Management Through Better Data Act, and I would like to thank Representative BEN RAY LUJÁN for joining me in making this a bipartisan effort as an introduction as it went through committee, and now here as we are continuing to address this on the floor.

Opioid addiction we know is plaguing our communities all across the country, creating victims, devastating families, and creating economic ruin. Long-term solutions to combating this crisis depend upon safety with existing therapies and deployment of novel next generation therapies.

We need to ensure the policy and regulatory environment allows for greater adoption and use of less addictive treatments. This legislation will facilitate better clinical data on nonopioid alternatives so that doctors have more prescribing options and fewer opioids are prescribed in the first place, lowering the risk of addiction.

The FDA is responsible for protecting public health by ensuring the safety and efficacy of drugs, biological products, and medical devices. While there may be alternatives to opioids for certain patients and conditions, there is a need for additional clarity and flexibility regarding what drug developers need to do to help reduce the need for opioids as part of the pain treatment regimen.

This bill directs the FDA to have public meetings and issue guidance to industry, addressing data collection and labeling for medical products that reduce pain and may replace, delay, or reduce the use of oral opioids. This is one more effort to remove the barriers to investment and unleash the full potential of biomedical expertise to address this growing crisis.

This is the primary reason, I am pleased to say, our bill has the strong support of the Biotechnology Innovation Organization, also known as BIO, which represents more than 1,000 businesses, academic institutions, State biotechnology centers, and related entities.

The experts believe this bill will stimulate renewed research and development, and more effectively prevent abuse. This is a step in the right direction and allows doctors to better meet their commitment to their most vulnerable patients by giving them both diverse and better options for nonaddictive treatments for pain.

Mr. Speaker, I thank the House today for addressing this issue, and really the ability to work together and find these solutions that we know are plaguing so many of our families. Everywhere we go we are all hearing about these stories, and I am heartened today we have joined together to provide more solutions.

Mr. WALDEN. Mr. Speaker, I have no other speakers on this bill, so I would encourage support of H.R. 449, and I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I would also urge my colleagues to support this legislation, and I yield back the balance of my time.

Ms. JACKSON LEE. Mr. Speaker, I rise in strong support of H.R. 449, the Synthetic Drug Awareness Act of 2017, which requires the Surgeon General to report to Congress on the public health effects of the in reased use since January 2010 by individuals who are 12 to 18 years old of drugs developed and manufactured to avoid control under the Controlled Substances Act.

The term "synthetic drug" means a drug which is developed and manufactured to avoid control under the Controlled Substances Act.

There are more than 200 identified synthetic drug compounds and more than 90 different synthetic drug marijuana compounds.

Many of these synthetic drugs are made in foreign countries and then smuggled into the United States.

These clandestinely-made drugs have no manufacturing safety standards that are normally required by the Food and Drug Administration.

Synthetic opioids have surpassed prescription opioids as the most common drug class involved in overdose deaths in the United States.

According to the Drug Enforcement Administration, fentanyl-related deaths nationwide are up from previous years by 73 percent.

Fentanyl, a synthetic opioid created using man-made chemical components rather than naturally occurring ingredients, is 50-100 times more potent than morphine.

Overall, drug overdose deaths involving fentanyl-type drugs in th United States rose from about 3,000 in 2010 to more than 19,400 in 2016.

The rate of teen drug overdose deaths in the United States climbed 19 percent from 2014 to 2015, from 3.1 deaths per 100,000 teens to 3.7 per 100,000.

The number of American teens to die of a drug overdose leapt by almost a fifth in 2015 after seven years of decline.

The opioid epidemic claimed more than 52,000 lives in 2015.

In Texas, Synthetic opioids account for almost one-fifth of drug related overdoses.

In 2016, there were 1,375 opioid-related overdose deaths in Texas specifically, according to the National Institute on Drug Abuse.

Last year, 364 drug-related overdose deaths happened in Houston.

Synthetic marijuana, methamphetamine, cocaine, and heroin top the list of drug-related problems in the Houston area.

Geographically, death rates from overdoses involving synthetic opioids increased in 21 states, with 10 states doubling their rates from 2016–2017.

No area of the United States is exempt from this epidemic—we all know a friend, family member or loved one devastated by opioids.

H.R. 449 is a positive step in the right direction, I urge my colleagues to vote yes on H.R. 449, the Synthetic Drug Awareness Act of 2017.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Ohio (Mr. LATTA), that the House suspend the rules and pass the bill, H.R. 449, as amended.

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

The title of the bill was amended so as to read: ''A bill to require the Surgeon General of the Public Health Service to submit to Congress a report on the health effects of new psychoactive substances (including synthetic drugs) use.''.

A motion to reconsider was laid on the table.

□ 1430

BETTER PAIN MANAGEMENT THROUGH BETTER DATA ACT OF 2018

Mr. WALDEN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5473) to direct the Secretary of Health and Human Services to update or issue one or more guidances addressing alternative methods for data collection on opioid sparing and inclusion of such data in product labeling, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5473

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Better Pain Management Through Better Data Act of 2018''.

SEC. 2. GUIDANCE ADDRESSING ALTERNATIVE APPROACHES TO DATA COLLECTION AND LABELING CLAIMS FOR OPIOID SPARING.

(a) IN GENERAL.—For purposes of assisting sponsors in collecting and incorporating opioid-sparing data in product labeling, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall conduct a public meeting and update or issue one or more guidances in accordance with subsection (b).

(b) GUIDANCE.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall update or issue one or more guidances addressing—

(A) alternative methods for data collection on opioid sparing;

(B) alternative methods for inclusion of such data in product labeling; and

(C) investigations other than clinical trials, including partially controlled studies and objective trials without matched controls such as historically controlled analyses, open-label studies, and meta-analyses, on opioid sparing for inclusion in product labeling.

(2) CONTENTS.—The guidances under paragraph (1) shall address—

(A) innovative clinical trial designs for ethically and efficiently collecting data on opioid sparing for inclusion in product labeling;

(B) primary and secondary endpoints for the reduction of opioid use while maintaining adequate pain control;

(C) use of real world evidence, including patient registries, and patient reported outcomes to support inclusion of opioid-sparing data in product labeling; and

(D) how sponsors may obtain feedback from the Secretary relating to such issues prior to—

(i) commencement of such data collection; or

(ii) the submission of resulting data to the Secretary.

(3) PUBLIC MEETING.—Prior to updating or issuing the guidances required by paragraph

(1), the Secretary shall consult with stakeholders, including representatives of regulated industry, academia, patients, and provider organizations, through a public meeting to be held not later than 12 months after the date of enactment of this Act.

(4) TIMING.—The Secretary shall—

(A) not later than 12 months after the date of the public meeting required by paragraph (3), update or issue the one or more draft guidances required by paragraph (1); and

(B) not later than 12 months after the date on which the public comment period for such draft guidances closes, finalize such guidances.

(c) DEFINITION.—In this section:

(1) The terms ''opioid sparing'' and ''opioid-sparing'' refer to the use of drugs or devices (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that reduce pain while enabling the reduction, replacement, or avoidance of oral opioids.

(2) The term ''Secretary'' means the Secretary of Health and Human Services.

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

The Chair recognizes the gentleman from Oregon.

GENERAL LEAVE

Mr. WALDEN. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days in which to revise and extend their remarks and insert extraneous materials in the RECORD on the bill.

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

There was no objection.

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

Mr. Speaker, I rise today to speak in favor of this legislation, and I want to thank Representatives COMSTOCK and LUJÁN for their leadership on it.

This bill would take steps to facilitate the development of products that reduce, replace, or prevent the use of opioids. Specifically, this legislation will direct the FDA to hold a public meeting and update the agency's guidance on opioid sparing data that can be used to support updated product labeling and claims.

For many Americans, Mr. Speaker, dealing with chronic or acute pain, there are limited alternatives to opioids, but for some patients, there may be therapeutic alternatives which do not share the same risks inherent in opioid use. This bill will facilitate the process of getting information to providers and patients at a critical juncture in their treatment.

By reducing the need to start an opioid, we can stop addiction before it starts, and we can save countless lives in the process. So I urge my colleagues to vote in favor of this narrowly tailored, commonsense, and noncontroversial measure.

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

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

Mr. Speaker, I rise in support of H.R. 5473, legislation offered by my colleagues, Representatives LUJÁN and COMSTOCK.

H.R. 5473 would provide greater clarity to drug and device manufacturers regarding the studies that should be conducted for purposes of making claims on the labeling of medical products that they may replace, delay, or reduce the use of opioids.

This is practical legislation, Mr. Speaker, that I believe will help to encourage manufacturers to do the necessary work to determine how we can identify for providers and patients medical products that can serve as alternatives to the use of opioids for purposes of pain treatment.

Mr. Speaker, I urge my colleagues to vote in support of H.R. 5473, and I reserve the balance of my time.

Mr. WALDEN. Mr. Speaker, I have no other speakers on this legislation, and I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield such time as he may consume to the gentleman from New Mexico (Mr. BEN RAY LUJÁN), who is one of the sponsors of this bill.

Mr. BEN RAY LUJÁN of New Mexico. Mr. Speaker, I rise in support of the Better Pain Management Through Better Data Act.

Current data collection models used by the Food and Drug Administration to measure clinical effectiveness are not ideally suited to accelerate development of opioid-sparing products. This bipartisan legislation will better allow the FDA to obtain the data they need to more quickly approve label claims for nonaddictive pain medications.

I think I have said this at least 100 times at this point, but we must work with our pharmaceutical partners and the FDA to make sure that patients across the country have nonaddictive pain management options.

I come from a blue-collar district with ironworkers and ranchers and a whole lot of jobs where wear and tear on the body is inevitable. It is simply unrealistic to think that we won't have people who need access to pain therapy. That is where nonaddictive therapies come in. This bill is another step forward in making sure that everyone has more options to treat pain.

While we are talking about nonaddictive pain medications and how important they are to break the cycle of addiction back home, I want to take a second to direct my comments toward all the pharmaceutical manufacturers who are developing or plan to develop drugs in this space: This is important. We need you to be innovative, and we need you to be aggressive.

That being said, Mr. Speaker, I am already starting to be concerned regarding the cost of these drugs. Let me put this in plain English. I am worried that the people living in different parts of America may be able to afford these drugs but families who are struggling and worrying about how to make that family budget work are going to be left out. If people can't afford these therapies and these treatments, they are not going to make a bit of difference.

We cannot create another layer of people who can afford medications and therapies and people who cannot, especially not when this issue is so important. All nonaddictive pain medications must be affordable, accessible, and of high quality.

I appreciate the hard work of the committee staff, Chairman WALDEN, Ranking Member PALLONE, and all the stakeholders who helped get this bill to the finish line.

This epidemic is affecting too many New Mexicans, too many Americans, to not think about long-term strategies for preventing opioid use disorder in the future.

I appreciate Chairman WALDEN's remarks. I thank him for acknowledging that this is not the end of our work.

This committee has much work to do not just with this package, but into the future, until we are able to help everyone who is fighting addiction in America. I look forward to working with our colleagues, with the administration, and with anyone and everyone out there to make a difference when it comes to addiction in our country.

Mr. WALDEN. Mr. Speaker, I have no further speakers on this legislation. I urge my colleagues to support it.

I commend the gentleman from New Mexico (Mr. BEN RAY LUJÁN) and the gentlewoman from Virginia (Mrs. COMSTOCK) for their tireless work on this legislation.

Mr. Speaker, I urge my colleagues to vote in favor of it, and I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I also ask that my colleagues support this bipartisan legislation, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Oregon (Mr. WALDEN) that the House suspend the rules and pass the bill, H.R. 5473, as amended.

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

A motion to reconsider was laid on the table.

TESTING INCENTIVE PAYMENTS FOR BEHAVIORAL HEALTH PROVIDERS FOR ADOPTION AND USE OF CERTIFIED ELECTRONIC HEALTH RECORD TECHNOLOGY

Mr. WALDEN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3331) to amend title XI of the Social Security Act to promote testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3331

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