As you know, my Administration is pursuing the renegotiation of the North American Free Trade Agreement—something many have promised but have failed to deliver. In addition, my Administration is exploring potential trade agreement partners, including in Africa and Southeast Asia.

I hope my Administration can continue to work with the Congress to pursue new and better trade deals for America's workers, farmers, ranchers, and businesses. Extension of trade authorities procedures is essential to fulfill that task and to demonstrate to our trading partners that my Administration and the Congress share a common goal when it comes to trade.

DONALD J. TRUMP.

THE WHITE HOUSE, *March 20, 2018.*

COMMUNICATION FROM THE CLERK OF THE HOUSE

The SPEAKER pro tempore laid before the House the following communication from the Clerk of the House of Representatives:

OFFICE OF THE CLERK,
HOUSE OF REPRESENTATIVES,
Washington, DC, March 21, 2018.

Hon. PAUL D. RYAN,
The Speaker, House of Representatives, Washington, DC.

DEAR MR. SPEAKER: Pursuant to the permission granted in Clause 2(h) of Rule II of the Rules of the U.S. House of Representatives, the Clerk received the following message from the Secretary of the Senate on March 21, 2018, at 8:52 a.m.:

That the Senate passed S. 899.

With best wishes, I am

Sincerely,

KAREN L. HAAS.

PROTECT SPECIAL COUNSEL MUELLER

(Mr. COHEN asked and was given permission to address the House for 1 minute.)

Mr. COHEN. Mr. Speaker, on Monday, I addressed this House on the issue of Mr. Mueller and his important investigation in the Special Counsel's Office.

I am concerned, as we leave on Thursday or Friday, that the President could fire Mr. Rosenstein—who has authority over Mr. Mueller—or fire Mr. Sessions and put somebody in who will jeopardize Mr. Mueller's investigation.

Accordingly, a bill I have, H.R. 4669, was filed in December to protect Mr. Mueller. It gives him due process rights—if he is fired—to go to court before a three-judge Federal panel to show that he was fired for purposes which were political and not relating to his job performance.

I am filing a discharge petition today. I will be filing it in 10 minutes, asking all Members of the House to sign it; to bring this bill to the floor immediately for a vote so that we can protect the special counsel, protect Mr. Mueller, and protect America.

God Bless America.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12(a) of rule I, the Chair declares the House in recess subject to the call of the Chair.

Accordingly (at 11 o'clock and 21 minutes a.m.), the House stood in recess.

□ 1300

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mr. POE of Texas) at 1 p.m.

TRICKETT WENDLER, FRANK MONGIELLO, JORDAN MCLINN, AND MATTHEW BELLINA RIGHT TO TRY ACT OF 2018

Mr. BURGESS. Mr. Speaker, pursuant to House Resolution 787, I call up the bill (H.R. 5247) to authorize the use of eligible investigational drugs by eligible patients who have been diagnosed with a stage of a disease or condition in which there is reasonable likelihood that death will occur within a matter of months, or with another eligible illness, and for other purposes, and ask for its immediate consideration in the House.

The Clerk read the title of the bill.

The SPEAKER pro tempore. Pursuant to House Resolution 787, the bill is considered read.

The text of the bill is as follows:

H.R. 5247

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 ''Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2018''.

SEC. 2. USE OF UNAPPROVED INVESTIGATIONAL DRUGS BY PATIENTS DIAGNOSED WITH A TERMINAL ILLNESS.

(a) IN GENERAL.—Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by inserting after section 561A (21 U.S.C. 360bbb–0) the following:

''SEC. 561B. INVESTIGATIONAL DRUGS FOR USE BY ELIGIBLE PATIENTS.

''(a) DEFINITIONS.—For purposes of this section:

''(1) The term 'eligible patient' means a patient—

''(A) who has been diagnosed with an eligible illness;

''(B) who has exhausted approved treatment options and is not eligible to participate in (for a reason such as the patient not meeting inclusion criteria) a clinical trial designed to evaluate an investigational drug for the treatment of such eligible illness with which the patient has been diagnosed, including one involving the eligible investigational drug, or for whom participation in such a clinical trial is not feasible (for a reason such as a lack of geographic proximity to the clinical trial), as certified by a physician, who—

''(i) is in good standing with the physician's licensing organization or board; and

''(ii) will not be compensated for so certifying; and

''(C) who has provided to the treating physician written informed consent, as described in part 50 of title 21, Code of Federal Regulations (or any successor regulations), regarding the eligible investigational drug, or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent.

''(2) The term 'eligible investigational drug' means an investigational drug (as such term is used in section 561)—

''(A) for which a phase 1 clinical trial has been completed;

''(B) that has not been approved or licensed for any use under section 505 of this Act or section 351 of the Public Health Service Act;

''(C)(i) for which an application has been filed under section 505(b) of this Act or section 351(a) of the Public Health Service Act, as applicable, that is active; or

''(ii) that is under investigation in a clinical trial that—

''(I) is intended to form the primary basis of a claim of effectiveness in support of approval or licensure under section 505 of this Act or section 351 of the Public Health Service Act; and

''(II) is the subject of an active investigational new drug application under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act, as applicable; and

''(D) the active development or production of which—

''(i) is ongoing;

''(ii) has not been discontinued by the manufacturer; and

''(iii) is not the subject of a clinical hold under the regulations implementing section 505(i) or section 351(a)(3) of the Public Health Service Act, as applicable.

''(3) The term 'phase 1 trial' means a phase 1 clinical investigation of a drug as described in section 312.21 of title 21, Code of Federal Regulations (or any successor regulations).

''(4) The term 'eligible illness' means—

''(A) a stage of a disease or condition in which there is reasonable likelihood that death will occur within a matter of months; or

''(B) a disease or condition that would result in significant irreversible morbidity that is likely to lead to severely premature death.

''(b) ALTERNATIVE PATHWAY FOR ELIGIBLE PATIENTS WITH A TERMINAL ILLNESS.—

''(1) IN GENERAL.—Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from sections 502(f), 503(b)(4), and subsections (a) and (i) of section 505 of this Act, and section 351(a) of the Public Health Service Act so long as the conditions specified in paragraphs (2), (3), and (4) are met with respect to the provision of such investigational drugs.

''(2) COMPLIANCE WITH CERTAIN REGULATIONS.—The conditions specified in this paragraph, with respect to an eligible investigational drug referred to in paragraph (1), are that—

''(A) the eligible investigational drug is labeled in accordance with section 312.6 of title 21, Code of Federal Regulations (or any successor regulations); and

''(B) the provision of such eligible investigational drug occurs in compliance with the applicable requirements set forth in sections 312.7 and 312.8(d)(1) of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational drugs, subject to paragraph (5).

''(3) NOTIFICATION.—The condition specified in this paragraph, with respect to an eligible investigational drug referred to in paragraph (1), is that the sponsor of such eligible investigational drug notifies the Secretary of the provision of such eligible investigational drug for use by an eligible patient pursuant to this section. Such notification shall be submitted within 7 business days of the provision of such eligible investigational drug

as correspondence to the investigational new drug application described in subsection (a)(2).

''(4) ADVERSE EVENT REPORTING.—The condition specified in this paragraph, with respect to an eligible investigational drug referred to in paragraph (1), is that the sponsor or manufacturer of such eligible investigational drug has required, as a condition of providing the drug to a physician for use by an eligible patient pursuant to this section, that such physician will immediately report to such sponsor or manufacturer any serious adverse events, as such term is defined in section 312.32 of title 21, Code of Federal Regulations (or any successor regulations), associated with the use of the eligible investigational drug by the eligible patient.

''(5) APPLICATION.—For purposes of this section, the requirements set forth in sections 312.7 and 312.8(d)(1) of title 21 of the Code of Federal Regulations (or any successor regulations) are deemed to apply to any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible investigational drug pursuant to this section.

''(c) USE OF CLINICAL OUTCOMES.—

''(1) IN GENERAL.—Notwithstanding any other provision of this Act, the Public Health Service Act, or any other provision of Federal law, the Secretary may not use a clinical outcome associated with the use of an eligible investigational drug pursuant to this section to delay or adversely affect the review or approval of such drug under section 505 of this Act or section 351 of the Public Health Service Act unless—

''(A) the Secretary makes a determination, in accordance with paragraph (2), that use of such clinical outcome is critical to determining the safety of the eligible investigational drug; or

''(B) the sponsor requests use of such outcomes.

''(2) LIMITATION.—If the Secretary makes a determination under paragraph (1)(A), the Secretary shall provide written notice of such determination to the sponsor, including a public health justification for such determination, and such notice shall be made part of the administrative record. Such determination shall not be delegated below the director of the agency center that is charged with the premarket review of the eligible investigational drug.

''(d) REPORTING.—The manufacturer or sponsor of an eligible investigational drug that provides an eligible investigational drug pursuant to this section shall post on the same publicly available internet website used by the manufacturer for purposes of section 561A(b) an annual summary of any provision by the manufacturer or sponsor of an eligible investigational drug under this section. The summary shall include the number of requests received, the number of requests granted, the number of patients treated, the therapeutic area of the drug made available, and any known or suspected serious adverse events, as such term is defined in section 312.32 of title 21, Code of Federal Regulations (or any successor regulations), associated with the use of the eligible investigational drug.

''(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as limiting the authority of the Secretary to require manufacturers or sponsors of investigational drugs to review and report information relevant to the safety of such investigational drug obtained or otherwise received by the sponsor pursuant to part 312 of title 21, Code of Federal Regulations (or successor regulations).''.

(b) NO LIABILITY.—Section 561B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), is amended by adding at the end the following:

''(f) LIABILITY.—

''(1) ALLEGED ACTS OR OMISSIONS.—

''(A) MANUFACTURER OR SPONSOR.—No manufacturer or sponsor (or their agent or representative) of an investigational drug shall be liable for any alleged act or omission related to the provision of such drug to a single patient or small group of patients for treatment use in accordance with subsection (b) or (c) of section 561 or the provision of an eligible investigational drug to an eligible patient in accordance with this section, including, with respect to the provision of an investigational drug under section 561 or an eligible investigational drug under this section, the reporting of safety information, from clinical trials or any other source, as required by section 312.32 of title 21, Code of Federal Regulations (or any successor regulations).

''(B) PHYSICIAN, CLINICAL INVESTIGATOR, OR HOSPITAL.—

''(i) No licensed physician, clinical investigator, or hospital shall be liable for any alleged act or omission related to the provision of an investigational drug to a single patient or small group of patients for treatment use in accordance with subsection (b) or (c) of section 561, as described in clause (ii), or the provision of an eligible investigational drug to an eligible patient in accordance with this section, unless such act or omission constitutes on the part of such physician, clinical investigator, or hospital with respect to such investigational drug or eligible investigational drug—

''(I) willful or criminal misconduct;

''(II) reckless misconduct;

''(III) gross negligence relative to the applicable standard of care and practice with respect to the administration or dispensing of such investigational drug; or

''(IV) an intentional tort under applicable State law.

''(ii) The requirements described in this clause are the requirements under subsection (b) or (c) of section 561, including—

''(I) the reporting of safety information, from clinical trials or any other source, as required by section 312.32 of title 21, Code of Federal Regulations (or any successor regulations);

''(II) ensuring that the informed consent requirements of part 50 of title 21, Code of the Federal Regulations (or any successor regulations) are met; and

''(III) ensuring that review by an institutional review board is obtained in a manner consistent with the requirements of part 56 of title 21, Code of the Federal Regulations (or any successor regulations).

''(2) DETERMINATION NOT TO PROVIDE DRUG.—No manufacturer, sponsor, licensed physician, clinical investigator, or hospital shall be liable for determining not to provide access to an investigational drug under this section or for discontinuing any such access that it initially determined to provide.

''(3) LIMITATION.—

''(A) IN GENERAL.—Except as set forth in paragraphs (1) and (2), nothing in this section shall be construed to modify or otherwise affect the right of any person to bring a private action against a manufacturer or sponsor (or their agent or representative), physician, clinical investigator, hospital, prescriber, dispenser, or other entity under any State or Federal product liability, tort, consumer protection, or warranty law.

''(B) FEDERAL GOVERNMENT.—Nothing in this section shall be construed to modify or otherwise affect the authority of the Federal Government to bring suit under any Federal law.''.

The SPEAKER pro tempore. The gentleman from Texas (Mr. BURGESS) and the gentleman from New Jersey (Mr. PALLONE) each will control 30 minutes.

The Chair recognizes the gentleman from Texas.

GENERAL LEAVE

Mr. BURGESS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and to insert extraneous material on H.R. 5247.

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

There was no objection.

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

Mr. Speaker, earlier this year, Members of Congress heard the President during his State of the Union Address make a specific promise to the American people that the passage of right-to-try legislation would occur. This afternoon, I am proud to stand with the President and the thousands of Americans with terminal illnesses, their families, and their friends, in passing this important bill in the House.

Since 2014, nearly three out of four States, including my home State of Texas, have passed a version of right-to-try laws. I am pleased that the House is again considering H.R. 5247, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2018, so that terminally ill patients have a chance, or maybe a second chance, at life. These patients are our constituents. They could be someone we know. Let us take this opportunity to improve access to experimental treatments for them.

Over the course of the past decade, our Nation has achieved an unprecedented number of innovations and scientific breakthroughs. Through the contributions of researchers in academia and the private sector, Americans have more innovative treatments at their fingertips.

Despite these achievements, I still hear from patients with serious, life-threatening conditions, including my own constituents in north Texas, who are frustrated with what they see as regulatory barriers from trying new therapies when everything else has failed.

Mr. Speaker, as a physician, I understand that access to investigational drugs and therapies is a deeply personal priority for those seeking treatment for their loved ones with serious, life-threatening conditions.

To my friends on the other side of the aisle, I have a simple question: Why do you not want to allow these patients to exercise their right to fight for their future?

It is worth mentioning that the bill before us today is a revised, more narrowly crafted version of the one that passed the Senate last August. Since that time, the Energy and Commerce Subcommittee on Health held a hearing in early October to consider the Senate bill, where Members heard from

the Commissioner of the Food and Drug Administration, Dr. Scott Gottlieb, about the agency's concerns. We also heard testimony from patients and groups that support and oppose right to try.

From then to just recently, our committee engaged in multistakeholder efforts to improve the original right-to-try bill, as passed by the Senate. It entailed numerous conversations with patients, advocates, the Administration, authors of the bill, and stakeholders on all sides of this complex topic.

The Food and Drug Administration was never left out of the discussion. In fact, the agency provided valuable input throughout the process and up until the introduction of H.R. 5247. The aim was to open the door to innovative, experimental drugs for terminally ill patients without necessarily compromising the vital work and the mission of the Food and Drug Administration.

The current compassionate use program at the Food and Drug Administration does make a good faith effort to help patients who do not qualify for clinical trials. But right to try would actually offer patients an alternative pathway to access eligible investigational drugs, so long as they are certified by a physician who is in good standing and abides by the rules laid out in the bill.

Again, we have worked closely with the Food and Drug Administration to ensure that this new, alternative pathway does not hinder or conflict with the critically important oversight that the agency conducts.

Additionally, this bill protects patients from manufacturers mislabeling or misbranding drugs, requires sponsors and manufacturers to report adverse events to the Food and Drug Administration, and provides certain liability protections for parties participating in the new pathway.

Mr. Speaker, this alternative pathway would also be limited to individuals who are suffering from a disease or a condition where there is a reasonable likelihood of death within a matter of months or significant, reversible morbidity, and who have exhausted all FDA-approved treatment options.

Lastly, it is essential that we do not create additional hurdles in this process so that manufacturers in the drug approval process have the certainty that they need.

The revised right-to-try bill clearly states that the Secretary of the Department of Health and Human Services ''may not use a clinical outcome associated with the use of an eligible investigational drug . . . to delay or adversely affect the review or approval of such drug. . . . ''

After months of work and thoughtful discussions, this legislation is a positive step forward in our shared goal of improving care for America's patients. It strikes the proper balance between ensuring patient safety and granting access to new treatments.

The President outlined in his State of the Union Address that this was an important priority for the administration. In the words of our Vice President and former colleague, MIKE PENCE: ''It's about restoring hope and giving patients with life-threatening diseases a fighting chance.''

Mr. Speaker, for these reasons, I urge my colleagues in the House to vote in support of H.R. 5247, and I reserve the balance of my time.

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

Mr. Speaker, I rise today to voice my strong opposition to H.R. 5247, the Right to Try Act of 2018.

This legislation, introduced only last week, is an egregious attempt, in my opinion, by the Goldwater Institute to undermine the gold standard drug approval process at the Food and Drug Administration.

The supporters of this bill claim to be helping desperate patients who are looking for hope.

If this is such a patient-centered bill, then why does every major patient organization overwhelmingly oppose it?

More than 100 patient organizations, including the National Organization for Rare Disorders, the Friends of Cancer Research, and the American Cancer Society have all written in opposition to this legislation.

In a letter to congressional leadership, these 103 patient organizations noted ''that the alternative pathway in the latest version of this legislation is still less safe for our patients than the current expanded access process under the FDA.''

It is not only the patient organizations that are voicing concerns. Four former FDA Commissioners—Drs. Hamburg and Califf, who served under the Obama administration; and Drs. McClellan and Andrew von Eschenbach, who served under the Bush administration—also oppose this legislation. That is two former Republican Commissioners and two former Democratic Commissioners who are opposed to both the House bill and the Senate bill on this same issue.

These four Commissioners explained their opposition by saying: ''There is no evidence that either bill would meaningfully improve access for patients, but both would remove the FDA from the process and create a dangerous precedent that would erode protections for vulnerable patients.''

Mr. Speaker, I think most importantly, I would stress that this legislation is simply not needed. There is already a successful program in place today at the FDA in which seriously ill patients and their doctors can request access to an experimental treatment from a manufacturer. This application process, which takes as little as 45 minutes for a physician to complete, has been overwhelmingly successful.

Last summer, a review by the Government Accountability Office found that the FDA approves 99 percent of the requests submitted to the agency. In fact, of the nearly 1,700 requests the FDA received last year, only 9 were not approved.

Physicians and patients also receive approval quickly. Emergency requests are often granted immediately over the phone and, on average, receive a response within 4 days.

While the FDA approves 99 percent of the treatments it reviews through this expanded access process, as it is called, it also adjusts applications for 11 percent of the patients to improve patient safety protections.

In order to protect patients, this review, in my opinion, should continue. We must protect patients from bad actors or from dangerous treatments that might make their lives worse. Just imagine the health consequences to patients if these 11 percent of applicants had not been adjusted.

This is the very reason that the FDA must be involved in the process. If you eliminate FDA review, as this bill does, you are putting patients at risk.

I want to talk a little bit about the fact that many States now have right-to-try statutes. I fear that some Members—and I heard this last week when the bill was on the suspension list—might support this legislation under the false belief that the State right-to-try laws in their States have provided help to patients. But nothing could be further from the truth.

One example supporters of this legislation like to bring up is Dr. Delpassand from Texas, who claims to have treated patients under the State right to try.

Mr. Speaker, I include in the RECORD a letter from Mr. Andrew McFadyen of The Isaac Foundation, who dispels this myth.

THE ISAAC FOUNDATION,
March 20, 2018.

Rep. GREG WALDEN, *Chair,*
Rep. FRANK PALLONE, *Ranking Member,*
Energy & Commerce Committee.

DEAR MR. PALLONE AND MR. WALDEN: I am writing to you regarding your upcoming debate on HR 5247, the Right to Try initiative fronted by the Goldwater Institute. I am the Executive Director of The Isaac Foundation, an organization that is dedicated to providing advocacy and support to patients dealing with a wide range of disorders and needing access to rare disease treatments. Our work pushes international boundaries, with the bulk of our efforts taking place in Canada and the United States. I am also a member of the NYU Working Group on Compassionate Use and Pre-Approval Access where we are making a concerted effort to improve and address the issues around access to experimental medications, and I'm involved with a non-profit called GE2P2.

I'm proud to say at The Isaac Foundation that we've never been unsuccessful gaining access to life-saving medications and treatments for patients in Canada, and our work directly with pharmaceutical companies is helping countless patients see similar results in the United States. We have had success by being collaborative partners with industry, regulatory authorities, and patients in need.

I watched the discussion last week with growing consternation that many of our elected officials have not taken the opportunity to fact-check claims being made by RTT proponents. Most notably, continued mention of Right to Try being used by Dr.

Delpassand out of Texas is both egregiously wrong and, indeed, is the perfect example of why RTT should not be passed by lawmakers.

In October 2016, I testified during Senator Ron Johnson's hearing on Right to Try, at which Johnson introduced and played a video created by the Goldwater Institute of Dr. Delpassand. During that 3-minute video, Dr. Delpassand explained that he was using the state RTT law to treat his patients because the FDA would not allow him to do it through an Expanded Access Program. Senator Johnson asked me what I thought about this video—which included few facts, no context, and was edited by the people fronting the RTT push themselves. I explained that there must be a reason why Dr. Delpassand was in the 1% of cases not allowed by the FDA and vowed I would investigate.

In March of 2017, I received a set of documents from the FDA under a FOIA request. They show that Dr. Delpassand's clinic failed inspections during the clinical trial of Lutathera (lutetium Lu 177 dotatate). Specifically, he failed inspection due to 3 key and very important reasons:

1. Enrolling subjects into the study during a partial clinical hold, issued by the Agency.
2. Underreporting of Adverse Events.
3. 1572-protocol noncompliance.

The failed inspections were discovered after complaint from the CDER Good Clinical Practice Compliance Oversight Branch, Division of Good Clinical Practice Compliance Evaluation, Office of Scientific Investigations (OSI). A ''Clinical Hold'' was placed on the lab and Dr. Delpassand. During a clinical hold, subjects may not be given an investigational drug. Dr. Delpassand and his clinic disregarded this clinical hold and enrolled 6 patients.

Additionally, and just as concerning in terms of patient safety, Dr. Delpassand's clinic failed to promptly report significant new adverse events or risks to the FDA. This failure to report was noted numerous times during the inspection. The inspection also found numerous other areas of concern. I have attached the full report for your consideration.

After these inspections, the FDA would not allow Dr. Delpassand to open an EAP at his clinic for patients in need, and rightly so. They FDA did, however, allow 42 different locations the ability to provide this drug for patients requiring access, including two sites in Texas. A quick search on ClinicialTrials.gov shows this information, further proving that the FDA has been able to provide patients the required access they need, ensuring the environment that they are receiving the drug they need is safe.

My understanding of the situation is that the company running the clinical trial distanced themselves from Dr. Delpassand after these failed inspections. Without company support, and without the FDA's permission to open an EAP, Dr. Delpassand had to use the state legislation to provide drug to his patients. Questions remain, however, such as how Dr. Delpassand paid for the product he was giving his patients, did patients themselves have to pay for that drug supply (which isn't allowed under the Texas RTT law) and who, if anyone, was overseeing the program to ensure safety of the patients, especially after multiple infractions were seen during the failed FDA inspection.

Most important, it should be noted that the FDA process here worked exactly how it is supposed to. A lab was inspected for safety to ensure patients are looked after in the appropriate fashion. That inspection placed a hold on further treating of patients due to numerous infractions. The FDA worked with the company to ensure access for patients across the USA in 42 different sites, helping to monitor adverse events while also allowing the product to advance to approval. That product was approved by the FDA in January 2018.

Also importantly, RTT was used because it was the only way for Dr. Delpassand to treat patients in his clinic after it failed inspection. RTT is a loophole designed to allow people who cannot otherwise follow safety rules set forth by the FDA that are meant to protect vulnerable patients. It's not being used—anywhere—to provide patients with hope or access to life-saving drugs.

One final note, and one that I've not see mentioned anywhere. HR 5247 includes the name of a young child—a brave child battling Duchenne Muscular Dystrophy—named Jordan McLinn. Jordan has been photographed numerous times with Vice President Pence, and is often used as an example of why Right to Try is needed. The problem with these optics is that Jordan has never received any treatment under Right to Try, even though Right to Try has been available in his state of Indiana for 3 years. He already has access to the life-saving treatment he needs—through an FDA approved clinical trial. He's doing well on that trial drug, as I understand it, and receives all the benefits of FDA oversite to ensure his safety on that trial. In essence, the child used to promote RTT is the perfect example of why the FDA process works and is needed.

The true reality is that the landscape for access to medications for dying patients does not change tomorrow if a Federal Right to Try law is passed today. Very clearly, those patients in dire need of help today will wake up tomorrow needing access to the same life-saving treatments, and feel the same despair because they will not be getting the access they need through Right to Try.

The barrier to that access here isn't the FDA, and no Right to Try law enacted by lawmakers in this country is going to remove the true barrier—pharmaceutical companies. The gatekeepers to these medications are the pharmaceutical companies themselves, and we need to be working collaboratively as a team—Industry, Government, physicians, and Patients—to craft solutions that will work for everyone, keeping in mind that we are all on the same side, that we all want the same thing—broad and expeditious access to life-saving medications for patients in need.

I understand how difficult this is for patients—I see it every day, and I feel it every night as I check in on my son (who is battling his own devastating and very rare disease) to make sure he is still breathing, to make sure he is still with us. But I also understand that the change we all need will not come with Right to Try. It will come through collaboration with all stakeholders and by providing companies the safety and assurances they need to make their medications available to our dying patients.

Lawmakers should be spending their time helping make that collaboration happen because that is how we are going to save our dying patients. They should not spin their wheels passing legislation like Right to Try that looks good, and feels good, but will do nothing for those in need. If they do, they are doing a disservice to a large and very vulnerable group of patients now and in the future, my own son, my own hero Isaac, included.

Thank you for your time on this matter.

Sincerely,

ANDREW MCFADYEN,
Executive Director, The Isaac Foundation.

Mr. PALLONE. Andrew McFadyen said:

Dr. Delpassand claims to have used right to try because FDA would not allow him to do expanded access. And this was for a very good reason. FDA placed a clinical hold on a study, due to the fact that his clinic was not reporting serious, adverse events, as required; and he continued to enroll patients, despite the clinic hold.

The work of Dr. Delpassand's study was associated with 40 deaths and 2 hospitalizations. FDA's clinical hold on Dr. Delpassand's work is a sign to me that FDA's expanded access pathway was working to prevent bad actors from continuing to expose vulnerable patients to experimental treatments.

Mr. Speaker, H.R. 5247 is dangerous for our patients. It is an unprecedented attempt to roll back the FDA's oversight of investigational treatments. I urge my colleagues to stand with more than 100 organizations that have come forward to oppose this misguided and, I believe, harmful legislation.

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

Mr. BURGESS. Mr. Speaker, I yield 3 minutes to the gentleman from Pennsylvania (Mr. FITZPATRICK), one of the authors of the bill.

Mr. FITZPATRICK. Mr. Speaker, I want to thank Chairman WALDEN, Mr. BURGESS, Mr. GRIFFITH, and my friends ANDY BIGGS and Senator JOHNSON for their unflinching commitment to see right to try debated, passed, and signed into law.

Moreover, I thank the overwhelming bipartisan majority of the House, who, just last week, supported the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act, and proved emphatically that right to try is about more than politics. It is about hope.

Each year, thousands of Americans receive a life-altering diagnosis of a terminal illness. Even with the amazing work done in American medical research and development, for too many families, access to these potentially lifesaving treatments will come too late or not at all.

□ 1315

As their Representatives, we should each endeavor to support these individuals in their time of need, as well as support new pathways to potentially lifesaving treatment. That is what right to try is all about.

For those patients caught between traditional drug approval delays, a clinical trial process for which they do not qualify and limited time, right to try simply establishes the freedom for patients and their doctors to try therapies where the benefits far outweigh the risks. It gives them the option of trying to save their life.

Although the FDA has a program that allows terminal patients to apply for early access to a promising treatment, right to try is needed because the FDA compassionate use process doesn't help enough people. Moreover, the application process is complicated, time consuming, and expensive. Only about 1,200 people each year can make it through the application process.

In 2014, more than 12,000 people in France were using investigational

treatments through that government's equivalent program. If a country with one-fifth the population of the United States can help 900 percent more people then the FDA's plan, clearly, is not working.

In Australia, doctors are allowed to work directly with drug and device manufacturers to provide investigational treatments to terminal patients without the government's approval. They simply must report to the government at some point that the patient received the drug. No permission slip is required.

This bill requires robust informed consent between the patient, doctor, and manufacturer, while requiring notification be given to the FDA after an unapproved drug becomes available to an eligible patient and requires doctors and manufacturers to report adverse events to the FDA.

Mr. Speaker, when a life hangs in the balance, the Federal Government should not stand in the way of access to these potential treatments. I have traveled our district in all corners and have met so many different people—L.J. Kidon and Claire Concilio, most recently. Mr. Speaker, these people are an inspiration for this bill. They want to see this bill passed. Let's get this done for them.

Mr. PALLONE. Mr. Speaker, I yield such time as she may consume to the gentlewoman from Illinois (Ms. SCHAKOWSKY), who is the ranking member for the Digital Commerce and Consumer Protection Subcommittee.

Ms. SCHAKOWSKY. Mr. Speaker, I thank the gentleman for his generosity and time.

I want to say, Mr. Speaker, that I rise in opposition to H.R. 5247 because it creates a dangerous back door for modern-day snake oil salesmen, a back door around the FDA approval process for people who may or may not be preying on desperate people, and it ignores that there actually is a safe pathway for terminally ill patients to get treatment.

This bill failed to pass last week and it should fail again. It is a harmful policy that both Republican-and Democratic-appointed former FDA Commissioners concluded there is ''no evidence'' that this bill ''would meaningfully improve access for patients, but would just remove the FDA from the approval process and create a dangerous precedent that would erode protections for vulnerable patients,'' the most vulnerable patients. People whose lives are in danger feel that they will try anything, and there are people out there who will prey on that.

This bill denies patients what they really need, which is safe and effective treatments. This bill strips away important safeguards in the name of helping patients, but it does not, and that is why 78 patient groups and doctors, groups like the American Cancer Society, the Cystic Fibrosis Foundation, and the Leukemia & Lymphoma Society, oppose this bill. In total, there are now 110 groups opposing this bill.

Mr. Speaker, I include in the CONGRESSIONAL RECORD a multipage list of opponents to this bill.

GROUPS OPPOSED TO RIGHT TO TRY LEGISLATION

ADNP Kids Research Foundation; AIDS Action Baltimore; Alliance for Aging Research; Alliance for Regenerative Medicine; American Academy of Neurology; American Association of Justice; American Cancer Society Cancer Action Network; American Lung Association; American Society of Clinical Oncology; American Syringomyelia and Chiari Alliance Project; Amyloidosis Support Groups; Association for Creatine Deficiencies; Benign Essential Blepharospasm Research Foundation; Biomarin; Bonnie J. Addario Lung Cancer Foundation; Breast Cancer Action; Bridge the Gap—SYNGAP Education and Research Foundation CancerCare; Cancer Prevention and Treatment Fund; Charlotte and Gwenyth Gray Foundation to Cure Batten Disease.

Children's Cause for Cancer Advocacy; Children's Cardiomyopathy Foundation; Congenital Hyperinsulinism International; CurePSP; Cutaneous Lymphoma Foundation; Cystic Fibrosis Foundation; Defeat MSA; The Desmoid Tumor Research Foundation; The Disability Rights Legal Center; Dupl5q Alliance; Dysautonomia Foundation; Equal Access for Rare Disorders; Fight Colorectal Cancer; FORCE: Facing Our Risk of Cancer Empowered; Former FDA Commissioner Margaret Hamburg; Former FDA Commissioner Robert Califf; Friedreich's Ataxia Research Alliance (FARA); Friends of Cancer Research; Georgia State University College of Law; The Global Foundation for Peroxisomal Disorders.

Glutl Deficiency Foundation; The Guthy-Jackson Charitable Foundation; Hemophilia Federation of America; Hematology/Oncology Pharmacy Association; HLRCC Family Alliance; Hope for Hypothalamic Hamartomas; Hyper IgM Foundation, Inc.; International Fibrodysplasia Ossificans Progressiva (FOP) Association; International Myeloma Foundation; International Pemphigus and Pemphigoid Foundation; International Society for Stem Cell Research; International Waldenstrom's Macroglobulinemia Foundation (IWMF); The Isaac Foundation; Jack McGovern Coats' Disease Foundation; The LAM Foundation; The Leukemia & Lymphoma Society; Lymphoma Research Foundation; Li-Fraumeni Syndrome Association (LFS Association/LFSA); LUNGevity Foundation; Max Cure Foundation.

M–CM Network; Mattie Miracle Cancer Foundation; MitoAction; MLD Foundation; Moebius Syndrome Foundation; The MSA Awareness Shoe; Mucolipidosis Type IV Foundation; The Myelin Project; Myotonic Dystrophy Foundation; National Brain Tumor Society; National Coalition for Cancer Survivorship; National Comprehensive Cancer Network; National Consumers League; National Health Council; National MPS Society; National Niemann-Pick Disease Foundation; National Organization for Rare Disorders (NORD); National Patient Advocate Foundation; National Physicians Alliance; National PKU Alliance.

National PKU News; National Women's Health Network; Neurofibromatosis Northeast; NYU Langone Health; Operation ASHA; Our Bodies Ourselves; PRP Alliance, Inc.; Prevent Cancer Foundation; Public Citizen; Rare and Undiagnosed Network (RUN); Sarcoma Foundation of America; Scleroderma Foundation; The Snyder-Robinson Foundation; Sofia Sees Hope; SSADH Association.

Susan G. Komen; TargetCancer Foundation; Treatment Action Group; The Turner Syndrome Society; TMJA (Temporomandibular Joint Disorders patient organization); United Leukodystrophy Foundation; United Mitochondrial Disease Foundation (UMDF); University of Pennsylvania Perelman School of Medicine; Veterans Health Council; Vietnam Veterans of America; VHL Alliance; Washington Advocates for Patient Safety; Woody Matters; Worldwide Syringomyelia & Chiari Task Force; Yale School of Public Health.

Ms. SCHAKOWSKY. Mr. Speaker, it opens the door for bad actors to take advantage of terminally ill patients. It is the FDA's job to ensure that drugs are safe and effective, and we can't trust manufacturers to act as this gatekeeper.

There is already a safe process for terminally ill patients to access experimental treatments. Under what is called the expanded access program, 99 percent of applications are approved. The expanded access program plays a vital safety role.

I am very troubled by what can happen to patients in some States who undergo treatment from right-to-try companies. In 19 States, patients using an investigational drug could actually lose their hospice coverage; in 6 States, they could be denied home care coverage. These are the very people who are dependent on hospice and home healthcare, and this bill would cause them to lose that coverage.

This is not a humane, patient-centered bill for people who are facing death; it is just a dangerous pathway for bad actors to exploit those very people.

Mr. Speaker, I urge my colleagues to oppose H.R. 5247, and, again, I thank the gentleman for the opportunity to speak against this piece of legislation.

Mr. BURGESS. Mr. Speaker, at this time, I am pleased to yield such time as he may consume to the gentleman from Oregon (Mr. WALDEN), the chairman of the full committee.

Mr. WALDEN. Mr. Speaker, I rise today on behalf of the patients, the patients who face terminal diagnoses but have exhausted all available known treatment options.

Before us today we have legislation that received 260 bipartisan votes last week; that was nearly 260 votes to increase patient access to investigational drugs through a new pathway.

I want to thank Dr. BURGESS for his incredible work on our Energy and Commerce Committee to do our due diligence, to take an issue that is important to our citizens and our colleagues and make sure that it has been properly vetted, reviewed, and improved upon from what we got from the Senate.

Mr. Speaker, 38 States have right-to-try laws, including my own State of Oregon. This is something that people want and deserve. Wisconsin will make it number 39 once the bill they have passed gets across Governor Scott Walker's desk.

While the State policies vary, they have a common goal, and that is helping vulnerable patients. President Trump praised the movement during

the State of the Union, saying: ''People who are terminally ill should not have to go from country to country to seek a cure—I want them to have a chance right here at home.''

I have spoken to the President directly about what we are doing here, and he gave me a shout-out when he was up in New Hampshire the other day about moving this bill forward. We worked closely with the Vice President and his team and with Scott Gottlieb, who is the doctor who heads the FDA, the Food and Drug Administration, to get a really good, thoughtful product before this House, and they support what we are doing here. President Trump also highlighted this bill, as I said, when he was in New Hampshire.

It is important to note that this isn't the first time we have considered this bill. As you may know, last week, we tried to move this on the suspension calendar, never imaging that the Democrats would actually whip against giving dying patients the right to try one of these drugs. We had 32 Democrats support this legislation, and that is why we brought it back under regular order in a rule today.

Now, today, there is an existing process, and you have heard about it—and we looked at this in the committee—for patients to access unapproved drugs. The FDA oversees expanded access, commonly known as compassionate use. This program has been critical in helping patients access experimental drugs. It does work.

Commissioner Gottlieb and the agency should be commended for their continued work to improve the expanded access program for patients. As you have heard from my colleagues on both sides of the aisle, this program works, and works effectively, but it doesn't do it all, and that is why this legislation is before us.

To improve upon this successful program, the bill before us today provides liability protections for manufacturers, sponsors, physicians, clinical investigators, and hospitals that participate in the existing expanded access program and the new alternative pathway that we create under this legislation.

This was a very big issue for those who needed to be brought into participation who otherwise might have sat on the sidelines and never made these drugs available. This provision removes one of the biggest hurdles that patients face and that was identified by the Government Accountability Office; it is the biggest hurdle they face in getting access to experimental therapies: manufacturers' hesitancy to participate. That is the hurdle we are trying to overcome today in a safe way.

The bill also creates a new alternative pathway for patients who do not qualify for a clinical trial. This legislation strengthens patient protections with clearer informed consent and adverse event reporting. The bill also ensures the FDA is notified when a patient receives an unapproved drug through the new alternative pathway to ensure proper oversight.

Mr. Speaker, I want to thank my colleagues in the House, and especially Dr. BURGESS on the Health Subcommittee, but also Representative BRIAN FITZPATRICK; ANDY BIGGS, who is behind me; MORGAN GRIFFITH; and our Vice President, MIKE PENCE. I am grateful for their work and for their understanding that our job here in the House is to do our work: to hear from people who are affected or might be affected, to improve upon products, to go through regular order, and to bring this bill to you today.

Mr. Speaker, I urge all of my colleagues in the House to support this legislation.

Mr. PALLONE. Mr. Speaker, I yield such time as she may consume to the gentlewoman from California (Ms. MATSUI).

Ms. MATSUI. Mr. Speaker, I thank the gentleman for yielding to me.

Mr. Speaker, I rise in opposition to H.R. 5247, the so-called right-to-try legislation. This bill does not give patients the right to try; rather, it gives patients the right to request, which fails to address real barriers to accessing experimental drugs such as drug costs or company restrictions.

I will reiterate that patients already have the right to try through an expedited process that approves 99 percent of requests it receives. This legislation, however, fails to recognize that, if a patient is denied access, it is usually because a drug manufacturer says no due to manufacturer concerns about safety or side effects, not because the FDA denied a request.

I know, like everyone else, I have heard from many constituents suffering from terminal illnesses such as ALS who are desperate for cures; and I believe that every single one of us in this Chamber has confronted, in some way, a family member—mother, father, spouse—who had, heartbreakingly, an illness that had no cure. We have gone through the process many times, and I think we all have felt desperate from time to time.

However, having said that, just because a person at the end has no hope, to try something that might make things worse so you cannot go on to a more peaceful resolution would be hurtful not only to the patient, but to the family.

Opening up unregulated pathways to drugs after only a phase 1 clinical trial may expose patients to severe and unpredictable side effects. This bill would prevent FDA from documenting these side effects and, worse, would prevent FDA from protecting other patients from a similar fate.

When a loved one is in pain, the last thing a family wants is to cause further suffering. We need clinical trials to ensure drugs are safe and effective and to find real cures for patients, and we need the FDA to be a part of the process as a matter of patient protection for all.

Rescinding any FDA oversight on unproven therapies that have not undergone multiple clinical trials is a slippery slope. The expedited process we have now is working, and I cannot support a bill that offers a ''right to ask'' alongside proposals that could be dangerous for all.

Mr. Speaker, I urge my colleagues to oppose this bill.

Mr. BURGESS. Mr. Speaker, I am pleased to yield 3 minutes to the gentleman from Virginia (Mr. GRIFFITH), a valuable member of the Energy and Commerce Committee, the vice chairman of the Oversight and Investigations Subcommittee.

Mr. GRIFFITH. Mr. Speaker, I have heard people say that they don't want to support a bill that makes things worse. We have people who are terminal, whose life expectancy is measured in months, not in decades, and how do you make things worse?

I said last week, and I repeat it today, that if I—if, and I am not, thank God—but if I were faced with one of these heart-rendering situations, I would take any risk, including injecting monkey urine, if that meant I could spend a few more days, months, or years with my children.

□ 1330

I think many people are in that same boat, and the American people deserve a right to try. When we were doing our hearings on this, we had an Energy and Commerce Subcommittee on Health hearing where Lieutenant Commander Matthew Bellina, who graduated from Virginia Tech in my district and served in the United States Navy, testified before us. He said, in the conclusion of his comments: ''I know that it is probably too late for me, and I have made my peace with that. I need to know before I die that, if my children find themselves in this unenviable position, this Nation that I proudly served will respect their liberties and their right to make their own decisions about their medical treatments.''

He suffered from ALS, as I said. I have had three friends during my lifetime die of that: Ray Robrecht, my predecessor a couple terms back in the Virginia House of Delegates; Julie Mullins, whose family I have known for decades; and Mike Ahern, who was connected with the United States Senate through his sister. All of these folks were people who lived in Salem County or Roanoke County, and they all died from ALS. They were all brave people. They should have had the right to try to see if they could make an improvement for others.

Even more poignant are my family friends who lost both a grandparent and their mother to Huntington's chorea. I was their family lawyer. I did their will. I would like to believe, and I know they would have liked the option, that their mother would have chosen the right to try, knowing that, even if it failed, it might help another generation because, as you know, Huntington's chorea is a genetically transmitted disease.

So I do not understand why people are afraid of letting people try who have no other hope, whose life is going to be cut short, without taking that Hail Mary pass. And so I hope that everyone will support this reasonable, measured effort to let people have a choice and a right to try.

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

Mr. Speaker, I want to explain some other reasons why I am very opposed to this bill. I am concerned that H.R. 5247 essentially does nothing to address what may be the true barrier to expanded access, and that is the determination by the manufacturer as to whether or not they will provide access to their product that is under development. And I want to stress, there is nothing in this legislation before us today that would compel a manufacturer to grant access upon request.

Further, I believe that trusted manufacturers like J&J, or Johnson & Johnson, which is headquartered in my district, have already said that any compassionate use request must be subject to FDA review. Now, I have heard my colleagues refer to this as a Hail Mary pass for the terminally ill. I think, in reality, it is offering false hope of a cure to patients and their families when there is no guarantee that any patient will receive access to treatment from a manufacturer.

In fact, H.R. 5247 sets an extremely low threshold for the types of experimental treatments that may be available through this alternative pathway by allowing patients access to investigational treatments that have only completed a phase 1 clinical trial. Patients will be exposed to treatments with no or relatively little data that they are actually effective. These extremely small trials only examine the safety and toxicity of a drug and do not determine the effectiveness or potential side effects. Access at this phase 1 stage in the development could expose patients to untested products and further harm and result in delaying access to a treatment that may be more appropriate and more beneficial for their underlying disease or condition.

Only 1 in 10 products move on from phase 1 clinical trials to FDA approval. Mr. Speaker, the bill does not make any adverse-event reporting to the FDA immediate. It also limits FDA's ability to use clinical outcomes associated with the use of an investigational product when reviewing a product for approval if it could adversely impact its review. It also prevents any entity from being held liable for use of the treatment.

Again, these are some of the many reasons that more than 100 organizations oppose this dangerous bill.

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

Mr. BURGESS. Mr. Speaker, I yield 4 minutes to the gentlewoman from Indiana (Mrs. BROOKS), another valuable member of the Committee On Energy and Commerce and the Subcommittee on Health.

Mrs. BROOKS of Indiana. Mr. Speaker, the right-to-try legislation will be considered on the House floor today. This is about giving people hope to try. It is about hope to try investigational drugs which have passed the first of three phases of the FDA clinical trial process, the safety testing phase. And these investigational drugs could possibly prolong or save the lives of terminally ill patients.

I like to remind my colleagues that a little boy was in Washington, D.C., on the House floor just last week when we first voted on this legislation. Prior to that vote, I had met Jordan during an Energy and Commerce Committee hearing focusing on the implementation of the 21st Century Cures Act.

Jordan McLinn is a second grader from Indianapolis who may look like any other healthy child, but he has Duchenne muscular dystrophy, or DMD, a fatal, degenerative condition which causes muscle weakness. DMD is caused by an absence of dystrophin, a protein that helps keep muscle cells intact. Oftentimes, kids born with DMD are wheelchair-bound by age 12, and they have a life expectancy of just 25 years old.

DMD is a genetic disease that is typically passed on to boys through their mother's X chromosome. But sometimes the mother is not a carrier, there is no family history of the disease, but a child is born with the disease anyway. This is what happened to Jordan McLinn. His mother, Laura, is not a carrier. This disease does not run in their family.

Jordan was born with DMD, but it was not diagnosed until he was 4 years old. So can you imagine what this family has been through? After Jordan was diagnosed, his family hit the ground running, trying to find the best possible treatment options and therapies for people with DMD. His mother, Laura, was quoted in The Indianapolis Star today in an article focused on the right-to-try bill saying: ''The reason we have remained on this journey and fighting so hard for it is not necessarily for Jordan immediately. It's for all the patients that we've met along the way.''

Jordan and his family have been on this journey advocating this fair and compassionate bill in Indiana and beyond for Jordan but also for so many others. In 2015, then-Governor MIKE PENCE signed Indiana's right-to-try law with Jordan McLinn by his side. Now a total of 38 States have already passed laws that take a variety of approaches to helping vulnerable patients. By passing this legislation in the House today, we will increase access—nationwide—to unapproved, investigational drugs for patients with a terminal illness.

In that same IndyStar article I mentioned earlier, Laura shared that Jordan has always wanted to be a firefighter, but now, after coming to the Nation's Capital many times, he has aspirations to be something else. He now wants to be President of the United States. This bill allows Jordan to have those big dreams, and it will be providing patients across this country with hope.

Yes, it is hope, hope for patients that they may find the cure someday that they have been searching and fighting for, hope for patients and their families that there will be more time to make more memories that can last a lifetime.

In closing, I would just like to emphasize how critically important it is that Congress join together to support the bill for the millions of Americans who fight for their lives because of a terminal illness. I urge my colleagues to support this bill.

Mr. PALLONE. Mr. Speaker, may I inquire how much time I have remaining?

The SPEAKER pro tempore. The gentleman from New Jersey has 15½ minutes remaining.

Mr. PALLONE. Mr. Speaker, I yield such time as he may consume to the gentleman from Texas (Mr. GENE GREEN), the ranking member of the Health Subcommittee.

Mr. GENE GREEN of Texas. Mr. Speaker, I thank my ranking member for yielding to me. I rise in opposition to the right-to-try legislation that would bypass the Food and Drug Administration's longstanding review and oversight of drug treatments and endanger patients with life-threatening diseases.

Many States have passed this right-to-try piece of legislation, including my home State of Texas, but the States don't have the FDA. The Federal Government has the right to be able to make sure we can protect both constituents and consumers. My heart goes out to the loved ones who are terminally ill and desperate for a breakthrough treatment. I cannot support legislation that offers false hope to the terminally ill and their families.

The FDA has a pathway whereby those in need of investigational medications may seek to obtain them. This program is known as the expanded access pathway, or compassionate use, and has been in the law since 1987. Over the last decade, the FDA has a clinical hold on only two commercial drug development programs due to adverse events associated with compassionate use.

There are many patient advocacy groups that are opposing this legislation. Groups such as the Alliance for Aging Research, the American Cancer Society Cancer Action Network, American Lung Association, the American Society of Clinical Oncology, the Cystic Fibrosis Foundation, Defeat MSA, the Disability Rights Legal Center, and dozens more that are committed to seeking effective treatment cures to many diseases which are terminal, are against this bill. These patients' rights groups seek to ensure that the medication that is offered to individuals is safe, has been tested, and has gone

through the proper approval process before it is given to a patient.

The most vulnerable and terminally ill individuals deserve to have access to safe therapies that have undergone the necessary approval process before being given to those who can least afford to receive unproven treatment that may do them more harm than good. In addition to the physical harm which unproven treatments may cause, there is also the risk of financial exploitation of terminally ill patients given that such treatments are not covered by insurance. Manufacturers are not required to cover the cost of investigational treatment.

The majority's decision to go around our committee's consideration and effort to pass the bill on suspension last week exemplifies what this legislation is trying to do, circumvent existing rules and processes that have been created to protect Americans from hasty decisions.

I ask my colleagues on both sides of the aisle to stand up for Americans facing serious and life-threatening diseases by opposing this unnecessary and potentially dangerous legislation.

Mr. BURGESS. Mr. Speaker, I yield 3 minutes to the gentleman from Arizona (Mr. BIGGS), one of the primary drivers on this legislation.

Mr. BIGGS. Mr. Speaker, I thank the gentleman from Texas for yielding. I also pay my respects and give honor to RON JOHNSON, the Senator from Wisconsin who championed the bill in the Senate and gave us a superb bill; also, Chairman WALDEN and his committee, who have worked hard to give us this bill today; and my original cosponsor on the bill that I introduced, Mr. FITZPATRICK from Pennsylvania.

Mr. Speaker, I want to address just a couple of things that I think are really intriguing to me because it certainly seems a bit condescending to me when I hear people say: I am not going to support this because it gives false hope that people might be taken advantage of by bad actors. They cannot identify the bad actors, but they might be taking advantage of them. That is a fallacious and specious argument to make when you are denying people who have a terminal illness, who have been diagnosed with a terminal illness, who have gone through the already approved FDA processes in order to get and petition a pharmaceutical company for an experimental drug that might prolong their life and might heal them.

False hope, that argument, is the argument that I am hearing. But the reality is these people are individuals. They have a higher sense of reality than virtually anybody else I know because their mortality is there. They want the opportunity. It is not false hope. It is hope. Support of this bill is compassionate. Support of this bill is fair.

I have also heard that there may be some liability issues on the part of pharmaceutical companies which might impede them from providing drugs. Yet, in order to satisfy them, the bill itself says that they are exculpated unless their conduct is willful or criminal. That means that they have protection.

What I am asking here today, and what everyone with whom I have met over the years who want a right to try is asking, is simply a chance to have some determination and control over their own lives.

□ 1345

One of the intriguing arguments I hear today and I heard last week is, well, you know what, the pharmaceutical companies aren't compelled to provide these drugs. So my immediate question is: Oh, so you would be more comfortable, then, if we would have included a compulsory means in the bill? Did you want the pharmaceutical companies to be compelled to provide these?

The answer would be no. It is simply they don't like this bill. They don't want the bill.

When you have 38, soon to be 39, States that want to give their citizens, Americans all, the right to try to preserve their lives and to be healed and have a chance, they need to get that; they need that opportunity. We need to give it to them today.

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

Mr. Speaker, there has been a lot of misinformation spread by supporters of this legislation that FDA is a barrier to patients receiving access to these investigational treatments, and I want to be very clear that that is simply not the case.

FDA's expanded access program approves nearly all requests for investigational drugs or biologics it receives. For the past 5 years, FDA's approval rate for expanded access requests has been over 99 percent. In fiscal year 2017, as I previously mentioned, only nine individual requests were denied.

FDA also conducts its review quickly. FDA physicians are available 24 hours a day to approve any emergency expanded access requests the agency receives, typically granting emergency requests immediately, over the phone, and nonemergency requests in a median time of 4 days and, generally, no longer than 30 days.

FDA has also taken actions to streamline the expanded access request process for physicians to make it less burdensome. I think that was mentioned by Mr. WALDEN, the chairman.

Pharmaceutical companies can choose to deny a patient access to an experimental treatment because, for example, there is not enough of the drug available or they are concerned about dangerous side effects. The fact is, when a patient is denied access to an experimental treatment, it is because the company has said no, not the FDA.

So let's be clear as to what this legislation is. It is an attempt to undermine the authority of the expert public health agency charged with reviewing drugs to ensure their safety and efficacy.

I would urge my colleagues to oppose this grab at FDA's authority. That is really what this legislation is all about.

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

Mr. BURGESS. Mr. Speaker, I yield 3 minutes to the gentleman from Georgia (Mr. ALLEN).

Mr. ALLEN. Mr. Speaker, I rise today to encourage my colleagues to join me in supporting H.R. 5247, the Right to Try Act, and I thank Dr. BURGESS and the Energy and Commerce Committee for bringing this important legislation to the floor of this House.

In certain States across our Nation, patients who are diagnosed as terminally ill are being told by doctors that all of the treatment options have been exhausted because they do not have access to experimental drugs. This type of overregulation by the Federal Government is creating hopeless situations for thousands of Americans whom we hold dearest to our hearts.

This right-to-try legislation allows terminal patients to have a choice on whether or not an experimental approach is the path for them, as sometimes, and many times, this is their only option.

Should this bill become Federal law, our terminally ill patients will have increased access, nationwide, to unapproved drugs, leading to more scientific breakthroughs that will benefit all Americans and, in lots of cases, will save a life.

Now is the time for Congress to take action and give terminally ill patients a fighting chance for their God-given right to life. How in God's name can this Congress deny an American the right to life?

Mr. Speaker, I urge all my colleagues to join me today in supporting this bill on this floor.

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

Mr. Speaker, I said before that I have found that some Members were looking to vote for this bill because they said: Well, we have the right to try in our State by State statute, so what is the difference if we do it on the Federal level?

I just want to stress again that the State right-to-try laws do not give patients a right to try effectively and have done little to expand access to investigational treatments.

There are 37 States and the District of Columbia that have enacted right-to-try laws, and there is no evidence that anyone has obtained an investigational treatment via these laws that couldn't have been obtained through FDA's expanded access program.

Right-to-try laws do not compel companies to provide patients access to investigational treatments; therefore, under these State laws, patients still do not have a right to try, only the

right to request the treatment from the company.

State right-to-try laws do not address the fundamental barriers of cost and company restrictions. Neither the FDA nor States require insurers or pharmaceutical companies to cover the cost or reduce the costs of these often expensive treatments. Instead, these laws put patients at higher risk by prohibiting or weakening FDA's oversight of investigational treatments.

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

Mr. BURGESS. Mr. Speaker, I yield 3 minutes to the gentleman from Tennessee (Mr. ROE), the chairman of the Committee on Veterans' Affairs.

Mr. ROE of Tennessee. Mr. Speaker, I rise today in strong support of H.R. 5247, the Right to Try Act.

I am a physician and scientist with over 40 years experience treating patients, some of whom had the dreaded diagnosis of cancer.

Six months ago, I was operated on for cancer, and I, to this day, am a cancer survivor. If needed, I would like to have the right to try.

A little over 3 years ago, my beloved wife, Pam Roe, a nurse and friend, died of stage IV colon cancer. She would have liked to have had the right to try.

Less than 2 months after that, one of the best friends I will ever have in my life, Phil Street, a Vietnam veteran, Air Force veteran, died of a cancer related to Agent Orange. Phil would have liked to have had the right to try.

My senior partner in medical practice, a year later, good friend, was diagnosed with brain cancer. Dr. Cone would have liked the right to try.

Shortly after that, Linda Baines, a scrub nurse that I have operated with hundreds of times in my medical practice, was diagnosed with cancer. Linda would have liked the right to try.

I have two dear friends at this moment who are both being treated for stage IV cancer. If those treatments don't work—and I have had to look patients in the eye and say, Mr. Speaker: ''Your life is not in my hands anymore. It is in God's hands''—they would like to have the right to try.

I tell you this: all these patients want and deserve is a right to try. Please, I am asking you to support this legislation.

Mr. PALLONE. Mr. Speaker, may I inquire how much time remains and whether the gentleman has additional speakers on his side.

Mr. BURGESS. Mr. Speaker, I will be closing.

The SPEAKER pro tempore. The gentleman from New Jersey has 9 minutes remaining. The gentleman from Texas has 3½ minutes remaining.

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

Mr. Speaker, I just want to stress that, as I said before, we have the four previous FDA Commissioners, two Democrats and two Republicans appointed by President Bush, who have raised serious concerns about this legislation because it excludes FDA review and they think could pose serious risks to vulnerable patients.

I just wanted to read, once again, a statement that they made jointly to The Washington Post, where they said: ''There is no evidence that either bill would meaningfully improve access for patients, but both would remove the FDA from the process and create a dangerous precedent that would erode protections for vulnerable patients.''

Mr. Speaker, I just want to stress to my colleagues on both sides of the aisle that my concern is that no one is actually going to be able to get an experimental drug by this bill. In other words, if you are a manufacturer that actually has done something and come up with an experimental drug that you believe will make a difference to someone who is terminally ill, you are likely going to want to go through the FDA expanded access process because then there is a seal of approval that the FDA has actually looked at this and said that it is relatively safe to use.

So my real fear is that the only thing this is going to do is open up to the possibility of some charlatan, fly-by-night snake oil drug company or manufacturer who is going to make all kinds of claims that have not been reviewed by the FDA for any kind of safety, and that then people may say: Okay. Well, I will take that because I am terminally ill and I might as well try something.

But that isn't really what we should be doing here. We should be providing a process, as the FDA does right now, where, if someone is terminally ill and they want to try something, they at least have some certification of approval by the FDA that this is something that may help them, that may make a difference, and that, in the case of about 11 percent of the cases where the application is made to the FDA, some changes are made to make sure that even though there is a certain level of risk, that that level of risk is reduced by the FDA putting on additional safety precautions.

So my real concern here is I don't want people to vote for this legislation thinking that somehow it is going to make a difference. I really don't believe that is true. Otherwise, I wouldn't urge the opposition that I am. But for all these reasons, I do urge strong opposition to this bill and ask that my colleagues vote ''no.''

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

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

Mr. Speaker, yesterday, during the rule debate on this bill, I outlined a case where the previous Speaker, NANCY PELOSI, provided the right to try for a patient, a Democratic donor, back in my home State of Texas. So, really, all we are asking today is that we give regular Americans, the forgotten men and women of this country, the same rights that the Speaker of the House provided to a Democratic donor back in October of 2008.

Yesterday I quoted from an article from the Dallas Morning News. I have a different but similar article today talking about the same case, talking about the individual who had a diagnosis of multiple myeloma.

There was a drug that perhaps would provide some hope. The individual was clearly terminal. This monoclonal antibody that was primarily used to treat multiple sclerosis might show some efficacy in treating the advanced form of multiple myeloma that this patient had. The drug had been through phase 1 clinical trials. The patient did not have time for the drug to go through phase 2 and phase 3 clinical trials.

The article says:

> Enter Nancy Pelosi. Through means to which we have never been privy, Ms. Pelosi got the FDA to give the manufacturer the all-clear to give the drug to the patient. The patient got the drug, the patient took the drug, but, unfortunately, the patient died anyway, but his family remains grateful to the Speaker for interceding on his behalf.

I don't doubt that they are.

Yesterday, I quoted the Dallas Morning News article where the patient's spouse said, somehow, NANCY PELOSI got it done.

Well, do you know what, Mr. Speaker? You shouldn't have to depend on the Speaker of the House to intercede on your behalf to get the FDA to get the manufacturer to make a drug available. If you are really up against a bad situation, wouldn't it be better if we provided everyone that same pathway?

That is what this bill does today. That is why the right-to-try legislation was advocated by the President of the United States. In fact, I think it was the only legislative priority that the President laid out during his State of the Union Address where he wanted to see Congress act.

So today, we are going to do that. Today, we are going to act. It is an important bill. I encourage my colleagues to vote in favor of it.

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

The SPEAKER pro tempore. All time for debate has expired.

Pursuant to House Resolution 787, the previous question is ordered on the bill.

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

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

□ 1400

MOTION TO RECOMMIT

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

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

Mr. PALLONE. I am opposed to the bill in its current form.

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

The Clerk read as follows:

Mr. Pallone moves to recommit the bill H.R. 5247 to the Committee on Energy and Commerce with instructions to report the same back to the House forthwith, with the following amendment:

Strike section 2 and insert the following:

SEC. 2. USE OF UNAPPROVED INVESTIGATIONAL DRUGS BY PATIENTS DIAGNOSED WITH A TERMINAL ILLNESS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 561A (21 U.S.C. 360bbb–0) the following:

''SEC. 561B. INVESTIGATIONAL DRUGS FOR USE BY ELIGIBLE PATIENTS.

''(a) USE OF CLINICAL OUTCOMES.—

''(1) IN GENERAL.—The Secretary shall issue guidance describing the Secretary's consideration and evaluation, for purposes of the review of, and decision on whether to approve, a marketing application under section 505 of this Act or section 351 of the Public Health Service Act for an investigational drug, of clinical outcomes associated with the provision by a sponsor or manufacturer of such drug under subsection (b) or (c) of section 561. Such guidance shall address—

''(A) specific instances in which the Secretary will determine that the public health requires such consideration and evaluation;

''(B) specific instances in which a sponsor may request such consideration and evaluation; and

''(C) the context in which such consideration and evaluation will occur, particularly with regard to information and data relevant to the evaluation of a marketing application under section 505 of this Act or section 351 of the Public Health Service Act for the investigational drug.

''(2) GUIDANCE.—

''(A) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of this section, the Secretary shall issue draft guidance with a public comment period regarding the use of clinical outcomes associated with the use of an investigational drug that a sponsor or manufacturer has provided under subsection (b) or (c) of section 561, as described in paragraph (1).

''(B) FINAL GUIDANCE.—Not later than 1 year after the public comment period on such draft guidance ends, the Secretary shall issue final guidance.

''(b) POSTING OF INFORMATION.—Not later than 1 year after the date of enactment of this section, the Secretary shall post on the internet website of the Food and Drug Administration and update annually, categorized by therapeutic area—

''(1) the number of requests that were received by the Food and Drug Administration for the provision by a sponsor or manufacturer of an investigational drug under subsection (b) or (c) of section 561; and

''(2) the number of such requests that were granted.''.

(b) REPORTING.—Section 561A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0) is amended adding at the end the following:

''(g) REPORTING.—The manufacturer or sponsor of an eligible investigational drug shall post on the same publicly available internet website used by the manufacturer for purposes of subsection (b) of this section an annual summary of any provision by the manufacturer or sponsor of an investigational drug under subsection (b) or (c) of section 561. The summary shall include the number of requests received, the number of requests granted, the number of patients treated, the therapeutic area of the drug made available, and any known or suspected serious adverse events. Such annual summary shall be provided to the Secretary upon request.''.

(c) LIABILITY.—Section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amended—

(1) by redesignating subsection (e) as subsection (f); and

(2) by inserting after subsection (d) the following:

''(e) LIABILITY.—

''(1) ALLEGED ACTS OR OMISSIONS.—

''(A) MANUFACTURER OR SPONSOR.—No manufacturer or sponsor (or their agent or representative) of an investigational drug provided to a single patient or small group of patients for treatment use shall be liable for any alleged act or omission related to the provision of such drug, so long as such drug was provided in accordance with subsection (b) or (c), including the reporting of safety information, from clinical trials or any other source, as required pursuant to section 312.32 of title 21, Code of Federal Regulations (or any successor regulations).

''(B) PHYSICIAN, CLINICAL INVESTIGATOR, OR HOSPITAL.—

''(i) No licensed physician, clinical investigator, or hospital shall be liable for any alleged act or omission related to the provision to a single patient or small group of patients for treatment use of an investigational drug in accordance with the requirements described in clause (ii), unless such act or omission constitutes on the part of such physician, clinical investigator, or hospital with respect to such investigational drug—

''(I) willful or criminal misconduct;

''(II) reckless misconduct;

''(III) gross negligence relative to the applicable standard of care and practice with respect to the administration or dispensing of such investigational drug; or

''(IV) an intentional tort under applicable State law.

''(ii) The requirements described in this clause are the requirements under subsection (b) or (c), including—

''(I) the reporting of safety information, from clinical trials or any other source, as required pursuant to under section 312.32 of title 21, Code of Federal Regulations (or any successor regulations);

''(II) ensuring that the informed consent requirements of part 50 of title 21, Code of the Federal Regulations (or any successor regulations) are met; and

''(III) ensuring that review by an institutional review board is obtained in a manner consistent with the requirements of part 56 of title 21, Code of the Federal Regulations (or any successor regulations).

''(2) DETERMINATION NOT TO PROVIDE DRUG.—No manufacturer, sponsor, licensed physician, clinical investigator, or hospital, nor the Secretary, shall be liable for determining not to provide access to an investigational drug under this section or for discontinuing any such access that it initially determined to provide.

''(3) LIMITATION.—

''(A) IN GENERAL.—Except as set forth in paragraphs (1) and (2), nothing in this section or section 561B shall be construed to modify or otherwise affect the right of any person to bring a private action against a manufacturer or sponsor (or their agent or representative), physician, clinical investigator, hospital, prescriber, dispenser, or other entity under any State or Federal product liability, tort, consumer protection, or warranty law.

''(B) FEDERAL GOVERNMENT.—Nothing in this section or section 561B shall be construed to modify or otherwise affect the authority of the Federal Government to bring suit under any Federal law.''.

Mr. PALLONE (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 Jersey?

There was no objection.

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

Mr. PALLONE. Mr. Speaker, this is an amendment to the bill, or 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. And this amendment would offer a more targeted approach to improving the FDA's current expanded access program.

In October, the Energy and Commerce Committee held a hearing on the widely opposed Senate right-to-try legislation. At that hearing, we heard concerns from FDA Commissioner Gottlieb and also from manufacturers, academic experts, and patient groups that S. 204 was legislation that would expose broad numbers of patients to harm, and sought to hamstrung the FDA's ability to oversee or engage in any meaningful way on the use of investigational treatments.

Since that time, my colleagues on the other side of the aisle have drafted new legislation that maintains, in my opinion, the same harmful approach prohibiting FDA review of experimental treatments. The FDA is part of the process for a reason. It protects patients from potentially bad actors or from experimental treatments that might do more harm than good.

So my motion to recommit, Mr. Speaker, abandons this harmful attempt to undermine the FDA's expanded access pathway and, instead, seeks to make two improvements that have been identified as meaningful by both manufacturers and patient groups.

This proposal will also not be any surprise to Chairman WALDEN or Chairman BURGESS because it was the bipartisan proposal our staffs were negotiating prior to the introduction of the current Republican bill.

So I want to stress that, unlike the current bill, H.R. 5247, this proposal is not based on the false premise that FDA approval is a barrier to accessing investigational treatments. Rather, it addresses the two key problems identified by expert witnesses at our hearing: how the FDA will utilize clinical outcomes of investigational treatments and liability protection.

To that end, under this motion to recommit, the FDA is directed to issue guidance to manufacturers specifically on how and when the FDA will consider clinical outcomes, and when a sponsor may request the consideration of such outcomes when it comes time to submit an application for approval for the investigational treatment.

This will provide manufacturers with the clarity they are seeking regarding

how allowing patients access to drugs that are still under development may impact their ability to gain full FDA approval. It will also ensure that there is a public process for such guidance, ensuring that stakeholders will have the opportunity to offer their views on this issue.

Mr. Speaker, the motion to recommit also provides liability protection to manufacturers, physicians, clinical investigators, and hospitals, if they are in compliance with the current law and regulations for expanded access. If you are a manufacturer, a physician, or a hospital that is in compliance with current rules and requirements related to expanded access, you will receive protection for allowing access to the investigational treatment.

Finally, it also provides transparency around the number of expanded access requests the FDA receives and grants, how many requests a manufacturer receives and grants, and if there are any serious adverse events. This transparency, I believe, will provide clear data as to how many patients are making expanded access requests and how often these requests are granted or denied by the FDA and manufacturers.

Mr. Speaker, I believe that these legislative fixes will go a long way to bolstering the existing successful expanded access pathway, while maintaining the critical review and oversight of the agency charged with protecting our public health, that being the FDA.

I just want to say that, last fall, FDA Commissioner Gottlieb testified on right-to-try efforts and told our committee: ''There is a perception that certain products that aren't being offered under FDA expanded access will be offered under right-to-try, and I don't see that.''

That is our current Commissioner Gottlieb, who I respect a great deal.

Rather than creating an unnecessary alternative pathway that threatens our drug approval process and our clinical trial program, I would urge my colleagues to join with Democrats and 103 patient organizations in supporting the current expanded access program.

These targeted improvements under the motion to recommit to the existing program are, I think, a way to achieve a better goal. So I urge my colleagues to support my motion to recommit and oppose this, what I consider, dangerous Republican proposal in the bill before us.

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

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

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

Mr. BURGESS. Mr. Speaker, while well-intentioned, this motion to recommit falls short of providing vulnerable patients full access to experimental treatments.

Providing clarity on how negative side effects will be accounted for during drug approvals is helpful. Giving manufacturers, sponsors, physicians, hospitals, and clinical investigators certainty on liability protections is meaningful. Taken together, these improvements to the existing expanded access program could lead to enhanced manufacturer and sponsor participation and increased patient access.

But this would not provide an alternative pathway for patients who cannot get into a clinical trial and have been rejected from participation in the existing compassionate use program.

This bill before us today does provide an alternative pathway, one that strengthens patient protections with clearer informed consent and real-time adverse event reporting. This bill—the underlying bill—also makes certain that the FDA is notified when a patient receives an unapproved drug through the new alternative pathway to ensure proper oversight. These are significant patient protections.

With this motion to recommit, we have a choice. The underlying bill is the only choice that gives those patients in the greatest need of help access to investigational drugs, with their consent, even after they were rejected from participating in a clinical trial or expanded access.

Mr. Speaker, the choice is clear. We need to vote to expand patient access. We need to vote down the motion to recommit. We need to vote for the underlying bill.

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

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

There was no objection.

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

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

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

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further proceedings on this question will be postponed.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12(a) of rule I, the Chair declares the House in recess subject to the call of the Chair.

Accordingly (at 2 o'clock and 8 minutes p.m.), the House stood in recess.

□ 2115

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mr. SIMPSON) at 9 o'clock and 15 minutes p.m.

COMMUNICATION FROM THE CLERK OF THE HOUSE

The SPEAKER pro tempore laid before the House the following communication from the Clerk of the House of Representatives:

OFFICE OF THE CLERK,
HOUSE OF REPRESENTATIVES,
Washington, DC, March 21, 2018.

Hon. PAUL D. RYAN,
The Speaker, House of Representatives, Washington, DC.

DEAR MR. SPEAKER: Pursuant to the permission granted in Clause 2(h) of Rule II of the Rules of the U.S. House of Representatives, the Clerk received the following message from the Secretary of the Senate on March 21, 2018, at 5:15 p.m.:

That the Senate passed without amendment H.R. 1865.

With best wishes, I am

Sincerely,

KAREN L. HAAS.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, proceedings will resume on questions previously postponed.

Votes will be taken in the following order:

The motion to recommit on H.R. 5247;

Passage of H.R. 5247, if ordered; and

Agreeing to the Speaker's approval of the Journal, if ordered.

The first electronic vote will be conducted as a 15-minute vote. Remaining electronic votes will be conducted as 5-minute votes.

TRICKETT WENDLER, FRANK MONGIELLO, JORDAN MCLINN, AND MATTHEW BELLINA RIGHT TO TRY ACT OF 2018

The SPEAKER pro tempore. The unfinished business is the vote on the motion to recommit on the bill (H.R. 5247) to authorize the use of eligible investigational drugs by eligible patients who have been diagnosed with a stage of a disease or condition in which there is reasonable likelihood that death will occur within a matter of months, or with another eligible illness, and for other purposes, offered by the gentleman from New Jersey (Mr. PALLONE), on which the yeas and nays were ordered.

The Clerk will redesignate the motion.

The Clerk redesignated the motion.

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

The vote was taken by electronic device, and there were—yeas 182, nays 233, not voting 14, as follows:

[Roll No. 120]

YEAS—182

Adams	Brady (PA)	Cicilline
Aguilar	Brown (MD)	Clark (MA)
Barragán	Brownley (CA)	Clarke (NY)
Bass	Bustos	Cleaver
Beatty	Butterfield	Clyburn
Bera	Capuano	Cohen
Beyer	Carbajal	Connolly
Bishop (GA)	Cárdenas	Cooper
Blumenauer	Carson (IN)	Correa
Blunt Rochester	Cartwright	Costa
Bonamici	Castor (FL)	Courtney
Boyle, Brendan F.	Castro (TX)	Crist
	Chu, Judy	Crowley