Barletta
Barr
Barton
Bass
Beatty
Becerra
Benishek
Bera
Beyer
Bilirakis
Bishop (GA)
Bishop (MI)
Bishop (UT)
Black
Blackburn
Blum
Blumenauer
Bonamici
Bost
Boustany
Boyle, Brendan F.
Brady (PA)
Brady (TX)
Brat
Bridenstine
Brooks (AL)
Brooks (IN)
Brown (FL)
Brownley (CA)
Buchanan
Buck
Bucshon
Burgess
Bustos
Butterfield
Byrne
Calvert
Capps
Capuano
Cárdenas
Carney
Carson (IN)
Carter (GA)
Carter (TX)
Castro (TX)
Chabot
Chaffetz
Chu, Judy
Cicilline
Clark (MA)
Clarke (NY)
Clawson (FL)
Clay
Cleaver
Clyburn
Coffman
Cohen
Cole
Collins (GA)
Collins (NY)
Comstock
Conaway
Connolly
Conyers
Cook
Cooper
Costa
Costello (PA)
Courtney
Cramer
Crawford
Crenshaw
Crowley
Cuellar
Culberson
Cummings
Curbelo (FL)
Davis (CA)
Davis, Danny
Davis, Rodney
DeFazio
DeGette
Delaney
DeLauro
DelBene
Denham
Dent
DeSantis
DeSaulnier
DesJarlais
Deutch
Diaz-Balart
Dingell
Doggett
Dold
Donovan
Doyle, Michael F.
Duckworth
Duffy
Duncan (SC)
Duncan (TN)
Edwards
Ellison
Ellmers (NC)
Emmer (MN)
Engel
Eshoo
Esty
Farenthold
Farr
Fitzpatrick
Fleischmann
Fleming
Flores
Forbes
Fortenberry
Foster
Foxx
Frankel (FL)
Frelinghuysen
Fudge
Gabbard
Gallego
Garamendi
Garrett
Gibbs
Gibson
Gohmert
Goodlatte
Gosar
Gowdy
Graham
Granger
Graves (GA)
Graves (LA)
Graves (MO)
Grayson
Green, Al
Green, Gene
Griffith
Grijalva
Grothman
Guinta
Guthrie
Gutiérrez
Hahn
Hanna
Hardy
Harper
Harris
Hartzler
Heck (NV)
Heck (WA)
Hensarling
Hice, Jody B.
Higgins
Hill
Himes
Hinojosa
Holding
Honda
Hoyer
Hudson
Huelskamp
Huffman
Huizenga (MI)
Hultgren
Hunter
Hurd (TX)
Hurt (VA)
Israel
Issa
Jackson Lee
Jeffries
Jenkins (KS)
Jenkins (WV)
Johnson (GA)
Johnson (OH)
Johnson, E. B.
Johnson, Sam
Jolly
Jones
Jordan
Joyce
Kaptur
Katko
Keating
Kelly (IL)
Kelly (MS)
Kelly (PA)
Kennedy
Kildee
Kilmer
Kind
King (IA)
King (NY)
Kinzinger (IL)
Kirkpatrick
Kline
Knight
Kuster
Labrador
LaHood
LaMalfa
Lamborn
Lance
Langevin
Larsen (WA)
Larson (CT)
Lawrence
Lee
Levin
Lewis
Lieu, Ted
Lipinski
LoBiondo
Loebsack
Lofgren
Long
Loudermilk
Love
Lowenthal
Lowey
Lucas
Luetkemeyer
Lujan Grisham (NM)
Luján, Ben Ray (NM)
Lummis
Lynch
MacArthur
Maloney, Carolyn
Maloney, Sean
Marchant
Marino
Massie
Matsui
McCarthy
McCaul
McClintock
McCollum
McDermott
McGovern
McHenry
McKinley
McMorris Rodgers
McNerney
McSally
Meadows
Meehan
Meeks
Meng
Messer
Mica
Miller (FL)
Miller (MI)
Moolenaar
Moore
Moulton
Mullin
Mulvaney
Murphy (FL)
Murphy (PA)
Nadler
Napolitano
Neal
Neugebauer
Newhouse
Noem
Nolan
Norcross
Nugent
Nunes
O'Rourke
Olson
Palazzo
Pallone
Palmer
Pascrell
Paulsen
Payne
Pearce
Pelosi
Perlmutter
Perry
Peters
Peterson
Pingree
Pittenger
Pocan
Poe (TX)
Poliquin
Polis
Pompeo
Posey
Price (NC)
Price, Tom
Quigley
Rangel
Ratcliffe
Reed
Reichert
Renacci
Ribble
Rice (NY)
Rice (SC)
Richmond
Rigell
Roby
Roe (TN)
Rogers (AL)
Rogers (KY)
Rohrabacher
Rokita
Rooney (FL)
Ros-Lehtinen
Roskam
Ross
Rothfus
Rouzer
Roybal-Allard
Royce
Ruiz
Ruppersberger
Rush
Russell
Ryan (OH)
Salmon
Sánchez, Linda T.
Sanchez, Loretta
Sanford
Sarbanes
Scalise
Schakowsky
Schiff
Schrader
Schweikert
Scott (VA)
Scott, Austin
Scott, David
Sensenbrenner
Serrano
Sessions
Sewell (AL)
Sherman
Shimkus
Shuster
Simpson
Sinema
Sires
Slaughter
Smith (MO)
Smith (NE)
Smith (NJ)
Smith (TX)
Smith (WA)
Speier
Stefanik
Stewart
Stivers
Stutzman
Swalwell (CA)
Takano
Thompson (CA)
Thompson (MS)
Thompson (PA)
Thornberry
Tiberi
Tipton
Titus
Tonko
Torres
Trott
Tsongas
Turner
Upton
Valadao
Van Hollen
Vargas
Veasey
Vela
Velázquez
Visclosky
Wagner
Walberg
Walden
Walker
Walorski
Walters, Mimi
Walz
Wasserman Schultz
Waters, Maxine
Watson Coleman
Weber (TX)
Webster (FL)
Welch
Wenstrup
Westerman
Westmoreland
Williams
Wilson (FL)
Wilson (SC)
Wittman
Womack
Woodall
Yarmuth
Yoder
Yoho
Young (AK)
Young (IA)
Young (IN)
Zeldin
Zinke

NOT VOTING—12

Cartwright
Castor (FL)
Fattah
Fincher
Franks (AZ)
Hastings
Herrera Beutler
Latta
Mooney (WV)
Pitts
Takai
Whitfield

□ 1622

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

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

WOMEN AIRFORCE SERVICE PILOT ARLINGTON INURNMENT RESTORATION ACT

Mr. ABRAHAM. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the bill (H.R. 4336) to amend title 38, United States Code, to provide for the burial in Arlington National Cemetery of the cremated remains of certain persons whose service has been determined to be active service, with the Senate amendments thereto, and concur in the Senate amendments.

The Clerk read the title of the bill.

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

The Clerk read as follows:

Senate amendments:

(1) On page 2, line 1, strike ''**BURIAL**'' and insert ''**INURNMENT**''.

(2) On page 2, line 8, strike ''that'' and insert ''that,''.

(3) On page 2, line 11, insert ''above ground'' before ''inurnment''.

Amend the title so as to read: ''An Act to amend title 38, United States Code, to provide for the inurnment in Arlington National Cemetery of the cremated remains of certain persons whose service has been determined to be active service.''.

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

There was no objection.

A motion to reconsider was laid on the table.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on additional motions to suspend the rules on which a recorded vote or the yeas and nays are ordered, or on which the vote incurs objection under clause 6 of rule XX.

Any record votes on postponed questions will be taken later.

OPIOID REVIEW MODERNIZATION ACT OF 2016

Mr. GUTHRIE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4976) to require the Commissioner of Food and Drugs to seek recommendations from an advisory committee of the Food and Drug Administration before approval of certain new drugs that are opioids without abuse-deterrent properties, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 4976

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 ''Opioid Review Modernization Act of 2016''.

SEC. 2. FDA OPIOID ACTION PLAN.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 569 of such Act (21 U.S.C. 350bbb–8) the following:

''SEC. 569–1. OPIOID ACTION PLAN.

''(a) NEW DRUG APPLICATION.—

''(1) IN GENERAL.—Subject to paragraph (2), prior to the approval pursuant to an application under section 505(b) of a new drug that is an opioid and does not have abuse-deterrent properties, the Secretary shall refer the application to an advisory committee of the Food and Drug Administration to seek recommendations from such advisory committee.

''(2) PUBLIC HEALTH EXEMPTION.—A referral to an advisory committee under paragraph (1) is not required with respect to a new drug if the Secretary—

''(A) finds that such a referral is not in the interest of protecting and promoting public health;

''(B) finds that such a referral is not necessary based on a review of the relevant scientific information; and

''(C) submits a notice containing the rationale for such findings to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

''(b) PEDIATRIC OPIOID LABELING.—The Secretary shall convene the Pediatric Advisory Committee of the Food and Drug Administration to seek recommendations from such Committee regarding a framework for the inclusion of information in the labeling of

drugs that are opioids relating to the use of such drugs in pediatric populations before the Secretary approves any labeling or change to labeling for any drug that is an opioid intended for use in a pediatric population.

''(c) SUNSET.—The requirements of subsections (a) and (b) shall cease to be effective on October 1, 2022.''.

SEC. 3. PRESCRIBER EDUCATION.

Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, as part of the Food and Drug Administration's evaluation of the Extended-Release/Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, and in consultation with relevant stakeholders, shall develop recommendations regarding education programs for prescribers of opioids pursuant to section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), including recommendations on—

(1) which prescribers should participate in such programs; and

(2) how often participation in such programs is necessary.

SEC. 4. GUIDANCE ON EVALUATING THE ABUSE DETERRENCE OF GENERIC SOLID ORAL OPIOID DRUG PRODUCTS.

Not later than 2 years after the end of the period for public comment on the draft guidance entitled ''General Principals for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products'' issued by the Center for Drug Evaluation and Research of the Food and Drug Administration in March 2016, the Commissioner of Food and Drugs shall publish in the Federal Register a final version of such guidance.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Kentucky (Mr. GUTHRIE) and the gentleman from Texas (Mr. GENE GREEN) each will control 20 minutes.

The Chair recognizes the gentleman from Kentucky.

GENERAL LEAVE

Mr. GUTHRIE. 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 Kentucky?

There was no objection.

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

Mr. Speaker, I rise in support of H.R. 4976, the Opioid Review Modernization Act of 2016, introduced by the gentleman from New York (Mr. SEAN PATRICK MALONEY) and the gentleman from New Jersey (Mr. LANCE).

□ 1630

Opioid use disorder and overdose deaths have reached epidemic levels. A comprehensive approach is needed to reverse these trends and the tragic toll they have taken on families and communities across our country.

The Food and Drug Administration does have a critical role to play in such an approach. Patients living with serious pain must have access to safe and effective therapies to help them function and lead productive lives. FDA reviews prescription pain relievers, like all new drug products, to determine whether their benefits outweigh their risks.

It is important that the FDA hear recommendations from expert advisory committees prior to making key product and labeling decisions, particularly to ensure that any such risks are effectively communicated, understood, and mitigated.

Specifically, H.R. 4976 requires that FDA receives input from an advisory committee regarding approval of new opioids that do not utilize abuse-deterrent properties, in addition to developing a framework for labeling any opioid intended for pediatric use.

The bill also requires the agency to finalize guidance on evaluating abuse deterrence in generic opioid medications and issue recommendations regarding prescriber education tied to the risk evaluation mitigation strategy programs.

This bill would strengthen FDA's Opioid Action Plan, defining outcomes with meaningful timeframes. I urge my colleagues to support H.R. 4976.

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

Mr. GENE GREEN of Texas. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in support of H.R. 4976, the Opioid Review Modernization Act.

We know that there is not one solution addressing the opioid crisis that is striking communities across the country. A comprehensive approach that balances the appropriate use of opioids, while deterring misuse and diversion, requires the involvement of many government agencies, including the Food and Drug Administration.

As the agency tasked with reviewing pain medications for safety and effectiveness, we know that the FDA can play a critical role in addressing the safe use of these products for patients with chronic or acute pain.

I was pleased when the FDA announced earlier this year that the agency developed a comprehensive action plan to help reduce the burden of opioid abuse on American families and communities. In this plan, the FDA outlined concrete steps it intended to take, including:

Expanding its use of advisory committees before approving any new opioid drug that does not have abuse-deterrent properties;

Updating the risk evaluation and mitigation strategy program to incorporate advisory committee recommendations regarding medical training on pain management and safe prescribing of opioids; and

Taking actions to expand patient access to abuse-deterrent formulations for opioids to help discourage their abuse.

The Opioid Review Modernization Act builds on these efforts and would require the FDA to work closely with expert advisory committees before making critical opioid approach and labeling decisions, develop recommendations regarding prescriber education programs that address extended-release and long-acting opioids, including those who should participate and how often, and encouraging development and approval of generic opioids with abuse-deterrent properties.

H.R. 4976 will engage a key public agency, the FDA, to help address our current opioid crisis by improving regulatory oversight of opioids early in the process while also assisting prescribers in the safe dispensing of these products.

I would like to thank Representative SEAN PATRICK MALONEY and Congressman LEONARD LANCE for their leadership in introducing this bill. I encourage my colleagues to support H.R. 4976.

I reserve the balance of my time.

Mr. GUTHRIE. Mr. Speaker, I yield 3 minutes to the gentleman from New Jersey (Mr. LANCE), my good friend and a fellow member of the Energy and Commerce Committee.

Mr. LANCE. Mr. Speaker, I certainly thank Mr. GUTHRIE of Kentucky and Mr. GENE GREEN of Texas for their leadership on this overall issue. We on the Energy and Commerce Committee have worked in a completely bipartisan fashion on this terrible crisis that affects the American people.

Mr. Speaker, I rise in strong support of H.R. 4976, the Opioid Review Modernization Act. I thank Congressman SEAN PATRICK MALONEY from the State of New York for his partnership on this legislation, and I certainly thank Chairman UPTON and Ranking Member PALLONE of the Energy and Commerce Committee for leading this and many other bipartisan bills to passage today that address this pressing national issue.

This bill and the larger package together are a great step forward in the fight against the scourge of drug addiction. In my home State of New Jersey, we face a drug epidemic that is hitting many communities hard, and that is true across the entire Nation. This crisis strains law enforcement and taxpayer resources, and, of course, tragically, it cuts too many lives short.

H.R. 4976 targets opioid addiction's strong ties to prescription drug abuse and the issue of overprescription. Studies have shown healthcare providers write nearly 300 million opioid prescriptions a year in this country. That number is truly staggering.

Our legislation will make sure that the Food and Drug Administration rigorously reviews the benefits and risks of opioid pain medications and how they are communicated to prescribers and patients. The bill reforms critical product approval and labeling decisions and encourages the development and approval of opioids with abuse-deterrent properties.

Our Federal health agencies must be working in concert with the medical and pharmaceutical communities to combat drug abuse, and this legislation helps make that happen.

Just last week I met with Hunterdon County, New Jersey, Prosecutor Anthony Kearns on what law enforcement is doing on the ground level to fight this epidemic. In New Jersey, Mr. Speaker, the county prosecutor is the equivalent of the county district attorney in most States across the Nation.

Public servants like Prosecutor Kearns and others are doing all they can to protect our children and keep our local communities drug free, but this legislative package will help in their efforts and give them and other governmental entities more critical tools.

Those in Washington and local leaders need to be working together for the benefit of the American people. H.R. 4976 and the larger package will work toward that goal and ultimately help combat this drug abuse crisis.

Mr. GENE GREEN of Texas. Mr. Speaker, I yield 3 minutes to the gentleman from New York (Mr. SEAN PATRICK MALONEY), a cosponsor of this bill.

Mr. SEAN PATRICK MALONEY of New York. Mr. Speaker, I thank my good friend from Texas for yielding. I want to echo my thanks as well to Chairman UPTON and Ranking Member PALLONE and my good friend, Mr. LANCE of New Jersey.

I rise in support of my legislation, H.R. 4976, the Opioid Review Modernization Act.

Heroin and opioid addiction is a serious and growing epidemic, especially in the communities I represent in the lower Hudson Valley of New York. After more than 55 townhalls with my neighbors across the Hudson Valley in the last 3½ years, I can say there is no subject I have heard about more in visits to communities throughout my district. Really, everywhere I go, I hear heartbreaking stories of addiction and of loss, and we have had far too many funerals.

I spoke to a woman named Cynthia in Newburgh who told me her son struggles every day with addiction. He is trying to stay clean, but he can't find a meeting locally to visit.

A woman named Samantha from Brewster said she is worried about the basic lack of options for treating addicts like her son.

Patricia in Warwick has said the facilities there lack the basic necessities for treating addicts like her son.

We have a shortage of beds for patients who are seeking treatment. In Dutchess County, New York, alone, we have seen a 160 percent increase in the number of drug overdoses since 2009. This epidemic is being felt nationwide. It doesn't care about the color of your skin or the size of your paycheck.

Deaths from heroin overdoses have more than tripled since 2010 in our country, and it is often driven by an addiction first to prescription pain medicine. We now have more than 47,000 people dying a year, the equivalent of 125 Americans every day. It is a staggering figure, Mr. Speaker, and we in Congress can and must do more to fight this growing epidemic.

So my bill takes an important, but simple, step to avoid opioid addiction and to avoid further loss by using both new technologies and a little common sense.

Specifically, it would require the Food and Drug Administration to consult with expert advisory committees for the approval of new opioids that do not use deterrent properties, such as extended-release capsules. We know this can thwart the misuse of these products by people who are struggling with addiction.

Additionally, the legislation will encourage the development of generic opioids that utilize these abuse-deterrent properties. And, of course, the FDA can do more.

We can require them to evaluate and make recommendations on better programs to prevent prescribers of opioids from overprescribing, since we often hear that it is that overprescription that leads people into trouble with opioids and, later, with heroin.

As part of a comprehensive package of legislation to combat the opioid epidemic, my bill is just one more tool in our toolkit, providing incentives for pharmaceutical companies to use antiabuse technologies and create a plan to educate our well-meaning doctors about the potential dangers of prescription opioids.

I urge my colleagues to vote ''yes'' on this important measure.

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

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

Mr. Speaker, this bill, the FDA's Opioid Action Plan, is important in our larger package of bills. I urge my colleagues to support this measure, H.R. 4976.

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

Mr. PALLONE. Mr. Speaker, I wish to voice my support for H.R. 4976, which would complement the efforts taken by the Food and Drug Administration to combat the opioid abuse crisis.

The opioid epidemic has hit nearly all communities across the country—young and old, rich and poor, urban and rural. The Energy and Commerce Committee has held a number of hearings on this issue, inviting a wide range of stakeholders to come and share with us their suggestions on how Congress can help to address this crisis. What has been made clear is that there is not one solution. It will take the collaboration and expertise of a variety of agencies, and it must not only appropriately account for the need for access to opioids for those with acute and chronic pain, but it must also discourage misuse and diversion.

As the public health agency responsible for reviewing pain medications for safety and efficacy, the Food and Drug Administration should play a critical role in making clear how prescription opioids can be safely used, in encouraging the development of technologies to prevent abuse, and identifying what education would assist prescribers who treat patients with opioids.

In February, FDA outlined an action plan that included a number of steps focused on the agency's regulatory approach to opioids.

These actions included: reassessing the risk-benefit approval framework for opioid use; convening an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties; consulting with the Pediatric Advisory Committee regarding recommendations for pediatric opioid labeling before any new labeling is approved; updating the Risk Evaluation and Mitigation Strategy or REMS program for extended-release and long-acting opioids regarding prescriber training; developing changes to immediate-release opioid labeling to include additional warnings and safety information; reviewing options to make naloxone more accessible, such as availability over-the-counter; and strengthening post-market requirements, among other steps.

I was pleased by the agency's announcement as I believe it was an important step forward in improving regulatory oversight of opioids, and would help to take another step towards addressing the opioid crisis holistically.

H.R. 4976, the Opioid Review Modernization Act, was introduced by Representatives SEAN PATRICK MALONEY and LEONARD LANCE to build on the actions announced by the FDA. The legislation would require the agency to work closely with expert advisory committees before making critical product approval and labeling decisions, make recommendations regarding education programs for prescribers of extended-release and long-acting opioids, and would encourage the development and approval of generic opioids with abuse-deterrent properties.

These actions will be critical to improving the way we regulate opioids to ensure that these products are used safely and appropriately and I urge my colleagues to support this legislation.

The SPEAKER pro tempore (Mr. STEWART). The question is on the motion offered by the gentleman from Kentucky (Mr. GUTHRIE) that the House suspend the rules and pass the bill, H.R. 4976.

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

A motion to reconsider was laid on the table.

CO-PRESCRIBING TO REDUCE OVERDOSES ACT OF 2016

Mr. GUTHRIE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3680) to provide for the Secretary of Health and Human Services to carry out a grant program for co-prescribing opioid overdose reversal drugs, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3680

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 ''Co-Prescribing to Reduce Overdoses Act of 2016''.

SEC. 2. OPIOID OVERDOSE REVERSAL DRUGS PRESCRIBING GRANT PROGRAM.

(a) ESTABLISHMENT.—