

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

## NOT VOTING—12

□ 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 Principles 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 la-

beling 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.—