

It may interest some of my colleagues to know that I was here in 1975 and was able to, of course, register my support for the establishment of that park.

Now, to be clear, the National Park Service administration already manages the 49 acres; but without a change in the law that permanently transfers the lands, a cumbersome and duplicative renewal process is required every 20 years. The procedure involves a notice, a publication in the Federal Register, and a review of comments, all of which are, essentially, a waste of taxpayers' money and everybody's time within the government who has to deal with it.

So make no mistake about it, as Mr. CURTIS pointed out, this bill saves the taxpayers' money and the bureaucracy time.

In addition, the bill would also authorize the National Park Service to acquire and integrate new land into Voyageurs National Park through land exchanges with the State and local governments that own land within or adjacent to the park's boundaries.

In short, Mr. Speaker, this bill would eliminate any future concerns related to the Department of the Interior's ownership and jurisdiction, facilitating the ease of management for the National Park Service, the State, and the county; and it would do so at no cost, in addition, of course, to saving money for the Federal Government as determined by the Congressional Budget Office.

Mr. Speaker, I urge my colleagues to adopt the measure.

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

Mr. Speaker, H.R. 1350 is a common-sense, good governance measure, and I want to congratulate Mr. NOLAN for his hard work in getting this bill through the legislative process.

Mr. Speaker, I urge my colleagues to support this bill, and I yield back the balance of my time.

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

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Utah (Mr. CURTIS) that the House suspend the rules and pass the bill, H.R. 1350.

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

A motion to reconsider was laid on the table.

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

Mr. WALDEN. Mr. Speaker, I move to suspend the rules and pass 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.

The Clerk read the title of the bill.

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 phy-

sician, 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 (Mr. CURTIS). Pursuant to the rule, the gentleman from Oregon (Mr. WALDEN) and the gentleman from New Jersey (Mr. PALLONE) each will control 20 minutes.

The Chair recognizes the gentleman from Oregon.

GENERAL LEAVE

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

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

There was no objection.

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

Mr. Speaker, I rise today on behalf of the patients who face terminal diagnoses but have exhausted all available treatment options. These are patients like Jordan McLinn, who is with us today.

Jordan is a tireless fighter who self-advocates for others living with Duchenne muscular dystrophy. He is a namesake of this bill we are considering, like Matt Bellina, who testified before the Health Subcommittee last

year. Because of folks like Jordan and Matt, we have a chance to increase patient access to experimental therapies.

Thirty-eight States across our great land have right-to-try laws, including my home State of Oregon. Wisconsin, with a bill on its way to Governor Scott Walker's desk, will soon make it 39. While the State policies vary, they have a common goal: 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 to give them a chance here at home.”

Now, today, there is an existing process 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.

Commissioner Scott Gottlieb and the Agency, the FDA, should be commended for their continued work to improve the expanded access program for patients.

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

This provision removes one of the biggest hurdles that patients have faced in getting access to these medicines, in gaining access to experimental therapies, as identified by the Government Accountability Office: manufacturer hesitancy to participate. That is the big hurdle. We seek to overcome it with this legislation.

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, the Food and Drug Administration, is notified when a patient receives an unapproved drug through the new alternative pathway to ensure there is proper oversight.

Mr. Speaker, I want to thank the House sponsors of this legislation who have worked tirelessly to bring this to a good place today: BRIAN FITZPATRICK, our colleague from Pennsylvania; ANDY BIGGS from Arizona; and MORGAN GRIFITH from Virginia. I also thank the Vice President, with whom Jordan and I met today. I am grateful for their work on behalf of these courageous patients, and I urge all my colleagues in the House to support this legislation.

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

□ 1745

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

I rise today in strong opposition to H.R. 5247, or the Right to Try Act of

2018. Supporters of this legislation, Mr. Speaker, have claimed that it will provide seriously ill patients, who have exhausted all of their available treatment options, access to experimental therapies free from the barriers of FDA oversight.

While it is understandable that someone suffering from a disease who has no more options would want to try anything that could help them fight their disease, this legislation delivers the false hope to patients and their families that they will receive a cure to their underlying disease or condition.

In fact, this legislation provides patients and their families nothing more than the right to ask a manufacturer for access to early stage, unproven treatments. Like other so-called right-to-try proposals, H.R. 5247 is based on the false premise that patients are not receiving access to the investigational treatments as a result of the Food and Drug Administration, and this simply not the case.

Through the FDA's existing expanded access program, seriously ill patients are able to request access to investigational products. The FDA approves 99 percent of all requests for investigational drugs or biologics that it receives through this program.

Last year, FDA received more than 1,500 requests, and only 9 were not approved. Despite this high-approval rate, supporters of right-to-try laws have argued that the process is too slow and burdensome, but I have not seen evidence that this is the case, Mr. Speaker. In fact, FDA often grants emergency requests for expanded access immediately over the phone, and nonemergency requests are processed in an average of 4 days.

FDA has even made improvements to streamline the process. For example, FDA has revised the application for physicians to ensure that it now takes less than an hour to complete. FDA has also released additional guidance to industry, outlining the expanded access program's requirements and addressing common questions related to the different programs and submission process, and how outcomes will be considered as part of the review process.

Last fall, FDA Commissioner Gottlieb testified on right-to-try efforts and told our committee that: "There is a perception that certain products that aren't being offered under FDA expanded access . . . will be offered under right-to-try. I don't see that," the commissioner said. As I have said, the review process is working well, but this legislation would completely take FDA out of the review process. This is dangerous and could put patients at serious risk.

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. While FDA approves 99 percent of the treatments it reviews, it also revises applications for 11 percent of patients to improve patient safety protections.

In order to protect patients, this review should continue. We must protect patients from bad actors or from dangerous treatments that would make their lives worse. I am extremely concerned that the legislation we are considering today is advancing a solution to address barriers to investigational treatments that do not exist and could expose seriously ill patients to greater harm instead of the greater access that they are looking for.

The true barrier to any expanded access is the determination by the manufacturer as to whether or not they will provide access to their products that are under development. But nothing in the legislation before us today would compel a manufacturer to grant access upon request.

Further, H.R. 5247 would allow patients access to investigational treatments that have only completed a phase I clinical trial. That is an extremely small trial. It does not determine the effectiveness, or the potential side effects of a drug. Access at this stage in the development could expose patients to untested products, further harm, and result in delaying access to a treatment that may be more appropriate and more beneficial for their underlying disease or condition.

H.R. 5247 also erodes important patient safeguards. It 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.

And while I appreciate, Mr. Speaker, the intent of this bill, I can't support it. The last thing I want to do is give patients false hope and to potentially put them at risk by completely removing FDA from the review and approval process.

Finally, Mr. Speaker, it is outrageous, in my opinion, that a bill of this magnitude is being considered under a suspension of the rule. As my Republican colleagues well know, bills considered under suspension are traditionally bipartisan bills that have worked their way through the appropriate committees with overwhelming bipartisan support.

This bill was never considered by the Energy and Commerce Committee. In fact, it was only introduced today. A bill with such critical patient safety implications should not be considered in this fashion. So I urge my colleagues to oppose this misguided legislation and stand with the more than 100 organizations that have come forward expressing their concern for patients and the unnecessary risk this legislation could expose our Nation's most vulnerable to.

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

Mr. WALDEN. Mr. Speaker, I now have the honor of yielding 3 minutes to the gentleman from Pennsylvania (Mr. FITZPATRICK), who has been, even be-

fore he got to the Congress, an extraordinary advocate for this cause and for the patients with terminally ill conditions.

Mr. FITZPATRICK. Mr. Speaker, I want to thank Chairman WALDEN; Mr. BURGESS; Mr. GRIFFITH; my friend, ANDY BIGGS; and Senator RON JOHNSON for their resolute commitment to see the Right to Try Act brought to a vote today.

Mr. Speaker, each year, thousands of Americans receive the devastating diagnosis of a terminal illness. And 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. 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 the right to try is all about. As the chairman indicated, 38 States have passed this bill with near unanimous, bipartisan support. A version of this bill unanimously passed the United States Senate.

However, we know Congress cannot legislate miracles. That is why, when talking about the right to try, we are careful not to represent it as a cure itself. The reality is that, while passing this measure is a step, the families and advocates we have worked closely with for years know that the right to try isn't a guarantee. It is about protecting hope and protecting opportunity—hope and opportunity for those like my constituent, Lieutenant Commander Matthew Bellina, a retired naval aviator and father of three, who was diagnosed with ALS in 2014.

Following the onset of his symptoms, Matt was grounded from flying. He eventually moved back home to Bucks County with his wife, Caitlin, and his three children to be surrounded by family and friends.

Although this disease stopped Matt's military service, he quickly picked up the fight with his new battle, involving himself in the ALS community and becoming a strong advocate for right-to-try legislation. Together with Jim Worthington and the Have a Heart Foundation, Matt advocated for the right to try across the Nation.

While the FDA has a program that allows terminally ill patients to apply for early access to promising treatment, the right to try is needed because the FDA's compassionate use process doesn't help enough people. Only about 1,200 people a year can make it through the current time-consuming and expensive application process. Comparatively, Mr. Speaker, 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 of the population of the United States can help 900 percent more people, the FDA program clearly is not working. This bill

does not gut the FDA or fundamentally change the relationship between doctor and patient. What it does is give Americans facing a terminal diagnosis a new pathway for treatments undergoing clinical trials.

I want to read something in closing, Mr. Speaker, that I received from Matt Bellina, who is with us today. "Please let them know that I have had ALS too long to meet the exclusion criteria for any promising trials. No drug company will offer me treatments under the current EAP guidelines. Two reputable companies have already indicated that they would try to treat me under the rules of this bill. A vote against this is essentially a vote to kill me. It is a vote to make my wife a widow and leave my boys fatherless. I can't stop anyone from voting that way, but please ask them to have the respect to look my family in the eye when they cast" that vote.

Mr. Speaker, when a life hangs in the balance, the Federal Government should not stand in the way of access to potentially lifesaving treatment.

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

Mr. GENE GREEN of Texas. Mr. Speaker, I thank my ranking member for allowing me to speak tonight.

Mr. Speaker, I rise in opposition to the Right to Try Act, legislation that would bypass the Food and Drug Administration's longstanding review and oversight of drug treatments and endanger patients with life-threatening diseases.

My heart goes out to the families of loved ones who are terminally ill and desperate for a breakthrough treatment. I, too, have lost loved ones and wished there was an experimental therapy available to save them.

FDA has decades of experience dealing with experimental therapies that have not received final approval. In 1987, the FDA created expanded access, better known as compassionate use, and gives terminally ill patients access to therapies still under clinical trials. FDA approves nearly all requests for investigational drugs. For the last 5 years, the FDA approval rate for this expanded access is over 99 percent. In fact, FDA physicians are available 24 hours a day to approve emergency requests.

My daughter is an infectious disease physician at the University of Nebraska Medical Center. They used the FDA's compassionate pathway to provide experimental therapy for an American doctor, a U.S. citizen, who had contracted Ebola while in Africa in 2014. FDA approved that request for that experimental treatment over the telephone in less than 24 hours. There is a solution other than this bill.

The new path created in this legislation is not necessary, and, in fact, may endanger the health and safety of terminally ill patients by bypassing FDA's oversight and expertise.

Mr. Speaker, I also want to speak on the importance of following regular order. The House Energy and Commerce Committee has been working with stakeholders and Federal agencies for years on creating incentives and pathways for the new generation of breakthrough therapies.

Two years ago, these efforts culminated with the passage of the 21st Century Cures Act, which I am proud to be a champion of. The 21st Century Cures Act went through regular order, including hearings; Member discussions; and compromises between regulators, stakeholders, and regulators.

It is not easy or quick, but regular order works because it gives the committees of jurisdiction the opportunity to debate and refine the legislation. This legislation we are currently considering did not go through regular order. In fact, it was just introduced earlier today, purposely avoiding consideration before our Energy and Commerce Committee due to its shortcomings.

I hope we can agree on the importance of following regular order and observe our Chamber's rules and traditions. The American people deserve nothing less. I ask my colleagues on both sides of the aisle to stand up for Americans facing these serious and life-threatening diseases by opposing this unnecessary and potentially dangerous legislation.

Mr. WALDEN. Mr. Speaker, I yield 2 minutes to the gentleman from Texas (Mr. BARTON), the former chairman of the full committee and the current vice chairman.

(Mr. BARTON asked and was given permission to revise and extend his remarks.)

Mr. BARTON. Mr. Speaker, I have listened to my friends on the minority talk about the reasons they are opposing this bill, and a normal piece of legislation that would have some merit didn't go through regular order, things of this sort. But, Mr. Speaker, when the house is burning down and you need the fire department, you don't ask if they followed proper procedure to get somebody out there to put out the fire.

My brother had liver cancer at the age of 44. He had tried every conventional therapy known to modern medicine, and it wasn't working. Now, he had a brother, myself, who was a subcommittee chairman of the committee of jurisdiction over the FDA. I contacted the FDA, and we got him in a special protocol for an investigational drug that was under approval. It wasn't approved. And the doctors and the people at the FDA told my brother and his family: If it works, it is going to really help you. But if it doesn't, you are going to die sooner.

Well, he was going to die anyway, Mr. Speaker. So he signed the informed consent and he took the drug and it didn't work, but he had that last shot. Now, I don't know what this debate about false hope is. When you have no hope, perhaps false hope is better than none at all.

All this bill does is let people who have no other hope for conventional therapy, if a drug has at least passed stage one at the FDA approval process, and their doctor thinks it will help them, if they give an informed consent, they can try it.

Now, my friends on the Democratic side are correct that, most of the time under the existing protocol, the FDA approves it without a problem. But why should the FDA approve it if you are about to die anyway? That is what this bill does. By the way, it passed the Senate with unanimous consent. Now, that is a miracle in itself.

Let's pass it here in the House and give hope a chance for these patients who are terminally ill and have no hope at all today.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentlewoman from California (Ms. MATSUI).

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

Mr. Speaker, I rise in opposition to this proposed right-to-try legislation. This bill offers patients false hope. It proposes a pathway to experimental drugs that offers absolutely no guarantee of access, while stripping patients of any legal or financial recourse, and places clinical trials at risk.

□ 1800

Last week, I am sure like everyone else, I heard from many constituents on behalf of their families and communities with devastating diseases, like multiple sclerosis.

When a family member is faced with a devastating diagnosis, you would do anything and try anything to improve their quality of life. I know. I have been there with family members in such heartbreaking situations. But this bill would not necessarily make it easier to get experimental treatments and it would definitely make it harder for patients in the future to get treatments. We need clinical trials to ensure drugs are safe and effective and to find real cures and treatments for these patients.

Because this bill would be dangerous for patients both today and in the future, many disease groups oppose the bill, including the National Organization for Rare Disorders, the American Cancer Society, the Cystic Fibrosis Foundation, and more.

Rushing this bill without proper bipartisan oversight places the American people in the way of real harm. Rescinding FDA oversight on unproven therapies is a perilous proposition.

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

Mr. WALDEN. Mr. Speaker, I yield myself 5 seconds.

Mr. Speaker, the last two speakers from California and Texas, two of our biggest States, a grand total of two legislators voted "no." Otherwise, it was unanimous in both those States to do what we are doing here today.

Mr. Speaker, I yield 2 minutes to the gentleman from Arizona (Mr. BIGGS), an incredible advocate of this legislation.

Mr. BIGGS. Mr. Speaker, I thank Chairman WALDEN for yielding. I am grateful for the work he has done on this. I am also grateful to my friends, Representatives FITZPATRICK and GRIFFITH, as well as Senator JOHNSON, for their advocacy here.

I don't want to get this crucial point lost: it is not us; it is the courageous patients and their friends and their families who deserve the most recognition about how far we have come to get this bill passed. Today is for them, not for us.

Thirty-eight States, soon to be 39 States, have passed this bill. That is enough to amend the U.S. Constitution, but here we stand because some have come and said we shouldn't give people false hope.

There is no such thing as false hope. You either have hope or you have no hope. In this instance, this bill gives tens of thousands, perhaps hundreds of thousands, or millions even, the hope that they can avail themselves of medication that might prolong their life or maybe even be a cure. These people who have advocated are fighters.

I hear about patient groups who oppose this, yet the States, our employers, they approve this. Every day, Laura McLinn, the mother of Jordan McLinn, receives countless emails from people similarly situated, saying: We need to pass the Right to Try Act. I need that right to try.

I am told: Oh, well, we take care of 1,500 a year.

Mr. Speaker, 1,500 a year, when there are literally tens of thousands of people who need their opportunity.

We are not mandating even. We are providing an opportunity. We are providing an option both for the patient and even the pharmaceutical company.

Now, I heard in the opening statement from my friend across the aisle that we are not compelling them to do it.

Would he feel more comfortable if we compelled pharmaceutical companies to provide those potential lifesaving medications?

We need to recognize that this bill is not for us in this Chamber. It is for Matt Bellina, Jordan McLinn, and Laura McLinn. It is for those who are similarly situated.

We have waited long enough. Let's get this done.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentlewoman from Illinois (Ms. SCHAKOWSKY).

Ms. SCHAKOWSKY. Mr. Speaker, I rise in opposition to H.R. 5247 because it actually creates a dangerous back door around the Food and Drug Administration approval process and it ignores that there is a safe pathway for terminally ill patients to get the treatment that they need.

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. It is not patient friendly. That is why 78 patients and doctor groups are all opposed to this legislation, like the American Cancer Society, the National Brain Tumor Society, the Leukemia and Lymphoma Society, and the Vietnam Veterans of America.

Mr. Speaker, I include in the RECORD this 5-page list of the opposing groups.

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 Gwendyth 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, Glut1 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 Waldenström's Macroglobulinemia Foundation (IWMMF), 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, Mucopolidosis 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. We can't trust manufacturers to act as a gatekeeper.

The important thing to know is there is already a safe process for terminally ill patients to access experimental treatments. Under the Expanded Access Program, 99 percent of applications are approved, and they are done in a speedy way.

This process is not merely a rubber stamp. The FDA plays a vital role in ensuring these experimental treatments are safe.

Even more important, in 19 States that have passed right-to-try laws, patients using an investigational drug can lose their hospice care; and in 6 States, they can be denied home healthcare. These are the very people who depend on hospice and home care, and they could lose those services.

This is not a humane, patient-centered bill for people who are facing death. It is just a dangerous pathway for bad actors to exist.

Let's go with the positive ability right now that we have. Ninety-nine percent of those desperate people looking for hope will get it from the Food and Drug Administration. So I urge my colleagues to oppose H.R. 5247.

Mr. WALDEN. Mr. Speaker, when Illinois took this up, they approved it 169-1 in their assembly.

Mr. Speaker, I yield as much time as he may consume to the gentleman from Virginia (Mr. GRIFFITH).

Mr. GRIFFITH. Mr. Speaker, I thank Chairman WALDEN for yielding.

Mr. Speaker, I have heard people say that this bill gives folks a false hope. There is no false hope.

They know it is a Hail Mary pass. They know it is unlikely to succeed, but they are willing to make the decision and the choice to take that chance.

I have heard that patients will be at risk, that they lose their safeguards. They have received a terminal diagnosis. They know they are at risk. They don't care about safeguards. They want to fight for life. They know they have that terminal disease or diagnosis and they may lose a few weeks, as we heard from my colleague, but they may gain years, and they are willing to take that risk.

Mr. Speaker, I have to tell you, if I had a terminal diagnosis, I would even consider injecting monkey urine if I thought it would give me a few more months or a few more years with my children, who are currently 18, 12, and 10. Others may choose not to try something. They may not want the right to try. They may not want to try the Hail Mary pass, but they should have the choice. They should have the right to try.

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

Mr. Speaker, as I have said, I have great concerns that H.R. 5247 would expose our most vulnerable and desperate patients to unnecessary risk.

Supporters of this legislation have argued that those patients who are suffering from a terminal illness deserve the right to take their health and treatment into their own hands, as they are faced without any other treatment options. Some have even asked: What risk could be worse than the risk of death?

As Arthur Caplan, a bioethicist from NYU, has pointed out: "There are things worse than death; being made to die faster, being made to die more miserably."

These are all very real scenarios that patients could be exposed to under the misleading and ill-conceived right-to-try pathway.

As I stated before, while the FDA approved 99 percent of the requests it received, of those, they revised 11 percent in order to protect patients. If this bill becomes law, the FDA no longer will have the opportunity to make those revisions and to protect vulnerable patients.

We must protect patients from bad actors or from dangerous treatments that might make their lives worse. That is why more than 100 organizations have written in opposition to this legislation, including 83 patient organizations like the National Organization for Rare Disorders, the Friends of Cancer Research, the American Cancer Society, Cancer Action Network.

In a letter to the Speaker and the Democratic leader, the patient organizations noted that "the alternative pathway in the latest version of the legislation is still less safe for our patients than the current expanded access process" that the FDA uses.

Dr. Ellen Sigal, the chair and founder of Friends of Cancer Research, said: "In its current form, the proposed legislation does nothing for patients other than provide false hope by allowing them to request a drug with no evidence of efficacy they may never receive and, should they receive it, may do more harm than good."

So I think we should all be concerned about protecting patients. Rather than rushing this bill through today, I would urge my colleagues to oppose this legislation and to come back to the table to find a solution that will streamline Expanded Access Programs while protecting patients from unnecessary harm.

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

Mr. WALDEN. Mr. Speaker, I yield 2 minutes to the gentleman from Texas (Mr. BURGESS), the chair of our Health Subcommittee. Texas voted unanimously for the Right to Try Act.

Mr. BURGESS. Mr. Speaker, I thank the chairman for yielding.

Mr. Speaker, just a little over a month ago, President Trump stood here at this podium behind me and told us: "People who are terminally ill should not have to go from country to country to seek a cure."

Along with President Trump, I want to give patients a chance right here at home.

A little over a year ago, this House passed the 21st Century Cures Act, made unprecedented acceleration of discoveries. Thanks to our researchers and our academic institutions, and those working in the pharmaceutical and medical device companies, Americans have access to more and more innovative treatments. However, I continue to hear from patients with serious life-threatening conditions, including my constituents in north Texas, who are frustrated with what they see as regulatory barriers from trying and experimenting with new therapies when everything else has failed.

When potentially lifesaving treatments exist but remain unavailable to patients, we have an opportunity to move past what has long been a dilemma towards delivering a hopeful message.

Since 2014, 38 States, including Texas, have passed a version of right-to-try laws.

I am pleased that the House of Representatives is considering right-to-try legislation that gives patients a chance at life by improving access to experimental treatments.

Mr. Speaker, a lot of people deserve thanks for getting this bill to us today, but, in particular, I want to thank the President of the United States, President Trump, and Vice President PENCE for their leadership in this effort.

Mr. Speaker, I urge my fellow Members to support this bill.

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

Mr. Speaker, there are a lot of reasons to oppose this bill today, and I have given a number of them, but the primary reason being the need to continue protecting patients by ensuring that the FDA remains a part of the process.

While we are speaking about process, I have to also oppose this legislation based on the inappropriate way the Republican majority is bringing this bill to the floor. Bills considered under suspension have traditionally gone through the committee process with overwhelming bipartisan support, and neither of those things is the case with this bill.

It was introduced today.

Does the majority really believe they are giving Members the appropriate

time to view this bill when it was introduced at 2 p.m.?

Patient access and patient safety should be shared goals among Democrats and Republicans, goals that could be achieved if this legislation was not being rushed to the floor under an arbitrary deadline.

Legislation such as this, that carries such great risk of patient harm, should be considered carefully, with attention paid to the unintended consequences that could follow.

Mr. Speaker, I would urge my colleagues to oppose this unnecessary and risky legislation, and to return to the regular order of the committee to consider legislation that would protect both patients from harm and the FDA from the weakening of the agency's role in our drug approval process.

We should not be voting on a bill of this consequence that was introduced this afternoon.

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

□ 1815

Mr. WALDEN. I yield 2 minutes to the gentleman from Georgia (Mr. CARTER), a distinguished member of our committee and a pharmacist by training and trade.

Mr. CARTER of Georgia. Mr. Speaker, I rise today in support of the Right to Try Act because this legislation will improve access to potentially lifesaving treatments for patients with terminal diseases or conditions.

Currently, patients can only receive drugs that are undergoing FDA review through clinical trials, through compassionate use, or expanding access. They access these unapproved treatments exclusively through the FDA but not through the drug sponsor. This critical legislation would establish informed consent for patients to access unapproved drugs that could save their lives.

This bill still guards patients from manufacturers misbranding or mislabeling drugs and specifies that any unapproved drug used in the alternative pathway must have an active application and is not the subject of a clinical hold.

I thank my good friend Chairman BURGESS and the rest of my colleagues on the committee for moving this legislation forward and working with the administration and stakeholders on all sides of these issues. This is a great step forward towards ensuring our patients get to take advantage of the incredible pharmaceutical therapies that our manufacturers are known for.

I applaud the Energy and Commerce Committee for their work in moving this legislation forward, and I urge my colleagues to support this legislation.

Mr. PALLONE. Mr. Speaker, may I ask the gentleman how many speakers he has left.

Mr. WALDEN. Mr. Speaker, we have two, I believe, left.

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

Mr. Speaker, I just want to talk about two other aspects of this bill that I haven't so far. One is the fact that States have actually implemented right-to-try laws that have done little to expand access to investigational treatment. Although 17 States and the District of Columbia have enacted right-to-try laws, 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 accompanying restrictions.

Neither the FDA nor States require insurers or pharmaceutical companies to cover the cost or reduce the cost of these expensive treatments. Instead, these laws put patients at a higher risk by prohibiting or weakening FDA oversight of investigational treatments.

With regard to clinical trials, the legislation could also expose patients to unnecessary risk by allowing access to investigational drugs that have only completed a phase I clinical trial. Phase I trials are extremely small trials, in the range of 20 to 80 patients, and are used primarily to determine toxicity. They do not determine effectiveness or potential side effects. Patients could suffer from harmful side effects or delay enrolling in a clinical trial program for a treatment that actually has evidence of efficacy for their disease or condition.

Finally, the bill would weaken the FDA's ability to oversee the adverse events or other clinical outcomes from the use of investigational drugs and provide broad liability protections for manufacturers, leaving patients with no recourse in the case of an adverse effect.

I just wanted to mention those.

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

Mr. WALDEN. Mr. Speaker, I yield 2 minutes to the gentleman from Georgia (Mr. ALLEN).

Mr. ALLEN. Mr. Speaker, I rise today to urge my colleagues to join me in supporting the Right to Try Act.

When those we hold dearest are diagnosed as terminally ill, the last thing we want to hear is that all treatment options have been exhausted. This is why I have been a longtime supporter of the Right to Try Act. Currently, 38 States have already passed right-to-try legislation to assist vulnerable patients, including my home State of Georgia.

By allowing terminally ill patients the access to unapproved drugs and therapies, we are giving them a fighting chance for their God-given right to

life. Although these drugs cannot guarantee a road to recovery, they can provide a better alternative in many hopeless situations and pave the way for more scientific breakthroughs.

Congress should keep breaking down regulatory barriers. Like the bill's name says, patients have a right to try. All Americans should have the right to choose.

Mr. Speaker, I thank the Energy and Commerce Committee for passing this important legislation out of committee, and I urge my colleagues to join me in supporting this bill on the House floor.

How in the world could anyone oppose the right to choose life?

Mr. WALDEN. Mr. Speaker, may I inquire as to how much time remains for each side.

The SPEAKER pro tempore (Mr. WEBER of Texas). The gentleman from Oregon has 3 minutes remaining. The gentleman from New Jersey has 1 minute remaining.

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

Mr. Speaker, I just want to conclude, if I could, in opposition to this bill by quoting some of the former FDA Commissioners.

This is from Dr. Margaret Hamburg, who said:

I am deeply concerned by the draft legislation being considered to remove the FDA from the proposals around right to try. Excluding the FDA will not benefit those patients and would be a mistake. There is no need to create a new potentially dangerous paradigm by passing this legislation which does not address the real issues at hand and could have unintended negative consequences, leading to a possible impediment of the development and approval of safe and effective therapies.

And then, finally, is the former FDA Principal Deputy Commissioner, Joshua Sharfstein, who said:

FDA review allows doctors and patients to tell the difference between a medication that works and one that does not. Evidence also orients the pharmaceutical market towards developing products that produce meaningful benefits for patients instead of just hope. Undermining FDA review by giving a right to patients to try anything at any time will leave more patients in desperate situations with fewer options and less understanding of what could really make a difference.

Again, Mr. Speaker, I would urge opposition to this legislation.

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

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

Mr. Speaker, when the Energy and Commerce Committee took up this issue in its broadest form, we heard from the FDA Commissioner, we heard from patients, we heard from family members, and what we heard was that there are barriers in States that preclude these State laws from working.

That is what the Government Accountability Office told us. They identified two issues—liability and use of

outcomes—as the two barriers as to why these laws passed in 38, soon to be 39, States. And in many cases—most cases, I would say—these laws have passed unanimously, with Republicans and Democrats back home supporting them, including in my own State. I think it was unanimous in both the house and the senate, all controlled by Democrats, in Oregon.

We have listened to our constituents; we have observed what has happened in our States—great laboratories—and we are acting here today to allow those who have been given this wretched, wretched prescription that their life is about to end to have a chance and a choice. That is what we are doing today. We are overcoming the barriers that exist at the State level. We are doing it in a reasonable and thoughtful way that protects patient safety and creates this new alternative pathway for them.

This is important legislation. It is not often in this body we get this opportunity to make this kind of a change and provide chance and hope for those who see their loved ones dying before their eyes.

I met with Jordan McLinn and his mother, Laura, earlier today. They have been incredible advocates for this cause. And they had just come from a meeting with Vice President PENCE, who, with the President, has been an extraordinary supporter of this effort.

From his Bible, Jordan showed me the Parable of the Lost Sheep, which is one of his favorites. It is a parable he had shared with the Vice President.

That Parable of the Lost Sheep tells us that not a single sheep should be lost, that the shepherd cares about them all. That same sentiment is what brings us here to right to try today.

Every opportunity to save a life matters, and every patient deserves that right to try. That is the legislation before us today, Mr. Speaker. It is well conceived, it is well thought out, and it will make a difference in saving lives.

I encourage my colleagues to vote “yes” and pass this legislation and give people a right to try.

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

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Oregon (Mr. WALDEN) that the House suspend the rules and pass the bill, H.R. 5247.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes 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 motion will be postponed.

REPORT ON RESOLUTION PROVIDING FOR CONSIDERATION OF H.R. 4545, FINANCIAL INSTITUTIONS EXAMINATION FAIRNESS AND REFORM ACT; PROVIDING FOR CONSIDERATION OF H.R. 1116, TAKING ACCOUNT OF INSTITUTIONS WITH LOW OPERATION RISK ACT OF 2017; AND PROVIDING FOR CONSIDERATION OF H.R. 4263, REGULATION AT IMPROVEMENT ACT OF 2017

Mr. BUCK, from the Committee on Rules, submitted a privileged report (Rept. No. 115–595) on the resolution (H. Res. 773) providing for consideration of the bill (H.R. 4545) to amend the Federal Financial Institutions Examination Council Act of 1978 to improve the examination of depository institutions, and for other purposes; providing for consideration of the bill (H.R. 1116) to require the Federal financial institutions regulatory agencies to take risk profiles and business models of institutions into account when taking regulatory actions, and for other purposes; and providing for consideration of the bill (H.R. 4263) to amend the Securities Act of 1933 with respect to small company capital formation, and for other purposes, which was referred to the House Calendar and ordered to be printed.

COMMUNICATION FROM DISTRICT DIRECTOR, THE HONORABLE PETE AGUILAR, MEMBER OF CONGRESS

The SPEAKER pro tempore laid before the House the following communication from Teresa Valdez, District Director, the Honorable PETE AGUILAR, Member of Congress:

Washington, DC, March 1, 2018.

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

DEAR MR. SPEAKER: This is to notify you formally pursuant to Rule VIII of the Rules of the House of Representatives that I have been served with a subpoena for documents and a separate subpoena for testimony, issued by the Superior Court of California, County of San Bernardino.

After consulting with the Office of General Counsel, I will make the determinations required by Rule VIII.

Sincerely,

TERESA VALDEZ,
District Director,
Congressman Pete Aguilar.

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 13, 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 Representa-

tives, the Clerk received the following message from the Secretary of the Senate on March 13, 2018, at 9:53 a.m.:

That the Secretary of the Senate request the House to return the official papers to the Senate H.R. 1207.

With best wishes, I am,
Sincerely,

KAREN L. HAAS.

REQUESTING RETURN OF H.R. 1207, TILDEN VETERANS POST OFFICE

The SPEAKER pro tempore laid before the House the following privileged message from the Senate:

In the Senate of the United States, March 12, 2018.

Ordered, That the Secretary be directed to request the House of Representatives to return to the Senate the bill (H.R. 1207) entitled "An Act to designate the facility of the United States Postal Service located at 306 River Street in Tilden, Texas, as the 'Tilden Veterans Post Office'."

Attest:

JULIE E. ADAMS,
Secretary.

The SPEAKER pro tempore. Without objection, the request is granted.

There was no objection.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, proceedings will resume on motions to suspend the rules previously postponed.

Votes will be taken in the following order:

H.R. 5247, by the yeas and nays;

H.R. 4465, by the yeas and nays.

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

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

The SPEAKER pro tempore. The unfinished business is the vote on the motion to suspend the rules and pass 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, on which the yeas and nays were ordered.

The Clerk read the title of the bill.

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

The vote was taken by electronic device, and there were—yeas 259, nays 140, not voting 31, as follows:

[Roll No. 102]

YEAS—259

Abraham	Allen	Amodei
Aderholt	Amash	Arrington

Babin	Gosar	Nunes
Bacon	Gottheimer	O'Halloran
Banks (IN)	Gowdy	O'Rourke
Barletta	Granger	Olson
Barr	Graves (GA)	Palazzo
Barragán	Graves (LA)	Palmer
Barton	Graves (MO)	Pearce
Bergman	Griffith	Perlmutter
Biggs	Grothman	Perry
Bilirakis	Guthrie	Peterson
Bishop (GA)	Hanabusa	Pittenger
Bishop (MI)	Handel	Poe (TX)
Bishop (UT)	Harper	Poliquin
Black	Harris	Polis
Blackburn	Hartzler	Posey
Blum	Hensarling	Ratcliffe
Bost	Herrera Beutler	Reichert
Brady (TX)	Hice, Jody B.	Renacci
Brat	Higgins (LA)	Rice (SC)
Bridenstine	Hill	Richmond
Brooks (AL)	Himes	Roby
Brooks (IN)	Holding	Roe (TN)
Brown (MD)	Hollingsworth	Rogers (AL)
Buchanan	Hudson	Rogers (KY)
Buck	Huizenga	Rokita
Bucshon	Hultgren	Rooney, Francis
Budd	Hurd	Rooney, Thomas J.
Burgess	Jenkins (KS)	Rosen
Byrne	Jenkins (WV)	Roskam
Calvert	Johnson (LA)	Ross
Carbajal	Johnson (OH)	Rothfus
Carter (GA)	Johnson, Sam	Rouzer
Carter (TX)	Jones	Royce (CA)
Chabot	Jordan	Russell
Cheney	Joyce (OH)	Rutherford
Coffman	Katko	Sanford
Cohen	Kelly (MS)	Scalise
Cole	Kelly (PA)	Schweikert
Collins (GA)	Kind	Scott, Austin
Collins (NY)	King (IA)	Sensenbrenner
Comer	King (NY)	Sessions
Comstock	Kinzinger	Shimkus
Conaway	Knight	Shuster
Cook	Kustoff (TN)	Sinema
Cooper	Labrador	Smith (MO)
Correa	LaHood	Smith (NE)
Costa	LaMalfa	Smith (NJ)
Costello (PA)	Lamborn	Smith (TX)
Cramer	Lance	Smucker
Crawford	Larson (CT)	Stefanik
Crist	Latta	Stewart
Cuellar	Lawson (FL)	Stivers
Culberson	Lewis (MN)	Suozi
Curbelo (FL)	LoBiondo	Taylor
Curtis	Loebach	Tenney
Davidson	Lofgren	Thompson (PA)
Davis, Rodney	Long	Thornberry
Delaney	Loudermilk	Tipton
Denham	Love	Trott
Dent	Lucas	Turner
DesJarlais	Lujan Grisham, M.	Upton
Diaz-Balart	MacArthur	Valadao
Donovan	Maloney, Sean	Veasey
Duffy	Marchant	Wagner
Duncan (SC)	Marino	Walberg
Duncan (TN)	Marshall	Walden
Dunn	Massie	Walker
Emmer	Mast	Walorski
Estes (KS)	McCarthy	Walters, Mimi
Evans	McCaul	Weber (TX)
Farenthold	McClintock	Webster (FL)
Faso	McHenry	Wenstrup
Ferguson	McKinley	Westerman
Fitzpatrick	McMorris	Williams
Fleischmann	Rodgers	Wilson (SC)
Flores	McSally	Wittman
Fortenberry	Meadows	Womack
Fox	Messer	Woodall
Frelinghuysen	Mitchell	Yoder
Gaetz	Moolenaar	Yoho
Gallagher	Mooney (WV)	Young (AK)
Garrett	Mullin	Young (IA)
Gianforte	Gibbs	Zeldin
Gohmert	Noem	
Goodlatte	Norman	

NAYS—140

Adams	Blumenauer	Bustos
Aguilar	Blunt Rochester	Butterfield
Bass	Bonamici	Cárdenas
Beatty	Boyle, Brendan F.	Carson (IN)
Bera		Cartwright
Beyer	Brownley (CA)	Castor (FL)