The question is on the amendment offered by the gentleman from Oregon (Mr. WALDEN).

The amendment was agreed to.

The Acting CHAIR. The Committee will rise informally.

The SPEAKER pro tempore (Mr. MARSHALL) assumed the chair.

MESSAGES FROM THE PRESIDENT

Messages in writing from the President of the United States were communicated to the House by Ms. Gabrielle Cuccia, one of his secretaries.

The SPEAKER pro tempore. The Committee will resume its sitting.

SUBSTANCE USE-DISORDER PRE-VENTION THAT PROMOTES OPIOID RECOVERY AND TREAT-MENT FOR PATIENTS AND COM-MUNITIES ACT

The Committee resumed its sitting.

AMENDMENT NO. 2 OFFERED BY MR. DUNN

The Acting CHAIR (Mr. POE of Texas). It is now in order to consider amendment No. 2 printed in part B of House Report 115–766.

 $\mbox{Mr. DUNN. Mr. Chair, I have an amendment at the desk.}$

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 93, strike lines 18 through 22 and insert the following:

(2) in subclause (II), by striking "during the period beginning on the date of enactment of the Comprehensive Addiction and Recovery Act of 2016 and ending on October 1, 2021.".

Page 93, strike line 23 and all that follows through page 94, line 17.

Page 94, line 18, strike "(e)" and insert "(c)".

The Acting CHAIR. Pursuant to House Resolution 949, the gentleman from Florida (Mr. DUNN) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Florida.

Mr. DUNN. Mr. Chair, I rise in support of my amendment to H.R. 6. I am grateful for the opportunity to speak about it.

My amendment strikes language that would expand the classes of healthcare workers who would be authorized to dispense narcotics for narcotic treatment.

Let me be clear at the outset. H.R. 6 is, in large part, a great bill; however, as currently written, it allows nurse specialists, nurse midwives, and nurse anesthetists to prescribe buprenorphine. I believe this is a significant and impulsive expansion of prescribing authority.

Allowing more providers with less clinical experience to provide buprenorphine, a highly addictive opioid, opens up dangerous new potential for increased opioid abuse. The point of H.R. 6 is to decrease opioid abuse, but this provision increases the potential for abuse and vastly increases the supply of a dangerous opioid that is one of the major causes of opioid overdose and death in Europe.

Mr. Chair, I appreciate the opportunity to bring these concerns to light in this amendment.

Mr. Chair, I include in the RECORD a letter in support of my amendment from The OTP Consortium.

THE OTP CONSORTIUM, June 19, 2018.

Hon. GREG WALDEN,

Chairman, Committee on Energy and Commerce, House of Representatives, Washington, DC. Hon. Kevin Brady.

Chairman, Committee on Ways and Means, House of Representatives, Washington, DC. Hon, Frank Pallone, Jr.

Ranking Member, Committee on Energy and Commerce, House of Representatives, Washington. DC.

Hon. RICHARD NEAL,

Ranking Member, Committee on Ways and Means, House of Representatives, Washington, DC.

DEAR CHAIRMEN WALDEN AND BRADY AND RANKING MEMBERS PALLONE AND NEAL: On behalf of the Opioid Treatment Program (OTP) Consortium we would like to offer our support for H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. In particular, we strongly support Section 207 which would provide Medicare beneficiaries with life-Medication-Assisted Treatment (MAT) for opioid use disorder (OUD) in the highly-effective OTP setting. This policy was introduced by Ranking Member Neal and Congressman George Holding as part of H.R. 5776, the Medicare and Opioid Safe Treatment (MOST) Act of 2018. The OTP Consortium is comprised of nearly 350 OTPs across the country that provide care to more than 140,000 patients daily in 37 states, including at our 22 facilities in Massachusetts, 16 facilities in Texas, nine facilities in Oregon, and two facilities in New Jersey.

OTPs are highly-regulated, highly-structured, comprehensive treatment programs that provide MAT—which the National Institutes of Health states is the most effective solution to treat OUD. OTPs are the only provider where patients are guaranteed to receive MAT—including individual and group counseling, random toxicology screens, medication, and other supportive services such as case management, primary care, mental health services, HIV and Hepatitis C testing and more.

Medicare beneficiaries have the highest and fastest growing rate of OUD, yet they do not currently have coverage for the most effective form of treatment—H.R. 6 provides such coverage. More than 300,000 Medicare beneficiaries have been diagnosed with OUD—your legislation could end up saving their lives and many more. Medicare hospitalizations due to complications caused by opioid abuse or misuse increased 10% every year from 1993 to 2012—your bill would help reverse this alarming trend.

We do, however, have concerns about the policies contained in Section 303. While we are pleased that the 275-patient threshold was not codified, we do not support expanding or making permanent buprenorphine prescribing authority to non-physician providers before policymakers can fully analyze the data resulting from the critical questions asked in subsection (e). Americans need effective treatment and decades of evidence and outcomes show that medication simply assists the other treatment interventions. Medication should never be the sole aspect of treating SUD—thus the term Medication-Assisted Treatment. Office-based practices that focus on medication alone run the risk of becoming the next-generation pill mill. We hope that Congress will revisit office-based buprenorphine prescribing thresholds once this quality assessment has been completed and it can be determined whether or not patients are indeed truly receiving MAT in these settings. Improving access to buprenorphine is important, but it must be paired with the evidence-based MAT services that are proven to lead to recovery.

We support H.R. 6 and stand ready to work with you see that this critical Medicare OTP benefit is signed into law, without delay.

Sincerely,

PETER MORRIS, DivisionPresident, Acadia Healthcare. ALEX DODD, CEO, Aegis Treatment Centers, LLC. DAVID WHITE, PH.D., CEO, BayMark Health Service. JAY HIGHAM, CEO, BehavioralHealth Group. JOHN STEINBRUN, CEO, New Season.

Mr. DUNN. Mr. Chair, I reserve the balance of my time.

Mr. WALDEN. Mr. Chair, I claim time in opposition to the amendment.

The Acting CHAIR. The gentleman from Oregon is recognized for 5 minutes.

Mr. WALDEN. Mr. Chair, I certainly appreciate Dr. DUNN and the good work that he has done on many of these issues, and I also appreciate his willingness to withdraw his amendment.

As a result of our committee process and various member conversations we have had, we have reached bipartisan compromise on the underlying bill on the issue of concern to Mr. DUNN.

I understand that thoughtful Members can find themselves on different sides of an issue at different times, and I certainly respect the gentleman's position. That being said, we believe our underlying policy represents a fair middle ground, and it ensures rigorous analysis on the issue going forward.

Mr. Chair, I appreciate the gentleman from Florida withdrawing the amendment.

Mr. Chair, I yield 2½ minutes to the gentleman from New York (Mr. Tonko).
Mr. TONKO. Mr. Chair, I thank

Chairman WALDEN for yielding.
Although I know my colleague plans to withdraw, I rise in opposition to this amendment, and I just want to articulate a bit of my reasoning.

I think my colleagues and I both share the same goal of safely expanding access to addiction treatment. Where we differ is that I believe that the provisions in H.R. 6 expanding buprenorphine prescribing privileges to advanced practice nurses meet that

We all know that there is a dire need for expanded treatment capacity to meet the demands of this current epidemic. As many as 40 percent of counties across the country lack even a single provider that is able to offer buprenorphine. Advanced practice nurses play an outsized role in providing care in rural America, and H.R. 6 will help expand addiction treatment capacity into these communities where it is most needed.

Expanding buprenorphine prescribing privileges to APRNs is supported by medical groups that serve on the front lines of this epidemic, such as the American Society for Addiction Medicine and the American Congress of Obstetricians and Gynecologists.

All advanced practice nurses who wish to prescribe medication-assisted treatment would have to receive a special waiver from the DEA and would have to undergo three times as much specialized addiction training as their physician colleagues.

In addition, in order to receive a waiver, practitioners are required to be able to provide appropriate counseling and ancillary services that are the hallmark of high-quality addiction treatment. All APRNs wishing to prescribe buprenorphine would still be subject to State laws regarding prescription authority, scope of practice, and collaboration or supervision requirements with a physician.

While I understand that providing addiction treatment is a complex and nuanced area of medicine with potential complications if done poorly, I would point out that we don't restrict advanced practice registered nurses in Federal law from providing such highrisk services as delivering babies, administering anesthesia, or prescribing

as many opioids as they wish. Why would we want to maintain an outdated barrier in Federal law that prevents these practitioners from being part of the solution to the opioid epidemic?

So in closing, I appreciate that my colleagues are withdrawing this amendment today, and I would urge that, as we move forward toward a potential conference committee, we continue to recognize the role that advanced practice nurses can play in addressing this epidemic.

Mr. WALDEN. Mr. Chairman, I reserve the balance of my time.

Mr. DUNN. Mr. Chair, I yield 1 minute to the gentleman from Tennessee (Mr. ROE), the chairman of the Veterans' Affairs Committee.

Mr. ROE of Tennessee. Mr. Chair, I thank the gentleman for yielding.

As a practicing physician for over 30 years, I have incredible respect for nurses and the work they do. I married a nurse. Some of the best employees I have worked with were nurses. I could not appreciate the job they do more, Mr. Chair, but care for patients is better directed with physician oversight.

Even with my training, we need fewer doctors like me writing these prescriptions and more physicians trained in pain management. The American Society of Addiction Medicine is establishing approved fellowships in training in addiction medicine today.

Expanding the scope of practice for nonphysician providers to dispense drugs like buprenorphine goes in the wrong direction, in my opinion.

There are many factors that contribute to the explosive growth in opioid use, but clearly a big factor was the lack of knowledge about opioids' addictive qualities. I would argue that we have a similar lack of knowledge about buprenorphine today, and allowing providers who have less training and less knowledge about these substances exponentially increases the chances of abuse in these substances.

□ 1045

If we remove the most highly-trained specialist from administration of buprenorphine, I fear that all the good we are trying to do in this bill could be negated

The Acting CHAIR. The time of the gentleman has expired.

Mr. DUNN. I yield the gentleman an additional 1 minute.

Mr. ROE of Tennessee. There are plenty of provisions to support in this underlying bill. It is a good bill, but section 303 is not one of them.

I encourage my colleagues to support the amendment.

Mr. WALDEN. Mr. Chairman, I continue to reserve the balance of my

Mr. DUNN. Mr. Chairman, I yield 1 minute to the gentleman from Kansas (Mr. MARSHALL).

Mr. MARSHALL. Mr. Chairman, I thank Dr. Dunn for leading this amendment.

I had an over three-decade experience and great working relationship with physician assistants, nurse practitioners, as well as nurse anesthetists. I believe one of the secrets to that great work that we did was the collaboration between us and how we worked together.

I firmly believe that whenever narcotics are involved, there needs to be a very close working relationship between the supervising physician and these other groups and societies. As narcotic and opioid abuse has become a national crisis, we need to be working even more closely together so as not to exacerbate the problem.

Mr. WALDEN. Mr. Chairman, I yield back the balance of my time.

Mr. DUNN. Mr. Chair, buprenorphine was introduced in Finland in 1997, and now it has become the most widely-abused opioid in that country. Buprenorphine can kill people. It does kill people. And office-based practices involving merely prescribing buprenorphine run a large risk of harming patients, not helping them to recover.

In closing, I want to thank you for working with me on this amendment, and I thank Chairman WALDEN for his gracious commitment to continue to examine.

I yield back the balance of my time. Mr. Chairman, I ask unanimous consent to withdraw my amendment.

The Acting CHAIR. Is there objection to the request of the gentleman from Florida?

There was no objection.

The Acting CHAIR. The amendment is withdrawn.

AMENDMENT NO. 3 OFFERED BY MR. BARTON

The Acting CHAIR. It is now in order to consider amendment No. 3 printed in part B of House Report 115-766.

Mr. BARTON. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

At the end of title III, insert the following new section:

SEC. 304. HIGH-QUALITY, EVIDENCE-BASED OPIOID ANALGESIC PRESCRIBING GUIDELINES AND REPORT.

(a) GUIDELINES.—The Commissioner of Food and Drugs shall develop high-quality, evidence-based opioid analgesic prescribing guidelines for the indication-specific treatment of acute pain in the relevant therapeutic areas where such guidelines do not exist.

(b) PUBLIC INPUT.—In developing the guidelines under subsection (a), the Commissioner of Food and Drugs shall—

(1) conduct a public workshop, open to representatives of State medical societies and medical boards, various medical specialties including pain medicine specialty societies, patient groups, pharmacists, universities, and others; and

(2) provide a period for the submission of comments by the public.

(c) REPORT.—Not later than the date that is 2 years after the date of enactment of this Act, the Commissioner of Food and Drugs 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,

and post on the public website of the Food and Drug Administration, a report on how the guidelines under subsection (a) will be utilized to protect the public health.

(d) UPDATES.—The Commissioner of Food and Drugs shall periodically—

(1) update the guidelines under subsection (a), informed by public input described in subsection (b); and

(2) submit to the committees specified in subsection (c) and post on the public website of the Food and Drug Administration an updated report under subsection (c).

(e) STATEMENT TO ACCOMPANY GUIDELINES AND RECOMMENDATIONS.—The Commissioner of Food and Drugs shall ensure that any opioid analgesic prescribing guidelines and other recommendations developed under this section are accompanied by a clear statement that such guidelines or recommendations, as applicable—

(1) are intended to help inform clinical decisionmaking by prescribers and patients; and

(2) should not be used by other parties, including pharmacy benefit management companies, retail or community pharmacies, or public and private payors, for the purposes of restricting, limiting, delaying, or denying coverage for or access to a prescription issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

(f) DEFINITION.—In this section, the term "evidence-based" means informed by a robust and systemic review of treatment efficacy and clinical evidence.

The Acting CHAIR. Pursuant to House Resolution 949, the gentleman from Texas (Mr. Barton) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Texas.

Mr. BARTON. Mr. Chairman, we have a great piece of legislation before us today. Chairman WALDEN and Ranking Member PALLONE have been great leaders in shepherding dozens of opioid-related bills through the Energy and Commerce Committee.

This particular bill, H.R. 6, is the crown jewel of all that legislation. We all know what a scourge the opioid epidemic is. Since 2015, more Americans have died annually from opioid overdoses than from the AIDS epidemic at its peak.

The amendment that is before us today is very simple. It requires the FDA, after consultation with all the stakeholders in open meetings and workshops, to develop some opioid prescription guidelines based on hard evidence.

This amendment gives the FDA 2 years to develop these guidelines. It requires the FDA to post the guidelines on their web page and to send the guidelines to the Energy and Commerce Committee in the House and to the Education and Workforce committee over in the Senate.

It is a bipartisan amendment. Congresswoman Annie Kuster of New Hampshire and Congressman Mark Meadows of North Carolina have both worked with myself and other members of the committee to develop this amendment.

Opioids are a little bit different than some of the other drugs that are

abused and lead to addiction in that most people are exposed to opioids the first time because of a prescription. They have some sort of acute pain that opioids can help manage and in prescribing these opioids the doctors are trying to help alleviate the pain. But everyone reacts to opioids somewhat differently, and sometimes what is acceptable in terms of the dosage for one individual is not acceptable with another individual.

These guidelines will, again, be based on facts, be based on evidence. They are advisory only. We are not trying to intervene in the doctor/patient relationship. It will still be up to the doctor to determine what is best for the patient. But at least the doctor will have some fact-based guidelines with which to make the decision on what level to prescribe these opioids if, in fact, opioids are necessary.

To quote the head of the FDA, Dr. Scott Gottlieb: "Without evidence-based dosing recommendations at the point of care to support and inform rational prescribing, we're at serious risk of both undertreating some patients who could benefit from opioid therapy, and overtreating a lot of patients who are then placed at a higher risk of addiction."

I will say that the amendment has drawn some concern, or at least interest, from the stakeholders, the chairman, the ranking member, myself and others are committed to working on this as it goes through the process. If we can fine-tune the amendment in some way, we are willing to at least consider that.

But as it is constructed today, Mr. Chairman, this is a good amendment, and I hope that the body will adopt it.

Mr. Chairman, I reserve the balance of my time.

Mr. PALLONE. Mr. Chairman, I would like to request time to speak in favor of the amendment.

The Acting CHAIR. Does anyone claim time in opposition?

Mr. WALDEN. I claim time in opposition, Mr. Chairman, although I am not opposed to the amendment, and I will yield to my friend from New Jersey in a second, but I do ask unanimous consent to claim the time in opposition.

The Acting CHAIR. Is there objection to the request of the gentleman from Oregon?

There was no objection.

The Acting CHAIR. The gentleman from Oregon is recognized for 5 minutes.

Mr. WALDEN. Mr. Chair, I rise in support of this amendment, and I want to thank Representatives Barton and Meadows and Kuster. They have really worked hard on this and it is a good amendment.

There is wide variation in the way acute, short-duration pain is treated with opioids, and there are concerns that patients may be over- or underprescribed opioid analysis to treat that pain.

This amendment would direct the FDA Commissioner to develop high-

quality, evidence-based opioid prescribing guidelines for the treatment of acute pain. By arming physicians with this type of information, we can give them more of the tools they need to treat patients' pain without overprescribing addictive medications.

The intent behind this policy is that evidence-based guidelines would add to the universe of available data in a way that would empower providers, patients, caregivers and others to make determinations about treatment in a more informed manner.

I understand that some stakeholders have raised some concerns about limitations on how these evidence-based guidelines can be used; so as we continue to work on these policies with our counterparts in the Senate, we are committed to working to ensure that the language accomplishes what the sponsors intend without having any unintended consequences.

I encourage my colleagues to support adoption of the amendment.

Mr. Chair, I yield to the gentleman from New Jersey (Mr. PALLONE) such time as he may consume.

Mr. PALLONE. Mr. Chairman, I rise in order to speak on the amendment offered by Representatives BARTON, MEADOWS and KUSTER.

FDA Commissioner Gottlieb testified before the Energy and Commerce Committee about the work the agency is doing currently to analyze and assess opioid analgesic use in situations of acute pain, such as following surgical procedures. The goal of this analysis is to provide evidence-based recommendations for appropriate opioid doses by indicators ensuring that prescribing more closely aligns with clinical need.

I believe this is a goal that we all support, which is why I support giving FDA the authority to conduct such work so as to inform policies that will better protect public health, and help to reduce the unneeded opioids from reaching individuals that are at risk for addiction.

Since this amendment has been filed, we have heard some concerns from stakeholders about the amendment possibly impeding the use of the FDA's evidence-based guidelines in making decisions related to dispensing or coverage of opioid prescriptions. I believe that such decisions should be informed by evidence-based guidelines such as those developed by the FDA, and I hope that we can work with the amendment's sponsors and the chairman to address these concerns moving forward.

Mr. WALDEN. Mr. Chairman, I have no further speakers on this matter. Again, I thank my friend, the former chairman of the full committee, Mr. BARTON, for his good leadership on this effort, along with other Members on both sides of the aisle.

I encourage our colleagues to support this amendment, and I yield back the balance of my time.

Mr. BARTON. Mr. Chairman, can I inquire how much time I still have.

The Acting CHAIR. The gentleman from Texas has 1 minute remaining.

Mr. BARTON. Mr. Chairman, I yield 1 minute to the gentlewoman from New Hampshire (Ms. Kuster), who is an original cosponsor of the amendment and has worked very hard on it.

Ms. KUSTER of New Hampshire. Mr. Chairman, I rise in support of the Barton amendment. This amendment would require the FDA to create high-quality, evidence-based opioid prescribing guidelines for acute pain. These would complement prescribing guidelines for chronic pain created in 2015 by the Centers for Disease Control and Prevention.

Taken together, these guidelines would finally provide providers evidence-based recommendations on best practices for all types of pain.

While the opioid epidemic has many origins, it is universally agreed upon that the treatment of pain over the latter half of the 20th century is a significant contributing factor. In recent years, efforts by this Congress and the public to reconcile addiction and chronic pain has had a real and positive impact.

One of the most impacted communities are veterans, and in just the last few years, the VA has reported a remarkable decline in opioid prescriptions.

Yet, the focus until very recently has been on chronic pain. Acute pain impacts more people and is responsible for a massive share of opioid prescriptions. The country needs evidence-based guidance on treatment of acute pain.

FDA is armed with a trove of data on acute pain prescription rates and patterns. They are uniquely positioned to provide this needed guidance.

FDA Commissioner Scott Gottlieb told my colleagues on the Energy & Commerce Committee that this is something he wants to do and he underscored the importance of evidence-based opioid prescribing guidelines at the 2018 National Rx Drug Abuse & Heroin Summit

While these guidelines are focused on the prescriber practices and patients, given the nature of pain management as team-based, we intend these recommendations to inform better practices by providers that have collaborative working relationships with prescribers

I am committed to working with all stakeholders to improve this amendment as Congress continues to consider opioid legislation to ensure that these guidelines are considered consistent with law while still providing effective pain care for all Americans.

Mr. BARTON. Mr. Chair, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Texas (Mr. BARTON).

The amendment was agreed to.

AMENDMENT NO. 4 OFFERED BY MR. CURTIS

The Acting CHAIR. It is now in order to consider amendment No. 4 printed in part B of House Report 115–766.

Mr. CURTIS. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Add at the end of title III the following:

SEC. 304. REPORT ON OPIOIDS PRESCRIBING
PRACTICES FOR PREGNANT WOMEN.

- (a) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services, in coordination with the Centers for Disease Control and Prevention, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration shall develop and submit to the Congress a report—
- (1) on opioids prescribing practices for pregnant women and recommendations for such practices;
- (2) that provides recommendations for identifying and reducing opioids misuse during pregnancy;
- (3) on prescription opioid misuse during pregnancy in urban and rural areas;
- (4) on prescription opioid use during pregnancy for the purpose of medication-assisted treatment in urban and rural areas;
- (5) evaluating current utilization of nonopiate pain management practices in place of prescription opioids during pregnancy;
- (6) providing guidelines encouraging the use of non-opioid pain management practices during pregnancy when safe and effective; and
- (7) that provides recommendations for increasing public awareness and education of opioid use disorder in pregnancy, including available treatment resources in urban and rural areas.
- (b) No Additional Funds.—No additional funds are authorized to be appropriated for purposes of carrying out subsection (a).

The Acting CHAIR. Pursuant to House Resolution 949, the gentleman from Utah (Mr. Curtis) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Utah.

Mr. CURTIS. Mr. Chairman, I rise today to offer an amendment to improve research and public awareness of opioid use during pregnancy. I introduced the POPPY Study Act earlier this year to address this issue, and I am pleased that it is being considered here today in this form.

We all know the opioid epidemic has widespread and devastating effects. Nearly all of us know someone who has been affected by the crisis, and many of us have grieved through the heartbreak of losing loved ones to addiction.

Sadly, the impact this has had on Utah has been overwhelming. In my State, six Utahns die every week as a result of the opioid overdose, and we rank among the highest in the Nation for drug overdose deaths. Areas of my district have some of the highest rates of opioid prescriptions dispensed nationwide.

Tragically, Utah also leads out in prescribing the most opioids to pregnant women. Across the Nation, 1 in 5 women receive an opioid prescription during pregnancy but, in Utah, that number is doubled.

Of course, opioid use during pregnancy can have dramatic consequences for a mother and her unborn child. Neonatal abstinence syndrome presents itself as babies go through withdrawal, constant screaming, shaking, vomiting, and difficulty sleeping and eating.

□ 1100

This condition often requires long and expensive hospitalization. For Medicaid-covered babies, this syndrome costs more than \$460 million in 2014 alone.

Tragically, from 2004 to 2014, the rate of infants diagnosed with opioid withdrawal symptoms increased more than 400 percent nationwide.

Across the Nation, women have been disproportionately impacted by the opioid epidemic, and little is known about the effect this has had on pregnant women.

Healthcare experts, providers, and patients agree there is simply too much we don't know about why pregnant women are being prescribed opioids and what possible alternatives might provide better healthcare outcomes for mothers and their unborn children.

My amendment calls for increased research on current opioid prescribing practices during pregnancy, more data on prescription opioid misuse during pregnancy, and evaluates and encourages nonopioid pain management therapies that are safe and effective during pregnancy.

I am proud of the work we have done here to curb the opioid epidemic, and I applaud the chairman, ranking member, and members of the committee for the work they have done to fight this crisis.

Mr. Chair, I encourage my colleagues to support this vital amendment as well as the underlying bill that will help us better serve our suffering communities, and I reserve the balance of my time.

Mr. WALDEN. Mr. Chair, although I am not opposed to the amendment, I ask unanimous consent to claim the time in opposition.

The Acting CHAIR. Is there objection to the request of the gentleman from Oregon?

There was no objection.

The Acting CHAIR. The gentleman from Oregon is recognized for 5 min-

Mr. WALDEN. Mr. Chairman, I rise to speak in support of the amendment and to thank my friend from Utah, Mr. CURTIS, for his hard work on this very thoughtful piece of legislation.

It is important that women who take opioid pain medications are aware of the possible risks during pregnancy. You heard him delineate those tragic, tragic risks, such as premature birth and neonatal abstinence syndrome, or NAS.

While there is increasing awareness and use of nonopioid approaches in the management of pain over all, information about their use in pregnant patients and unique considerations of mother and child are simply lacking.

So this amendment requires the Department of Health and Human Services to report on the opioid prescribing practices and opioid misuse during pregnancy, and evaluate nonopioid alternatives to pain management during pregnancy.

This will complement the efforts of the Protecting Our Infants Act, which required a report on prenatal opioid exposure and NAS, presenting a strategy and clinical recommendations for preventing and treating infants withdrawal.

I encourage my colleagues to support this amendment.

Mr. Chair, I yield such time as he may consume to the gentleman from Louisiana (Mr. SCALISE), a very important Member not only of the U.S. House of Representatives as our whip, but a very influential and effective member on our Energy and Commerce Committee.

Mr. SCALISE. Mr. Chairman, I thank the chairman for yielding me the time and for leading on this important issue.

Mr. Chairman, I rise in strong support of my friend from Utah's amendment. As he mentioned, Mr. Chairman, you look at this crisis in our country, and I am so glad that Congress is taking a wide array of actions to address the opioid crisis in our country, because it doesn't affect just one community or another. Everybody might think "mine is the only problem," and then you talk to other Members of Congress from around the country, and you find out they are experiencing the same kind of crisis. And it is widespread. It is killing people every single day.

But as we are talking about on this amendment, Mr. Chairman, we are talking about children, children that are born to a mother that is addicted to opioids.

I highlight Kemper, a young boy from my district in Slidell, Louisiana. He was born addicted to opioids because his mother, while she was pregnant, was addicted to opioids herself.

Now, I wish that this was the only time that it had happened. Fortunately for all of us, Kemper is now a healthy young boy, but he spent his first 11 days of life in the hospital fighting to beat a drug addiction that was not created, of course, on his own.

We would like to think that this might be an isolated example, but, Mr. Chairman, this example highlights something the Centers for Disease Control has noted, and that is, once every 25 minutes in America, a baby is born addicted to opioids—one every 25 minutes. That is how widespread it is just for babies that are born.

When we talk about this entire package of bills, today, H.R. 6 is going to pull together 50 different bills covering many different parts of this problem. It is an incredibly bipartisan effort. I know, Mr. Chairman, so often we hear about the partisan wrangling in Congress. Clearly, there are divided lines on some high-profile issues, but this is an issue where Republicans and Democrats have come together.

I want to thank my friends from both sides of the aisle for recognizing this problem and coming together in a bipartisan way to solve it.

This is going to give real tools to our communities so that they can combat this at every different level we are seeing, including treatment, including law enforcement to stop these deadly drugs from getting on the streets so that more babies like Kemper are not born addicted to opioids.

Mr. Chairman, I encourage all my colleagues to support this amendment and the underlying package of bills.

Mr. WALDEN. Mr. Chairman, I urge passage, and I yield back the balance of my time.

Mr. CURTIS. Mr. Chairman, I thank the gentleman from Louisiana and the chairman for their speaking out in support of this important bill.

Mr. Chairman, this amendment is essential in helping us improve our understanding of the impact of using opioid prescription during pregnancy and, ultimately, preventing opioid use disorder entirely. It is vital that we have sound and accurate research to guide us in the best ways to help pregnant women suffering from addiction.

Mr. Chairman, this is a critical amendment. I urge my colleagues to support it, and I yield back the balance of my time.

The Acting CHAIR (Mr. WEBER of Texas). The question is on the amendment offered by the gentleman from Utah (Mr. CURTIS).

The amendment was agreed to.

AMENDMENT NO. 5 OFFERED BY MR. KEATING

The Acting CHAIR. It is now in order to consider amendment No. 5 printed in part B of House Report 115–766.

Mr. KEATING. Mr. Chair, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Add at the end of title III the following:
SEC. 304. GUIDELINES FOR PRESCRIBING
NALOXONE.

(a) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue guidelines for prescribing an opioid overdose reversal drug.

(b) CONTENTS.—In issuing guidelines under subsection (a), the Secretary shall address the following:

- (1) Co-prescribing an opioid overdose reversal drug in conjunction with any prescribed opioid.
- (2) Dosage safety.
- (3) Prescribing an opioid overdose reversal drug to an individual other than a patient.
- (4) Standing orders.
- (5) Other distribution, education, and safety measures as determined necessary.

The Acting CHAIR. Pursuant to House Resolution 949, the gentleman from Massachusetts (Mr. KEATING) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Massachusetts.

Mr. KEATING. Mr. Chairman, I rise in support of my amendment that directs the Department of the Health and Human Services to issue and expand guidelines for medical providers for prescribing naloxone to reflect a major shift that has occurred in the opioid health crisis that we continue to work to counter today.

Mr. Chairman, earlier this year, I sat in a room with my colleagues on the Bipartisan Heroin Task Force and listened to Dr. Francis Collins and the NIH leadership present data revealing how we have seen a shift in the opioid crisis

For the first time, we learned that opioid overdoses from prescriptions of opioid drugs have dropped. That is good news.

The shocking news was that overdose rates for illicit opioids, heroin and fentanyl, had risen at an alarming rate.

If we are going to save lives of people overdosing from increasingly prevalent and increasingly unpredictable illicit compounds, we need to make sure naloxone gets in the right hands.

My amendment would provide necessary guidance to patients, providers, public health professionals, first responders, and loved ones on the ability to obtain effective doses of naloxone to combat overdoses of all types of opioids, prescriptions or otherwise.

It is so crucial that people dealing with this brain disease know how to use naloxone in an emergency and, importantly, understand that it is okay to have naloxone in the home.

I was proud that I and the gentleman from Pennsylvania (Mr. ROTHFUS), who also joins me as a cosponsor of this bipartisan amendment, were able to insert legislative language on prescribing guidelines into the Comprehensive Addiction and Recovery Act that passed Congress and became law last year. But giving HHS the option to issue guidelines didn't go far enough.

This amendment before us is firm in its requirement, and I believe my amendment will more explicitly and more expansively direct and yield necessary change.

Mr. Chairman, I conclude by reaffirming our commitment to ending this devastating epidemic that takes the lives of 115 people every day on average in our country.

I share this commitment with the Members of the House, and I pledge to work with you all to see this amendment's passage and to effect necessary change that reflects the ever-shifting landscape in this battle.

Mr. Chairman, I yield 2 minutes to the gentleman from Pennsylvania (Mr. ROTHFUS), the cosponsor of this amendment.

Mr. ROTHFUS. Mr. Chairman, I thank the gentleman for yielding time

Mr. Chairman, I rise to urge my colleagues to support this amendment to H.R. 6, and I want to thank my colleague, the gentleman from Massachusetts (Mr. Keating), for his work on this effort. We have worked before on this issue of naloxone, and it is great that he is bringing forth this amendment. I am happy to be cosponsoring it with him.

The House has been doing amazing, wide-ranging work over the last 2 weeks to combat the opioid crisis, and

I am proud to have assisted with these efforts.

The amendment that I have cojoined with Congressman KEATING today is simple. It instructs the Secretary of Health and Human Services to give additional guidance to prescribing naloxone.

Naloxone is the drug used to reverse opioid overdoses, a situation that far too many Americans have found themselves in across the country and across western Pennsylvania.

Opioid addiction is tearing families apart. Unfortunately, an overdose is frequently the grim end to a long struggle.

If we can help some of our fellow Americans come back from the brink with increased knowledge for our Nation's medical professionals, I see no reason not to do it.

Mr. Chairman, I urge my colleagues to support this amendment. I again thank Congressman Keating for his leadership on this.

Mr. WALDEN. Mr. Chairman, although I am not opposed to the amendment, I ask unanimous consent to claim time in opposition.

The Acting CHAIR. Is there objection to the request of the gentleman from Oregon?

There was no objection.

The Acting CHAIR. The gentleman from Oregon is recognized for 5 minutes.

Mr. WALDEN. Mr. Chairman, I rise to speak in support of the amendment that requires the Department of Health and Human Services to issue guidelines for prescribing an opioid overdose reversal drug.

The guidelines would cover dosage safety, standing orders and other education, and distribution measures.

In April, the Surgeon General issued an advisory calling for more people to carry naloxone.

Expanding the use of this lifesaving drug is a key part of the public health response to the opioid crisis, along with effective prevention, treatment, and recovery programs for substance use disorder.

I can just tell you, Mr. Chairman, from my own district, I have had multiple roundtables in every corner of the district. I have, of course, met with families that have been affected. I have met with addiction treatment specialists. I have met with medical providers. But I have also met with law enforcement.

In Oregon, we lead in a lot of this recovery effort, but also in making sure naloxone is available. This is the anti-

Mr. Chair, these fentanyls that are coming into our country illegally, if I had a little salt shaker here and put out, I don't know, a half a dozen, a dozen grains of salt, and you put your hand on it, you would likely absorb that through your skin and pass out. And if somebody in this Chamber didn't have naloxone, or the medical people who are nearby didn't get to you

in time, you would be one of those 115 people who will die in the next 24 hours, or one of the thousand that will show up in our emergency rooms.

So moving forward with guidelines for prescribing an opioid overdose reversal drug really makes sense. Moving forward with naloxone really makes sense.

We will save lives with this amendment, and I commend my colleagues from Massachusetts and Pennsylvania for their good work on this. We are happy to accept it as part of H.R. 6, and I yield back the balance of my time.

Mr. KEATING. Mr. Chairman, in Cape Cod, the islands, and South Shore and south coast of Massachusetts, the real cause of death in overdoses now is fentanyl. It is being mixed with cocaine. It is being mixed with marijuana. And this is very important.

This bipartisan amendment will save lives. I want to thank Chairman WALDEN, I want to thank Chairman BRADY. I want to thank my cosponsor Mr. ROTHFUS. I want to thank Ranking Member PALLONE and Ranking Member NEAL for their work on an amendment that will truly save lives.

Mr. WALDEN. Will the gentleman yield?

Mr. KEATING. Mr. Chairman, I yield to the gentleman from Oregon.

Mr. WALDEN. Mr. Chairman, because the gentleman raised the issue of these synthetics on other—we have talked a lot about fentanyl being cut into heroin over the course of this debate over 2 weeks.

We haven't talked as much about these synthetics being sprayed on marijuana or other things that you go: Oh, that is natural, mom. I can smoke that.

And what these evil people are doing is taking these deadly synthetics and literally creating a liquid or a spray and then spraying it.

And I talked to a father the other day whose daughter died of a heroin overdose, but when they did the autopsy, they discovered it was 100 percent fentanyl. So I thank the gentleman for his good work on this amendment.

Mr. KEATING. Mr. Chairman, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Massachusetts (Mr. Keating)

The amendment was agreed to.

The Acting CHAIR. It is now in order to consider amendment No. 6 printed in part B of House Report 115–766.

AMENDMENT NO. 7 OFFERED BY MS. MAXINE WATERS OF CALIFORNIA

The Acting CHAIR. It is now in order to consider amendment No. 7 printed in part B of House Report 115–766.

Ms. MAXINE WATERS of California. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Add at the end of title III the following new section:

- (a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall conduct a survey of all entities that receive Federal funding for the purpose of providing substance use disorder treatment services. The survey shall direct such entities to provide the following information:
- (1) The length of time the entity has provided substance use disorder treatment services.
- (2) A detailed description of the patient population served by the entity, including but not limited to the number of patients, type of addictions, geographic area served, as well as gender, racial, ethnic and socioeconomic demographics of such patients.
- (3) A detailed description of the types of addiction for which the entity has the experience, capability, and capacity to provide such services.
- (4) An explanation of how the entity handles patients requiring treatment for a substance use disorder that the organization is not able to treat.
- (5) A description of what is needed, in the opinion of the entity, in order to improve the entity's ability to meet the addiction treatment needs of the communities served by that entity.
- (6) Based on the identified needs of the communities served, a description of unmet needs and inadequate services and how such needs and services could be better addressed through additional Federal, State, or local government resources or funding to treat addiction to methamphetamine, crack cocaine, other types of cocaine, heroin, opioids, and other commonly abused drugs.
- (b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall develop and submit to Congress a plan to direct appropriate resources to entities that provide substance use disorder treatment services in order to address inadequacies in services or funding identified through the survey described in subsection (a).

The Acting CHAIR. Pursuant to House Resolution 949, the gentlewoman from California (Ms. MAXINE WATERS) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentle-woman from California.

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Ms. MAXINE WATERS of California. Mr. Chairman, first I would like to say that I appreciate the bipartisan work of the bill's sponsor, Chairman GREG WALDEN, and, of course, Chairman KEVIN BRADY and our cosponsor FRANK PALLONE and cosponsor RICHARD NEAL on this bill, H.R. 6, the SUPPORT for Patients and Communities Act.

The bill, as drafted, includes many positive provisions and extends well-intended legislative efforts to address the opioid crisis in this country. That said, as we all know, in the United States, people suffer from a wide range of substance use disorders, including alcoholism and the abuse of illegal drugs like heroin, methamphetamine, crack, and other forms of cocaine. Likewise, there are a range of entities that provide different types of substance abuse treatment services.

The purpose of my amendment is to ensure that we have a clear understanding of the substance abuse treatment services available, the communities and the populations that are being served, the types of substance use disorders being addressed, and any other unmet needs or inadequacies in the way we are addressing substance abuse issues

My amendment would direct that the Department of Health and Human Services conduct a nationwide survey of entities that provide substance use disorder treatment services. Based on the results of that survey, my amendment directs HHS to develop and submit to Congress a plan to direct appropriate resources in order to address inadequacies in services or funding identified through the survey.

The survey called for by my amendment is intended to complement existing efforts by the Substance Abuse and Mental Health Services Administration, SAMHSA, to examine substance use treatment services in order to develop a concrete plan to address unmet needs.

Mr. Chairman, let me just say that I appreciate the information that was shared by the majority whip, Mr. SCA-LISE, when he talked about the baby who was born addicted, and we are going to have a lot of that.

I have one regret, having worked on the issue of crack cocaine, that we did not do something to do the research that was necessary on these babies that are born addicted, to find out what happens to them later on in life and whether or not these children are handicapped and disabled in some ways, have learning disabilities, and on and on so I would like to work with Mr. Scalise to do the follow-up for the research that is so necessary.

Mr. Chair, I reserve the balance of my time.

Mr. WALDEN. Mr. Chairman, although I am not opposed to the amendment, I ask unanimous consent to claim the time in opposition.

The Acting CHAIR. Is there objection to the request of the gentleman from Oregon?

There was no objection.

The Acting CHAIR. The gentleman from Oregon is recognized for 5 minutes.

Mr. WALDEN. Mr. Chair, I rise to speak in support of this amendment and to thank my friend, Ms. WATERS, for her work on this initiative.

Before I go through that, I just want to say we are more than happy to team up with the gentlewoman on this issue of crack cocaine and its effects, and I am sure that Mr. Scalise, although I can't officially speak for him, I am sure that he would work in partnership with the gentlewoman.

The gentlewoman has raised an issue that we have dealt with in other parts of this legislation but not in the part that the gentlewoman has brought to us. There will be more going forward, I assure you, and we would be happy to work with the gentlewoman on that.

Mr. RUSH brought an amendment on the IMD issue to make sure that those suffering from cocaine and crack cocaine addiction also could get treatment under expansion in the IMD, so we would be happy to work with the gentlewoman on that.

This amendment directs the Secretary of Health and Human Services to conduct a survey of organizations that provide substance abuse treatment services and then develop a plan to direct resources to address any identified gaps in services for specific types of substance use disorders. This information will help us better understand how our Federal dollars are invested in interdiction treatment at the local level and what more can be done with Federal resources to yield even better returns in reducing drug-related crimes, accidents, overdoses, deaths.

So I certainly appreciate the gentlewoman's work on this effort. It is important work that will help save lives and bring about the kind of treatment we need in our communities.

I encourage adoption of the amendment, and I yield back the balance of my time.

Ms. MAXINE WATERS of California. Mr. Chairman, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentlewoman from California (Ms. MAXINE WATERS).

The amendment was agreed to.

The Acting CHAIR (Mrs. WALORSKI). The Chair understands that amendment No. 8 will not be offered.

There being no further amendments, under the rule, the Committee rises.

Accordingly, the Committee rose; and the Speaker pro tempore (Mr. Weber of Texas) having assumed the chair, Mrs. Walorski, Acting Chair of the Committee of the Whole House on the state of the Union, reported that that Committee, having had under consideration the bill (H.R. 6) to provide for opioid use disorder prevention, recovery, and treatment, and for other purposes, and, pursuant to House Resolution 949, she reported the bill, as amended by that resolution, back to the House with sundry further amendments adopted in the Committee of the Whole.

The SPEAKER pro tempore. Under the rule, the previous question is ordered.

Is a separate vote demanded on any further amendment reported from the Committee of the Whole? If not, the Chair will put them en gros.

The amendments were agreed to.

The SPEAKER pro tempore. The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed and read a third time, and was read the third time.

MOTION TO RECOMMIT

Mr. TONKO. Mr. Speaker, I have a motion to recommit at the desk.

The SPEAKER pro tempore. Is the gentleman opposed to the bill?

Mr. TONKO. I am opposed in its current form.

The SPEAKER pro tempore. The Clerk will report the motion to recommit.

The Clerk read as follows:

Mr. Tonko moves to recommit the bill H.R. 6 to the Committee on Energy and Commerce and the Committee on Ways and Means with instructions to report the same back to the House forthwith with the following amendment:

Page 84, after line 14, insert the following:
SEC. 208. DISTRIBUTION OF ADDITIONAL RESIDENCY POSITIONS TO HELP COMBAT
OPIOID CRISIS.

- (a) In General.—Section 1886(h) of the Social Security Act (42 U.S.C. 1395ww(h)) is amended—
- (1) in paragraph (4)(F)(i), by striking "paragraphs (7) and (8)" and inserting "paragraphs (7), (8), and (9)";
- (2) in paragraph (4)(H)(i), by striking "paragraphs (7) and (8)" and inserting "paragraphs (7), (8), and (9)";
- (3) in paragraph (7)(E), by inserting "paragraph (9)," after "paragraph (8),"; and
- (4) by adding at the end the following new paragraph:
- "(9) DISTRIBUTION OF ADDITIONAL RESIDENCY POSITIONS TO HELP COMBAT OPIOID CRISIS.—
- "(A) ADDITIONAL RESIDENCY POSITIONS.-For each of fiscal years 2021 through 2025 (and succeeding fiscal years if the Secretary determines that there are additional residency positions available to distribute under subparagraph (D)), the Secretary shall increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after July 1 of the fiscal year of the increase. Except as provided in subparagraph (B)(iv) or (D), the aggregate number of increases in the otherwise applicable resident limit under this subparagraph shall be equal to 500 over the period of fiscal years 2021 through 2025, distributed in accordance with the succeeding subparagraphs of this paragraph.
- "(B) DISTRIBUTION FOR FISCAL YEAR 2021.—
 "(i) IN GENERAL.—For fiscal year 2021, the positions available for distribution with respect to the fiscal year as described in subparagraph (A) shall be distributed to hospitals that have existing established approved programs in addiction medicine, addiction psychiatry, or pain medicine as determined by the Secretary. The Secretary shall establish standards and a process for ensuring additional residency positions under this subparagraph are used to increase the number of residents studying in the
- "(ii) NUMBER OF POSITIONS HOSPITAL ELIGIBLE TO RECEIVE.—Subject to clauses (iii) and (iv), the aggregate number of positions a hospital may receive under this subparagraph with respect to fiscal year 2021 is equal to the sum of the following:

fields specified in the previous sentence.

- "(I) The number of full-time-equivalent residents that will be training in addiction medicine, addiction psychiatry, or pain medicine as determined by the Secretary with respect to the fiscal year.
- "(II) The associated number, as defined by the Secretary, of residents training in a prerequisite program, such as internal medicine, necessary for the number of full-time residents for the programs described in sub-
- "(iii) ADDITIONAL POSITIONS FOR EXPANSION OF EXISTING PROGRAM.—If a hospital demonstrates to the Secretary that the hospital is planning to increase the number of full-

time-equivalent residents in existing programs described in clause (i), the Secretary may increase the number of positions a hospital is eligible to receive under clause (ii) in order to accommodate that expansion, as determined by the Secretary.

"(iv) Considerations in distribution.— The Secretary shall distribute additional residency positions under this subparagraph based on—

"(I) in the case of positions made available under clause (ii), the demonstrated likelihood, as defined by the Secretary, of the hospital filling such positions by July 1, 2021; and

"(II) in the case of positions made available under clause (iii), the demonstrated likelihood, as so defined, of the hospital filling such positions within the first three cost reporting periods beginning on or after July 1, 2021.

"(v) LIMITATION.—Notwithstanding clauses (ii) and (iv), an individual hospital may not receive more than 25 full-time-equivalent residency positions under this paragraph.

"(vi) Positions not distributed during the fiscal year.—If the number of resident full-time-equivalent positions distributed under this subparagraph is less than the aggregate number of positions available for distribution in the fiscal year (as described in subparagraph (A)), the difference between such number distributed and such number available for distribution shall be added to the aggregate number of positions available for distribution under subparagraph (C).

"(C) DISTRIBUTION FOR FISCAL YEARS 2022 THROUGH 2025 —

"(i) IN GENERAL.—For the period of fiscal years 2022 through 2025, the positions available for distribution with respect to such period (as described in subparagraph (A), including after application of subparagraph (B)(vi)) shall be distributed to hospitals which demonstrate to the Secretary that the hospital—

"(I) will establish an approved program in addiction medicine, addiction psychiatry, or pain medicine; and

"(II) will use all of the additional positions made available under this subparagraph in such program or a prerequisite residency program for such program within the first four cost reporting periods after the increase would be effective.

"(ii) REQUIREMENTS.—Subject to clause (iii), a hospital that receives an increase in the otherwise applicable resident limit under this subparagraph shall ensure, during the 10-year period beginning after the date of such increase, that the hospital uses the positions received under clauses (i)(I) and (i)(II) for the programs for which the positions were distributed, or similar programs (as determined by the Secretary). The Secretary may determine whether a hospital has met the requirements under this clause during such 10-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 10year period.

"(iii) REDISTRIBUTION OF POSITIONS IF HOS-PITAL NO LONGER MEETS CERTAIN REQUIRE-MENTS.—In the case where the Secretary determines that a hospital described in clause (ii) does not meet the requirements of such clause, the Secretary shall—

"(I) reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this subparagraph; and

"(II) provide for the distribution of positions attributable to such reduction in accordance with the requirements of this paragraph.

"(D) DISTRIBUTION OF REMAINING POSITIONS.—If the aggregate number of positions distributed under subparagraphs (B) and (C)

during the period of fiscal years 2021 through 2025 is less than 500, the Secretary shall distribute the remaining residency positions in succeeding fiscal years according to criteria consistent with this paragraph until such time as the aggregate amount of positions distributed under this paragraph is equal to 500.

"(E) NOTIFICATION.—The Secretary shall notify hospitals of the number of positions distributed to the hospital under this paragraph as a result on an increase in the otherwise applicable resident limit by January 1 of the fiscal year of the increase. Such increase shall be effective for portions of cost reporting periods beginning on or after July 1 of that fiscal year.

"(F) APPLICATION OF PER RESIDENT AMOUNTS FOR PRIMARY CARE AND NONPRIMARY CARE.—With respect to additional residency positions in a hospital attributable to the increase provided under this paragraph, the approved FTE per resident amounts are deemed to be equal to the hospital per resident amounts for primary care and nonprimary care computed under paragraph (2)(D) for that hospital.

"(G) PERMITTING FACILITIES TO APPLY AGGREGATION RULES.—The Secretary shall permit hospitals receiving additional residency positions attributable to the increase provided under this paragraph to, beginning in the fifth year after the effective date of such increase, apply such positions to the limitation amount under paragraph (4)(F) that may be aggregated pursuant to paragraph (4)(H) among members of the same affiliated group.

"(H) DEFINITIONS.—In this paragraph:

"(i) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term 'otherwise applicable resident limit' means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraphs (7)(A), (7)(B), (8)(A), and (8)(B).

"(ii) RESIDENT LEVEL.—The term 'resident level' has the meaning given such term in paragraph (7)(C)(i)."

(b) IME.—

(1) IN GENERAL.—Section 1886(d)(5)(B)(v) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)(v)), in the third sentence, is amended by striking "and (h)(8)" and inserting "(h)(8), and (h)(9)".

(2) CONFORMING PROVISION.—Section 1886(d)(5)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)) is amended—

(A) by redesignating clause (x), as added by section 5505(b) of the Patient Protection and Affordable Care Act (Public Law 111–148), as clause (xi) and moving such clause 4 ems to the left; and

(B) by adding after clause (xi), as redesignated by subparagraph (A), the following new clause:

"(xii) For discharges occurring on or after July 1, 2021, insofar as an additional payment amount under this subparagraph is attributable to resident positions distributed to a hospital under subsection (h)(9), the indirect teaching adjustment factor shall be computed in the same manner as provided under clause (ii) with respect to such resident positions."

Page 95, after line 21, insert the following: SEC. 304. ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIOSIMILAR BIOLOGI-CAL PRODUCTS.

(a) DEFINITIONS.—In this section—

(1) the term "commercially reasonable, market-based terms" means—

(A) a non-discriminatory price for the sale of the covered product at or below, but not greater than, the most recent wholesale acquisition cost for the drug, as defined in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w-3a(c)(6)(B));

(B) a schedule for delivery that results in the transfer of the covered product to the eligible product developer consistent with the timing under subsection (b)(2)(A)(iv); and

(C) no additional conditions are imposed on the sale of the covered product;

(2) the term "covered product"—

(A) means-

(i) any drug approved under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) any combination of a drug or biological product described in clause (i); or

(iii) when reasonably necessary to support approval of an application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or section 351 of the Public Health Service Act (42 U.S.C. 262), as applicable, or otherwise meet the requirements for approval under either such section, any product, including any device, that is marketed or intended for use with such a drug or biological product; and

(B) does not include any drug or biological product that the Secretary has determined to be currently in shortage and that appears on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), unless the shortage will not be promptly resolved—

(i) as demonstrated by the fact that the drug or biological product has been in shortage for more than 6 months; or

(ii) as otherwise determined by the Secretary;

(3) the term "device" has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321):

(4) the term "eligible product developer" means a person that seeks to develop a product for approval pursuant to an application for approval under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or for licensing pursuant to an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k));

(5) the term "license holder" means the holder of an application approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the holder of a license under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) for a covered product:

(6) the term "REMS" means a risk evaluation and mitigation strategy under section 505-1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355-1);

(7) the term "REMS with ETASU" means a REMS that contains elements to assure safe use under section 505-1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355-1);

(8) the term "Secretary" means the Secretary of Health and Human Services;

(9) the term "single, shared system of elements to assure safe use" means a single, shared system of elements to assure safe use under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1); and

(10) the term "sufficient quantities" means an amount of a covered product that allows the eligible product developer to—

(A) conduct testing to support an application—

(i) for approval under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

(ii) for licensing under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k));

- (B) fulfill any regulatory requirements relating to such an application for approval or licensing.
- (b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITIES OF A COVERED PRODUCT.—
- (1) IN GENERAL.—An eligible product developer may bring a civil action against the license holder for a covered product seeking relief under this subsection in an appropriate district court of the United States alleging that the license holder has declined to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.
 - (2) Elements.—
- (A) IN GENERAL.—To prevail in a civil action brought under paragraph (1), an eligible product developer shall prove, by a preponderance of the evidence—
 - (i) that—
- (I) the covered product is not subject to a REMS with ETASU; or
- (II) if the covered product is subject to a REMS with ETASU—
- (aa) the eligible product developer has obtained a covered product authorization from the Secretary in accordance with subparagraph (B); and
- (bb) the eligible product developer has provided a copy of the covered product authorization to the license holder;
- (ii) that, as of the date on which the civil action is filed, the product developer has not obtained sufficient quantities of the covered product on commercially reasonable, market-based terms;
- (iii) that the eligible product developer has requested to purchase sufficient quantities of the covered product from the license holder; and
- (iv) that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product on commercially reasonable, market-based terms—
- (I) for a covered product that is not subject to a REMS with ETASU, by the date that is 31 days after the date on which the license holder received the request for the covered product: and
- (II) for a covered product that is subject to a REMS with ETASU, by 31 days after the later of—
- (aa) the date on which the license holder received the request for the covered product; or
- (bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with subparagraph (B).
- (B) AUTHORIZATION FOR COVERED PRODUCT SUBJECT TO A REMS WITH ETASU.—
- (i) REQUEST.—An eligible product developer may submit to the Secretary a written request for the eligible product developer to be authorized to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU.
- (ii) AUTHORIZATION.—Not later than 120 days after the date on which a request under clause (i) is received, the Secretary shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for purposes of—
- (I) development and testing that does not involve human clinical trials, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or
- (II) development and testing that involves human clinical trials, if the eligible product developer has—
- (aa)(AA) submitted protocols, informed consent documents, and informational materials for testing that include protections

- that provide safety protections comparable to those provided by the REMS for the covered product; or
- (BB) otherwise satisfied the Secretary that such protections will be provided; and
- (bb) met any other requirements the Secretary may establish.
- (iii) NOTICE.—A covered product authorization issued under this subparagraph shall state that the provision of the covered product by the license holder under the terms of the authorization will not be a violation of the REMS for the covered product.
- (3) AFFIRMATIVE DEFENSE.—In a civil action brought under paragraph (1), it shall be an affirmative defense, on which the defendant has the burden of persuasion by a preponderance of the evidence—
- (A) that, on the date on which the eligible product developer requested to purchase sufficient quantities of the covered product from the license holder—
- (i) neither the license holder nor any of its agents, wholesalers, or distributors was engaged in the manufacturing or commercial marketing of the covered product; and
- (ii) neither the license holder nor any of its agents, wholesalers, or distributors otherwise had access to inventory of the covered product to supply to the eligible product developer on commercially reasonable, market-based terms: or
 - (B) that-
- (i) the license holder sells the covered product through agents, distributors, or wholesalers:
- (ii) the license holder has placed no restrictions, explicit or implicit, on its agents, distributors, or wholesalers to sell covered products to eligible product developers; and
- (iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder
- (4) Remedies.—
- (A) IN GENERAL.—If an eligible product developer prevails in a civil action brought under paragraph (1), the court shall—
- (i) order the license holder to provide to the eligible product developer without delay sufficient quantities of the covered product on commercially reasonable, market-based terms:
- (ii) award to the eligible product developer reasonable attorney fees and costs of the civil action; and
- (iii) award to the eligible product developer a monetary amount sufficient to deter the license holder from failing to provide other eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—
- (I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or
- (II) that the license holder failed to comply with an order issued under clause (i).
- (B) MAXIMUM MONETARY AMOUNT.—A monetary amount awarded under subparagraph (A)(iii) shall not be greater than the revenue that the license holder earned on the covered product during the period—
- (i) beginning on-
- (I) for a covered product that is not subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder received the request; or
- (II) for a covered product that is subject to a REMS with ETASU, the date that is 31 days after the later of—
- (aa) the date on which the license holder received the request; or

- (bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with paragraph (2)(B); and
- (ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.
- (C) AVOIDANCE OF DELAY.—The court may issue an order under subparagraph (A)(i) before conducting further proceedings that may be necessary to determine whether the eligible product developer is entitled to an award under clause (ii) or (iii) of subparagraph (A), or the amount of any such award.
- (c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim under Federal, State, or local law arising out of the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered product during development or testing activities described in this section, including transportation, handling, use, or disposal of the covered product by the eligible product developer.
- (d) No Violation of REMS.—The provision of samples of a drug pursuant to an authorization under subsection (b)(2)(B) shall not be considered a violation of the requirements of any risk evaluation and mitigation strategy that may be in place under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) for such drug.
 - (e) RULE OF CONSTRUCTION.—
- (1) DEFINITION.—In this subsection, the term "antitrust laws"—
- (A) has the meaning given the term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12); and
- (B) includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.
- (2) ANTITRUST LAWS.—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

 SEC. 305. REMS APPROVAL PROCESS FOR SUBSEQUENT FILERS.

Section 505-1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355-1) is amended—

- (1) in subsection (g)(4)(B)—
- (A) in clause (i) by striking "or" after the semicolon;
- (B) in clause (ii) by striking the period at the end and inserting "; or"; and
 - (C) by adding at the end the following:
- "(iii) accommodate different, comparable approved risk evaluation and mitigation strategies for a drug that is the subject of an abbreviated new drug application, and its reference drug product.";
- (2) in subsection (i)(1), by striking subparagraph (B) and inserting the following:
- "(B) Elements to assure safe use, if required under subsection (f) for the listed drug.
- "(i) Subject to clause (ii), a drug that is the subject of an abbreviated new drug application may use—
- "(I) a single, shared system with the listed drug under subsection (f); or
- "(II) a different, comparable aspect of the elements to assure safe use under subsection (f)
- "(ii) The Secretary may require a drug that is the subject of an abbreviated new drug application and the listed drug to use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the elements to assure safe use could satisfy the requirements of subsection (f).": and
 - (3) by adding at the end the following:
- "(1) SEPARATE REMS.—When used in this section, the terms "different, comparable aspect of the elements to assure safe use" or "different, comparable approved risk evaluation and mitigation strategies" means a risk

evaluation and mitigation strategy for a drug that is the subject of an application under section 505(j) that uses different methods or operational means than the strategy required under subsection (a) for the applicable reference drug, or other application under section 505(j) with the same such reference listed drug, but achieves the same level of safety as such strategy.".

SEC. 306. FUNDING FOR OPIOID GRANT PRO-GRAM FOR STATE RESPONSE TO OPIOID ABUSE CRISIS.

Section 1003(c) of the 21st Century Cures Act (42 U.S.C. 290ee-3 note) is amended by adding at the end the following new paragraph:

"(3) For purposes of carrying out this subsection, there is appropriated, out of any funds in the Treasury not otherwise appropriated, \$995,000,000 for each of fiscal years 2019 through 2021."

Page 98, strike line 20 and all that follows through page 99, line 9.

Mr. TONKO (during the reading). Mr. Speaker, I ask unanimous consent to dispense with the reading.

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

There was no objection.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New York is recognized for 5 minutes in support of his motion.

Mr. TONKO. Mr. Speaker, this is the final amendment to the bill, which will not kill the bill or send it back to committee. If adopted, the bill will immediately proceed to final passage, as amended.

For more than a year and a half, Republicans in the House have been engaged in an all-out ideological assault to weaken healthcare for Americans by working to repeal the Affordable Care Act and gutting protections for preexisting conditions. Republicans have repeatedly voted to strip Medicaid coverage for millions struggling with addiction. Thanks to Republican policies, we are seeing this uninsured rate rise sharply for the first time in years.

This attack on our healthcare has had serious consequences for our ability to adequately address the needs of those struggling with the opioid epidemic. I remind my friends that we can't have it both ways: We either are for fighting this epidemic every way we can, or we are not.

I have seen the carnage this epidemic can produce in my own backyard, where my hometown of Amsterdam, New York, with a population of a little over 18,000 people, saw four overdose deaths and a dozen close calls within a single month.

We know that, as of today, less than 20 percent of Americans who need substance abuse treatment are able to receive it. We need to move toward a system of treatment on demand so that, when an individual has that moment of clarity, we are ready with a helping hand to pull them away from the deadly grip of addiction.

While I am pleased that the bill before us will make some incremental progress in our fight against the opioid epidemic and is the product of a significant amount of bipartisan work, every single Member of this Chamber knows that we can and we should be doing more. This motion to recommit is our chance to do just that and to make additional progress in this fight.

First, the motion would invest in our addiction workforce by incorporating a proposal advanced by Representatives Crowley and Costello to add 500 new resident physician slots to hospitals that have developed or are developing training programs in addiction medicine, addiction psychiatry, or pain medicine. We all have seen firsthand the need for more addiction specialists out there, and we have a chance to take action on that right now.

Secondly, this motion would allot an additional \$1 billion annually to States through 2021 so that we can continue to invest in locally designed prevention, treatment, and recovery solutions. It is clearly going to take more than 2 years to battle the epidemic, and we need to let providers in States know that we are making sustained, meaningful investments in this area.

Finally, our motion to recommit includes a commonsense prescription drug policy which will reduce prescription drug prices for all Americans by reducing gaming by drug manufacturers to prevent generics from coming to market.

The CREATES Act, introduced by Representatives Marino and Cicilline, is estimated to save the Federal Government some \$3.8 billion and patients far more. This legislation has been passed by the Senate Judiciary Committee on a bipartisan basis, but we have been denied a vote on the House floor to consider this practical, positive policy to halt pharma gaming and mischief.

Each of the policies contained in this package is bipartisan, fully paid for, and would bolster our ability to respond to the crisis. We have the opportunity to provide a more robust response for the American people and to save the lives of countless of our friends and neighbors all across this country who could be the next to fall victim to this deadly disease of addiction.

Every day, every week, every month, every year that passes, the challenge rests in our collective laps: Will we do more?

We need to do more. Let's do it for those families living with the pain and loss. Let's do it for those individuals who struggle with the illness of addiction. Let's be the light, the candle that brightens their darkness. Let's go forward with the recovery that is inspired by this legislation.

Mr. Speaker, I urge all of my colleagues on both sides of the aisle to support this motion to recommit, and I yield back the balance of my time.

Mr. WALDEN. Mr. Speaker, I claim the time in opposition to the motion.

The SPEAKER pro tempore. The gentleman from Oregon is recognized for 5 minutes

Mr. WALDEN. Mr. Speaker, like a lot of our work here that has been bipartisan, we would hope, going forward, this, too, could become bipartisan, because we believe that getting prescription drug prices down is essential. The Trump administration believes that as well and is doing some things administratively. We are going to be working on this in the committee.

We also agree that this unmet workforce need is important as well. Over the course of five hearings, a full markup in subcommittee, two full markups in the full committee, this issue was never fully brought and vetted. There is more work to be done here, and we are committed to doing work on both the CREATES Act and on the Opioid Workforce Act.

As the gentleman from New York, my friend, knows, we have worked out our differences on many, many issues on this and other topics, and we intend to move forward. It is just that the agreement we have today, Mr. Speaker, is about all of us coming together with bills that were ready for prime time that would not somehow cause problems with the underlying document.

This proposal, while well-intended and, frankly, on the big scope of things makes a lot of sense, it is just not ready and agreed to yet. The gentleman knows that. We know that. We appreciate his passion on this issue. We share it. But I have to reluctantly oppose the motion to recommit because we have agreement that only issues we all agree on are going into this bill—that is, Republicans and Democrats at the top of both committees.

So I take the signal that he remains committed to this effort to fill the gap. We will work with him and others going forward because we have a lot more work to do, Mr. Speaker. This one is just not ready for prime time.

Mr. Speaker, I urge opposition to the motion to recommit, and I yield back the balance of my time.

The SPEAKER pro tempore. Without objection, the previous question is ordered on the motion to recommit.

There was no objection.

The SPEAKER pro tempore. The question is on the motion to recommit.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

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

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 and clause 9 of rule XX, this 15-minute vote on the motion to recommit will be followed by 5-minute votes on passage of the bill, if ordered, and agreeing to the Speaker's approval of the Journal, if ordered.

The vote was taken by electronic device, and there were—yeas 185, nays 226, not voting 16, as follows:

[Roll No. 287]

YEAS—185

Adams Barragán Beatty Aguilar Bass Bera

Shimkus

Shuster

Simpson

Smith (MO)

Smith (NE)

Smith (NJ)

Smith (TX)

Smucker

Stefanik

Stewart

Stivers

Taylor

Tenney

Tipton

Turner

Upton

Valadao

Wagner

Walberg

Walden

Walker

Walorski

Walters, Mimi

Weber (TX)

Wenstrup

Williams

Wittman

Womack

Woodall

Yoder

Yoho

Zeldin

Westerman

Wilson (SC)

Young (AK)

Young (IA)

Webster (FL)

Trott

Thompson (PA)

Thornberry

Brownley (CA)

Bever Bishop (GA) Blum Blumenauer Blunt Rochester Bonamici Boyle, Brendan Brady (PA) Brown (MD) Brownley (CA) Bustos Butterfield Capuano Carbajal Cárdenas Carson (IN) Cartwright Castor (FL) Castro (TX) Chu, Judy Cicilline Clark (MA) Clarke (NY) Clav Cleaver Clyburn Cohen Connolly Cooper Correa Costa Courtney Crist Cuellar Cummings Davis (CA) Davis, Danny DeFazio DeGette DeLauro DelBene Demings DeSaulnier Deutch Dingell Doggett Doyle, Michael Engel Eshoo Espaillat Esty (CT) Evans Foster Frankel (FL) Moore Moulton Fudge Gabbard Murphy (FL) Gallego Nadler Garamendi Napolitano

Gottheimer Green, Al Green, Gene Grijalya. Gutiérrez Hastings Heck Higgins (NY) Himes Hover Huffman Jackson Lee Javanal Jeffries Johnson (GA) Johnson, E. B. Kaptur Keating Kelly (IL) Kennedy Khanna Kihuen Kildee Kilmer Kind Krishnamoorthi Kuster (NH) Lamb Langevin Larsen (WA) Larson (CT) Lawrence Lawson (FL) Lee Levin Lewis (GA) Lieu, Ted Lipinski Loebsack Lofgren Lowenthal Lowey Lujan Grisham, M Luján, Ben Ray Lynch Maloney Carolyn B. Maloney, Sean Matsui McCollum McEachin McGovern McNerney Meeks

Norcross O'Halleran O'Rourke Pallone Panetta Pascrell Pelosi Perlmutter Peters Peterson Pingree Pocan Polis Price (NC) Quigley Raskin Rice (NY) Richmond Rosen Roybal-Allard Ruiz Ruppersberger Rush Ryan (OH) Sánchez Sarbanes Schakowsky Schiff Schneider Schrader Scott (VA) Scott, David Serrano Sewell (AL) Shea-Porter Sherman Sinema Sires Smith (WA) Soto Speier Suozzi Swalwell (CA) Takano Thompson (CA) Thompson (MS) Tonko Torres Tsongas Vargas Vela Velázquez Visclosky Wasserman Schultz Waters, Maxine

Nolan NAYS-226

Cole

Comer

Cook

Cramer

Curtis

Crawford

Culberson

Davidson

Denham

DeSantis

Donovan

Duffv

Dunn

Faso

Flores

Foxx Frelinghuysen

Gaetz

Gallagher

Emmer

Estes (KS)

Ferguson

Fitzpatrick

Fortenberry

Fleischmann

DesJarlais

Diaz-Balart

Duncan (SC)

Duncan (TN)

Curbelo (FL)

Davis, Rodney

Comstock

Conaway

Collins (NY)

Costello (PA)

Abraham Aderholt Allen Amash Amodei Arrington Babin Bacon Banks (IN) Barletta Barr Barton Bergman Biggs Bilirakis Bishop (MI) Bishop (UT) Blackburn Brady (TX) Brat Brooks (AL) Brooks (IN) Buchanan Buck Bucshon Budd Burgess Byrne Calvert Carter (GA) Carter (TX) Chabot

Cheney

Coffman

Gonzalez (TX)

Gianforte Gibbs Gohmert Goodlatte Gosar Gowdy Granger Graves (GA) Graves (LA) Graves (MO) Griffith Grothman Guthrie Handel Harper Harris Hartzler Hensarling Herrera Beutler Hice, Jody B. Higgins (LA) Hill. Holding Hollingsworth Hudson Huizenga Hultgren Hunter Hurd Issa Jenkins (KS) Jenkins (WV) Johnson (LA) Johnson (OH)

Watson Coleman

Welch

Wilson (FL)

Yarmuth

Garrett

Mitchell Johnson, Sam Jones Moolenaar Jordan Mooney (WV) Joyce (OH) Mullin Newhouse Katko Kelly (MS) Norman Kelly (PA) Nunes King (IA) Olson King (NY) Palazzo Palmer Kinzinger Knight Paulsen Kustoff (TN) Pearce Labrador Perry Pittenger LaHood LaMalfa Poe (TX) Lamborn Poliquin Lance Posey Ratcliffe Latta Lesko Reichert Lewis (MN) Renacci LoBiondo Rice (SC) Roby Long Roe (TN) Loudermilk Rogers (AL) Love Rogers (KY) Lucas Luetkemeyer Rohrabacher MacArthur Rooney, Francis Ros-Lehtinen Marino Marshall Roskam Massie Ross Rothfus Mast McCarthy Rouzer Royce (CA) McCaul McClintock Russell McHenry Rutherford McKinley Sanford McMorris Scalise Rodgers Schweikert McSallv Scott, Austin

Meadows

Messer

NOT VOTING-

Sensenbrenner

Sessions

Black Marchant Rooney, Thomas Collins (GA) Meng J. Crowley Noem Titus Payne Delaney Veasey Ellison Reed Walz Hanabusa Rokita

□ 1152

Messrs. DAVIDSON, RUTHERFORD, ROYCE of California, YOUNG of Iowa, BISHOP of Michigan, MCHENRY. BISHOP of Utah, HOLLINGSWORTH, and COLE changed their vote from "vea" to "nay."

Ms. SANCHEZ changed her vote from "nay" to "yea."

So the motion to recommit was reiected.

The result of the vote was announced as above recorded.

The SPEAKER pro tempore. The question is on the passage of the bill.

The question was taken; and the Speaker pro tempore announced that the aves appeared to have it.

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

The yeas and nays were ordered.

The SPEAKER pro tempore. This is a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 396, nays 14, not voting 17, as follows:

[Roll No. 288] YEAS-396

Abraham	Barragán	Blum
Adams	Barton	Blumenauer
Aderholt	Bass	Blunt Rochester
Aguilar	Beatty	Bonamici
Allen	Bera	Bost
Amodei	Bergman	Boyle, Brendan
Arrington	Beyer	F.
Babin	Bilirakis	Brady (PA)
Bacon	Bishop (GA)	Brady (TX)
Banks (IN)	Bishop (MI)	Brat
Barletta	Bishop (UT)	Brooks (IN)
Barr	Blackburn	Brown (MD)

Buchanan Gottheimer Buck Gowdy Bucshon Granger Graves (GA) Budd Burgess Graves (LA) Bustos Graves (MO) Butterfield Green, Al Green, Gene Byrne Calvert Griffith Capuano Grijalva Carbajal Grothman Cárdenas Guthrie Carson (IN) Gutiérrez Carter (GA) Handel Carter (TX) Harper Cartwright Harris Castor (FL) Hartzler Castro (TX) Hastings Chabot Heck Cheney Hensarling Herrera Beutler Chu, Judy Cicilline Clark (MA) Hice, Jody B. Higgins (LA) Clarke (NY) Higgins (NY) Clay Hill Cleaver Himes Clyburn Holding Coffman Hollingsworth Cohen Hover Cole Hudson Huffman Collins (NY) Comer Huizenga Comstock Hultgren Conaway Hunter Connolly Hurd Cook Issa Jackson Lee Cooper Correa Jayapal Jeffries Costa Costello (PA) Jenkins (KS) Courtney Jenkins (WV) Johnson (GA) Cramer Crawford Johnson (LA) Johnson (OH) Crist Cuellar Johnson, E. B. Culberson Johnson, Sam Jordan Cummings Joyce (OH) Curbelo (FL) Curtis Kaptur Davidson Katko Davis (CA) Keating Davis, Danny Kelly (IL) Davis, Rodney Kelly (MS) DeFazio Kelly (PA) DeGette Kennedy DeLauro Khanna DelBene Kihuen Kildee Demings Kilmer Denham DeSantis Kind DeSaulnier King (IA) King (NY) DesJarlais Deutch Kinzinger Diaz-Balart Knight Dingell Krishnamoorthi Doggett Kuster (NH) Kustoff (TN) Donovan Doyle, Michael LaHood

LaMalfa

Lamborn

Lamb

Lance

Latta

Lesko

Levin

Lipinski

Lofgren

Long

Love

Lowey

Lucas

Lynch

Sensenbrenner

Duffy Duncan (SC) Duncan (TN) Dunn Emmer Engel Eshoo Espaillat Estes (KS) Esty (CT) Evans Faso Ferguson Fitzpatrick Fleischmann Flores Fortenberry Foster Foxx Frankel (FL) Frelinghuysen Fudge Gabbard Gallagher Gallego Garamendi Gianforte Gibbs Gomez

F.

MacArthur Goodlatte Malonev. Carolyn B. Maloney, Sean Marino Marshall Mast Matsui McCarthy McCaul McCollum McEachin McGovern McHenry McKinley McMorris Rodgers McNerney McSally Meadows Meeks Messer Mitchell Moolenaar Mooney (WV) Moore Moulton Mullin Murphy (FL) Nadler Napolitano Neal Newhouse Nolan Norcross Norman Nunes O'Halleran Olson Palazzo Pallone Palmer Panetta Pascrell Paulsen Pearce Pelosi Perlmutter Perry Peters Peterson Pingree Pittenger Pocan Poe (TX) Poliquin Polis Posev Price (NC) Quigley Raskin Ratcliffe Reichert Renacci Rice (NY) Rice (SC) Richmond Roby Roe (TN) Rogers (AL) Rogers (KY) Rohrabacher Rooney, Francis Langevin Ros-Lehtinen Larsen (WA) Rosen Larson (CT) Roskam RossLawrence Rothfus Lawson (FL) Rouzer Roybal-Allard Royce (CA) Ruiz Lewis (GA) Ruppersberger Lewis (MN) Rush Lieu, Ted Russell Rutherford Rvan (OH) LoBiondo Loebsack Sánchez Sarbanes Scalise Schakowsky Lowenthal Schiff Schneider Schrader Luetkemeyer Lujan Grisham, Schweikert Scott (VA) Scott, Austin Luján, Ben Ray Scott, David

Serrano Takano Walorski Taylor Walters, Mimi Sessions Sewell (AL) Tenney Wasserman Thompson (CA) Shea-Porter Schultz Sherman Waters, Maxine Thompson (MS) Shimkus Thompson (PA) Watson Coleman Shuster Thornberry Weber (TX) Tipton Simpson Webster (FL) Sinema Tonko Welch Sires Torres Wenstrup Smith (MO) Trott Westerman Smith (NE) Tsongas Williams Wilson (FL) Smith (NJ) Turner Upton Wilson (SC) Smith (WA) Valadao Wittman Smucker Vargas Womack Woodall Speier Velázquez Yarmuth Stefanik Visclosky Yoder Stewart Wagner Yoho Young (AK) Stivers Walberg Walden Young (IA) Suozzi Swalwell (CA) Walker Zeldin

NAYS-14

Amash Gohmert Loudermilk Biggs Gonzalez (TX) Massie Brooks (AL) Gosar McClintock Gaetz Jones Sanford Garrett Labrador

NOT VOTING-17

Black Marchant Rokita Collins (GA) Meng Rooney, Thomas Crowley Noem Delaney O'Rourke Titus Ellison Payne Veasey Hanabusa Reed Walz

□ 1201

So the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

THE JOURNAL

The SPEAKER pro tempore (Mr. MITCHELL). The unfinished business is the question on agreeing to the Speaker's approval of the Journal, which the Chair will put de novo.

The question is on the Speaker's approval of the Journal.

Pursuant to clause 1, rule I, the Journal stands approved.

FIREFIGHTER CANCER REGISTRY ACT OF 2017

Mr. COLLINS of New York. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the bill (H.R. 931) to require the Secretary of Health and Human Services to develop a voluntary registry to collect data on cancer incidence among firefighters, with the Senate amendment thereto, and concur in the Senate amendment.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The Clerk will report the Senate amendment.

The Clerk read as follows: Senate amendment:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the Firefighter Cancer Registry Act of 2018.

SEC. 2. VOLUNTARY REGISTRY FOR FIREFIGHTER CANCER INCIDENCE.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the Secretary), acting through the Director of the Centers for Disease Control and Prevention and in coordination with other agencies as the Secretary determines appropriate, shall develop and maintain, directly or through a grant or cooperative agreement, a voluntary registry of firefighters (referred to in this section as the Firefighter Registry) to collect relevant health and occupational information of such firefighters for purposes of determining cancer incidence.

(b) USE OF FIREFIGHTER REGISTRY.—The Firefighter Registry may be used for the following purposes:

(1) To improve data collection and data coordination activities related to the nationwide monitoring of the incidence of cancer among firefighters.

(2) To collect, consolidate, and maintain, consistent with subsection (g), epidemiological information and analyses related to cancer incidence and trends among firefighters

(c) RELEVANT DATA.

(1) DATA COLLECTION.—In carrying out the voluntary data collection for purposes of inclusion under the Firefighter Registry, the Secretary may collect the following:

(A) Information, as determined by the Secretary under subsection (d)(1), of volunteer, paid-on-call, and career firefighters, independent of cancer status or diagnosis.

(B) Individual risk factors and occupational history of firefighters.

(C) Information, if available, related to—

- (i) basic demographic information, including—
 (I) the age of the firefighter involved during the relevant dates of occupation as a firefighter; and
- (II) the age of cancer diagnosis;

(ii) the status of the firefighter as either volunteer, paid-on-call, or career firefighter;

(iii) the total number of years of occupation as a firefighter and a detailing of additional employment experience, whether concurrent, before, or anytime thereafter;

(iv)(I) the approximate number of fire incidents attended, including information related to the type of fire incidents and the role of the firefighter in responding to the incident; or

(II) in the case of a firefighter for whom information on such number and type is unavailable, an estimate of such number and type based on the method developed under subsection (d)(1)(D); and

(v) other medical information and health history, including additional risk factors, as appropriate, and other information relevant to a cancer incidence study of firefighters.

(2) INFORMATION ON DIAGNOSES AND TREAT-MENT.—In carrying out paragraph (1), with respect to diagnoses and treatment of firefighters with cancer, the Secretary shall, as appropriate, enable the Firefighter Registry to electronically connect to State-based cancer registries, for a purpose described by clause (vi) or (vii) of section 399B(c)(2)(D) of the Public Health Service Act (42 U.S.C. 280e(c)(2)(D)), to obtain—

(A) date of diagnoses and source of information; and

(B) pathological data characterizing the cancer, including cancer site, state of disease (pursuant to Staging Guide), incidence, and type of treatment

(d) FIREFIGHTER REGISTRY COORDINATION STRATEGY.—

(1) REQUIRED STRATEGY.—The Secretary shall, in consultation with the relevant stakeholders identified in subsection (e), including epidemiologists and pathologists, develop a strategy to coordinate data collection activities, including within existing State registries, for inclusion in the Firefighter Registry established under this Act. The strategy may include the following:

(A) Increasing awareness of the Firefighter Registry and encouraging participation among volunteer, paid-on-call, and career firefighters.

(B) Consideration of unique data collection needs that may arise to generate a statistically reliable representation of minority, female, and volunteer firefighters, including methods, as needed, to encourage participation from such populations.

- (C) Information on how the Secretary will store data described in subsection (c)(1) and provide electronic access to relevant health information described in subsection (c)(2).
- (D) Working in consultation with the experts described in subsection (e), a reliable and standardized method for estimating the number of fire incidents attended by a firefighter as well as the type of fire incident so attended in the case such firefighter is unable to provide such information.
- (2) REPORT TO CONGRESS.—The Secretary shall submit the strategy described in paragraph (1) to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate not later than 30 days after the date of the completion of the strategy.
- (3) GUIDANCE FOR INCLUSION AND MAINTE-NANCE OF DATA ON FIREFIGHTERS.—The Secretary shall develop, in consultation with the stakeholders identified in subsection (e), State health agencies, State departments of homeland security, and volunteer, paid-on-call, combination, and career firefighting agencies, a strategy for inclusion of firefighters in the registry that are representative of the general population of firefighters, that outlines the following:
- (A) How new information about firefighters will be submitted to the Firefighter Registry for inclusion.
- (B) How information about firefighters will be maintained and updated in the Firefighter Registry over time.
- (C) A method for estimating the number of fire incidents attended by a firefighter as well as the type of fire incident so attended in the case such firefighter is unable to provide such information
- (D) Further information, as deemed necessary by the Secretary.
- (e) CONSULTATION AND REPORT.—The Secretary shall consult with non-Federal experts on the Firefighter Registry established under this section, and shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes, as appropriate, information on goals achieved and improvements needed to strengthen the Firefighter Registry. Such non-Federal experts shall include the following:
- (1) Public health experts with experience in developing and maintaining cancer registries.
- (2) Epidemiologists with experience in studying cancer incidence.
- (3) Clinicians with experience in diagnosing and treating cancer incidence.
- (4) Active and retired volunteer, paid-on-call, and career firefighters as well as relevant national fire and emergency response organizations.
- (f) RESEARCH AVAILABILITY.—Subject to subsection (g), the Secretary shall ensure that information and analysis in the Firefighter Registry are available, as appropriate, to the public, including researchers, firefighters, and national fire service organizations.
- (g) PRIVACY.—In carrying out this Act, the Secretary shall ensure that information in and analysis of the Firefighter Registry are made available in a manner that, at a minimum, protects personal privacy to the extent required by applicable Federal and State privacy law.
- (h) AUTHORIZATION OF FUNDS.—To carry out this section, there are authorized to be appropriated \$2,500,000 for each of the fiscal years 2018 through 2022.

Mr. COLLINS of New York (during the reading). Mr. Speaker, I ask unanimous consent to dispense with the reading.