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, 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 team work of my colleagues and our terrific staffs who have joined me in introducing H.R. 6.

Mr. Chair, I support 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).

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

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

SHARING THE RECORD

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

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

MESSAGES FROM THE PRESIDENT

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 for Patients and Communities Act.

The Committee repeated its sitting.

AMENDMENT NO. 2 OFFERED BY MR. DUNN

The Acting CHAIR (Mr. POC of Texas). I think it is now in order to consider amendment No. 2 printed in part B of House Report 115-766.

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 (I), 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 practitioners, 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 treating patients 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

Sincerely,

PETER MORRIS,
Division President, Acadia Healthcare.

JOHN STEINBRUN,
CEO, Aegis Treatment Centers, LLC.

ALEX DODD,
CEO, Acadia Healthcare.

JAY HIGRAM,
CEO, BayMark Health Services.

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 appreciate the different sides of an issue at different times, and I certainly respect the gentleman’s position. That being said, I 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 colleagues plans to withdraw, I rise in opposition to this amendment, and I just want to articulate a bit of my reasoning.

I get it. I get the 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 test.

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 a single primary care 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 undergo training in addiction medicine. I urge my colleagues to support this amendment and to consider amendment No. 3 printed in the Appendix.

In addition, in order to receive a waiver, practitioners are required to be able to provide appropriate counseling and clinical services that are the hallmark of high-quality addiction treatment. All APRNs wishing to prescribe buprenorphine would still be subject to State laws regarding prescriptive authority, scope of practice, and collaboration or supervision required by a supervising 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 high-risk 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), in the opinion 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. 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 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.

If we remove the most highly-trained specialist from the administration of buprenorphine, I fear that all the good work 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 amendments.

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

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

The Acting CHAIR. Mr. 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.

The Acting CHAIR. 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.

(4) STATEMENT TO ACCOMPANY GUIDELINES AND RECOMMENDATIONS.—The Commissioner of Food and Drugs shall periodically—

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

(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 or 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 informed, 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 why we charge the opioid epidemic. 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 in the Senate.

It is a bipartisan amendment. Congresswoman KUSTER of New Hampshire and Congressman 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 treated with 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 chairmen, 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. 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, 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 under-prescribed opioid analgesics 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 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 gentleman 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 the 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 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 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. The question is on the amendment offered by the gentleman from Texas (Mr. BARTON).

The amendment was agreed to.

THE TEXT OF THE AMENDMENT IS AS FOLLOWS:

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 non-opioid pain management practices in place of prescription opioids during pregnancy;

(6) providing guidance on 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. 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 everyone I know has been affected by the crisis, and many of us have grieved through the heartbreaking loss of 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 life-threatening withdrawal, constant screaming, shaking, vomiting, and difficulty sleeping and eating.

This condition often requires long and expensive hospitalization. For Medicaid-covered babies, this syndrome costs more than $400 million in 2014 alone.

Tragically, from 2004 to 2014, the rate of postpartum deaths 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 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 minutes.

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.

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

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 and I 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. 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 months in America, a baby is born.

As he mentioned, Mr. Chairman, this is a critical amendment. I urge my colleagues to support it, 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. Webster 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.

(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 the Secretary considers necessary.

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

Mr. Keating. Mr. Chair, 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 reduce the 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 from illicit 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 leave 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 naloxone 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 116 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 to me.

Mr. Chairman, I rise to urge my colleagues to support this amendment to H.R. 6, and I want to thank my colleagues for joining me 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 antidote.

Mr. Chair, these fentanylls 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 in 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 yield back to 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. The Clerk will now designate the amendment. The text of the amendment is as follows:

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

SEC. 2. REQUIRING A SURVEY OF SUBSTANCE USE DISORDER TREATMENT PROVIDERS RECEIVING FEDERAL FUNDING.

(a) IN GENERAL.—The Secretary of Health and Human Services (as hereinafter 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.

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 HEGG 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. But, said, as we all know, in the United States, people suffer from a wide range of substance use disorders, including alcoholism and the use 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 abuse services 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 unmet needs 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. Scalise, 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 they have other children who are handicapped and disabled in some ways, have learning disabilities, and on 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. Chairman, I reserve the balance of my time.

Mr. WALDEN. Mr. Chairman, although I am not opposed to the amendment, I ask unanimous consent to request that the gentlewoman from Oregon be recognized for 5 minutes.

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 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 possibly 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, and 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 this 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 community health Centers, 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 gross.

The amendments were agreed to.

The SPEAKER pro tempore. The question on the amendment 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 RECONSIDER

Mr. TONKO. Mr. Speaker, I have a motion to reconsider the bill.

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

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

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 388(h) of the Social Security Act (42 U.S.C. 1395ww(h)) is amended—

(1) in paragraph (2)(F)(i), by striking “paragraphs (7) and (8) and inserting “paragraphs (7), (8), and (9);”

(2) in paragraph (3)(F)(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.—

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 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 145 positions for each covered hospital that has existing established approved programs in addiction medicine, addiction psychiatry, or pain medicine as determined by the Secretary.

“(ii) Number of Positions to Help Combat Opioid Crisis.

The number of positions to help combat opioid crisis (and succeeding fiscal years if the Secretary determines that there are additional residency positions available to distribute under subparagraph (D)) shall be equal to the number of residents studying in the fields specified in the previous sentence.

“(ii) Number of Positions Hospital Eligible to Receive.—Subject to clauses (i) and (ii) the aggregate number of distributed hospital positions may receive under this subparagraph with respect to fiscal year 2021 is equal to the sum of the following:

(1) 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.

(2) The associated number, as defined by the Secretary, of residents training in a pre-requisite program, such as internal medicine, necessary for the number of full-time residents for the programs described in sub-clause (i).

“(II) The associated number, as defined by the Secretary, for residents training in a pre-requisite program, such as internal medicine, necessary for the number of full-time residents for the programs described in sub-clause (i).

“(III) ADDITIONAL POSITIONS ON EXPANSION OF OPIOID PREVENTION INITIATIVE.

The Secretary shall take appropriate action to ensure that 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—

(1) in the case of positions made available under clause (ii), 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; and

(2) 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 (B)(vi)), 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 this subparagraph.

(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 fiscal year (as described in subparagraph (A), including after application of subparagraphs (B) and (C)) shall be distributed to hospitals which demonstrate to the Secretary that the hospital—

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

(2) 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 increased number of positions were available.

(ii) REQUIREMENTS.—Subject to clause (iii), a hospital that receives an increase in the number of resident positions distributed under this subparagraph shall ensure, during the 10-year period beginning after the date of such increase, that the hospital uses the positions, or the positions attributed to the increase, as determined by the Secretary, in accordance with the requirements of this subparagraph.

(iii) REDISTRIBUTION OF POSITIONS IF HOSPITAL NO LONGER MEETS CERTAIN REQUIREMENTS.—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—

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

(2) redistribute the hospital positions attributable to such reduction in accordance with the requirements of this paragraph.

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 specified in this subparagraph such that at no 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 in the other fiscal year applicable to the 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 PTE 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, in the fifth year after the effective date of such increase, apply such positions to the limitation amount under paragraph (4)(F) that is determined by the Secretary pursuant to paragraph (4)(H) of 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 subparagraph (B) of section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)(v)), increased by any combination of a drug or biological product that the Secretary determines 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 cannot be promptly resolved—

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

(B) as otherwise determined by the Secretary.

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

(i) IME.—

(1) IN GENERAL.—Section 1886(d)(5)(B)(v) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)(v)) is amended—

(A) by redesigning 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 paragraph is attributable to resident positions distributed to a hospital under subsection (b)(9), the indirect teaching adjustment factor shall be computed in the usual manner as provided under clause (ii) with respect to such resident positions.

(ii) IME.—

(A) DEFINITIONS.—In this section—

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

(A) a non-discriminatory price for the sale of the drug or biological product, or any combination of a drug or biological product, that is lower than, 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–3(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;

(ii) FOR AMENDMENTS.—(A) amends—

(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); and

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

(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), unless the shortage cannot be promptly resolved—

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

(B) as otherwise determined by the Secretary.

(iii) IME.—

(A) amends—

(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); and

(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;
(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.—

(I) 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.

(II) Elements.—

(A) In General.—To prevail in a civil action brought under paragraph (I), 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 was brought, 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;

(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 authorized by the Secretary in accordance with paragraph (2)(B); and

(iii) met any other requirements the Secretary determines to be necessary; or

(ii) otherwise satisfied the Secretary that the license holder earned on the covered product during development or testing adequate safeguards to assure safe use of the covered product.

(3) AFFIRMATIVE DEFENSE.—In a civil action brought under paragraph (1), it shall be an affirmative defense on which the defendant shall have the burden of persuasion by a preponderance of the evidence—

(I) that, on the date on which the eligible product developer requested to purchase sufficient quantities of the covered product from the license holder—

(aa) the license holder is not required to sell sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms; or

(bb) the date on which the license holder received a copy of the covered product authorized by the Secretary in accordance with paragraph (2)(B); and

(ii) the eligible product developer received sufficient quantities of the covered product.

(4) AVOIDANCE OF DELAY.—The court may suspend the civil action and stay any other action under paragraph (2)(B) for cause shown to a REMS with ETASU for purposes of—

(I) for a covered product that is subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder provided to the eligible product developer requested to purchase sufficient quantities of 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 authorized by the Secretary in accordance with paragraph (2)(B); and

(iii) met any other requirements the Secretary may establish.

(III) NOTICE.—A covered product authorization issued by the Secretary in the form described in subsection (f) 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 with ETASU.

(3) REMS with ETASU for purposes of—

(A) in general.—If a covered product is subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder received the request; or

(B) otherwise satisfied the Secretary that the license holder earned on the covered product during development or testing adequate safeguards to assure safe use of the covered product.

(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 sufficient quantities of the covered product on commercially reasonable, market-based terms; or

(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).

(II) the Secretary may require a drug that is the subject of an abbreviated new drug application and its reference drug product.

(II) a different, comparable aspect of the elements to assure safe use within the meaning of section (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 Federal antitrust laws.

SEC. 305. REMS APPROVAL PROCESS FOR SUBSEQUENT FILERS.

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

(1) in subsection (c)(4)(B)—

(I) by adding at the end the following:

"(ii) when the provision 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) the license holder failed to comply with an order issued under clause (I).

(II) a different, comparable aspect of the elements to assure safe use within the meaning of section (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) by adding at the end the following:

"Elements to assure safe use, if required under subsection (f) for the listed drug.

(b) 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), unless—

(I) the Secretary may require a drug that is the subject of an abbreviated new drug application and its reference drug product."

"(i) a single, shared system with the listed drug under subsection (f) or

(II) the Secretary may require a drug that is the subject of an abbreviated new drug application and its reference drug product, 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:

"(I) SEPARATE REMS.—When used in this section, the terms "different, comparable aspect of the elements to assure safe use, if required under subsection (f) for the listed drug" and "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 506(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 506(j) with the same such reference listed drug, but achieves the same level of safety as such strategy."

SEC. 306. FUNDING FOR OPIOID GRANT PROGRAM FOR STATE RESPONSE TO OPIOID ABUSE CRISIS.

Section 1033(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, $955,000,000 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 (Mr. TONKO) 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 gutting protections for pre-existing conditions. Republicans have repeatedly voted to strip Medicaid coverage for millions suffering 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, 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.

When I was 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, one in pain medicine, or one in pain medicine. We all have seen firsthand the need for 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 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. I also appreciate 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?

This one needs 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 and offer an amendment.

The SPEAKER pro tempore. The gentleman from Oregon, if you wish to respond, you are recognized for 5 minutes.

The SPEAKER pro tempore. The previous question is ordered to the决议 by consent.

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 subcommittee in 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 going 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 yeas and nays were ordered.

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 6 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. 237]
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 mandatory cooperative 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 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), about 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) 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

(v) in the case of a firefighter for whom information on such number and type is unavailable, whether the firefighter is unable to provide such information.

(2) INFORMATION ON DIAGNOSES AND TREATMENT.—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. 280c(c)(2)(D)), to obtain—

(A) data on diagnoses and source of information; and

(B) pathological data characterizing the cancer, including additional risk factors, as appropriate, and other information relevant to a cancer incidence study of firefighters.

(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 voluntary, 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.

(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 MAINTENANCE 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 firefighters, 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 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 is made available in a manner that, at a minimum, protects personal privacy to the extent required by applicable Federal and State laws.

(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 laws.

(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.