it is in God's hands. In that moment, I will tell you this: all that these patients want and deserve is a right to try.

Please support this legislation.

Mr. PALLONE. Mr. Speaker, I just want to urge support for this legislation. The support is obviously bipartisan, and I urge all my colleagues to support it.

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

Mr. BURGESS. Mr. Speaker, I, too, want to express my strong support for S. 292, the Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2018, Childhood Cancer STAR Act.

And, once again, I want to thank my colleague, the gentleman from Texas (Mr. MCCAUL), for spearheading this effort.

I urge all my colleagues to support the legislation.

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

Ms. SPEIER. Mr. Speaker, I rise today in support of the Childhood Cancer Survivorship, Treatment, Access & Research (STAR) Act, a bill that will touch many lives affected by childhood cancer. This has been a true example of bipartisanship. I particularly want to thank my colleague Congressman MCCAUL for his leadership on this critical bill and my other fellow co-chairs of the Congressional Childhood Cancer Caucus, Congressmen BUTTERFIELD and KELLY. I also want to thank our Senate partners, Senators REED, MOORE CAPITO, VAN HOLLEN, and ISAKSON. And to all children and families affected by childhood cancer, this is their victory. It is because of their tireless advocacy that this landmark legislation will be sent to the President's desk and signed into law.

With the STAR Act, we have won a battle in our long-fought war against childhood cancer. This bill creates an arsenal of tools for the National Institutes of Health to promote vital research into childhood cancer, such as the establishment of National Biorepositories. It also improves the quality of life for survivors, including by funding models of long-term care to help monitor the progress of survivors as they age.

Mr. Speaker, I want to take a moment to recognize two of my constituents who have personally inspired my work on this important bill. The first is Christie Chaudry, who after surviving childhood cancer grew up to become a pediatric oncology nurse practitioner. For the last seven years, Christie has helped run the inpatient chemotherapy unit at Lucile Packard Children's Hospital at Stanford—the same hospital where she was treated as a child.

The second is Andrea Church, a childhood cancer advocate from San Carlos, California, who set a goal to have San Francisco City Hall lit up in gold in honor of Childhood Cancer Awareness Month. Andrea's daughter, Riley, passed away at age 14 due to an inoperable brain tumor. In her daughter's honor, Andrea reached and surpassed her goal two years ago. Not only did San Francisco City Hall go gold, so did Oakland City Hall, AT&T Park—the home of the San Francisco Giants—and the Oakland Coliseum—the home of the Oakland A's.

Mr. Speaker, the STAR Act opens the door to numerous opportunities for research and innovation in the treatment of childhood cancer. It addresses critical gaps in the care of childhood cancer survivors, and it creates a holistic approach to studying the disease. With the passage of this legislation, we are moving closer to a future where children and their families may one day live cancer-free. I thank my colleagues for their support.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Texas (Mr. BURGESS) that the House suspend the rules and pass the bill, S. 292.

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 2017

Mr. BURGESS. Mr. Speaker, pursuant to House Resolution 905, I call up the bill (S. 204) to authorize the use of unapproved medical products by patients diagnosed with a terminal illness in accordance with State law, 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 905, the bill is considered read.

The text of the bill is as follows:

S. 204

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 2017''.

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) DEFINITIONS.—For purposes of this section—

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

''(A) who has been diagnosed with a life-threatening disease or condition (as defined in section 312.81 of title 21, Code of Federal Regulations (or any successor regulations));

''(B) who has exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug, 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 directly by the manufacturer for so certifying; and

''(C) who has provided to the treating physician written informed consent 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; 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 is ongoing and has not been discontinued by the manufacturer or placed on clinical hold under section 505(i); and

''(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).

''(b) EXEMPTIONS.—Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from sections 502(f), 503(b)(4), 505(a), and 505(i) of this Act, section 351(a) of the Public Health Service Act, and parts 50, 56, and 312 of title 21, Code of Federal Regulations (or any successor regulations), provided that the sponsor of such eligible investigational drug or 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 is in compliance with the applicable requirements set forth in sections 312.6, 312.7, and 312.8(d)(1) of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational drugs.

''(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.—

''(1) IN GENERAL.—The manufacturer or sponsor of an eligible investigational drug shall submit to the Secretary an annual summary of any use of such drug under this section. The summary shall include the number of doses supplied, the number of patients treated, the uses for which the drug was made available, and any known serious adverse events. The Secretary shall specify by regulation the deadline of submission of such annual summary and may amend section

312.33 of title 21, Code of Federal Regulations (or any successor regulations) to require the submission of such annual summary in conjunction with the annual report for an applicable investigational new drug application for such drug.

''(2) POSTING OF INFORMATION.—The Secretary shall post an annual summary report of the use of this section on the internet website of the Food and Drug Administration, including the number of drugs for which clinical outcomes associated with the use of an eligible investigational drug pursuant to this section was—

''(A) used in accordance with subsection (c)(1)(A);

''(B) used in accordance with subsection (c)(1)(B); and

''(C) not used in the review of an application under section 505 of this Act or section 351 of the Public Health Service Act.''.

(b) NO LIABILITY.—

(1) ALLEGED ACTS OR OMISSIONS.—With respect to any alleged act or omission with respect to an eligible investigational drug provided to an eligible patient pursuant to section 561B of the Federal Food, Drug, and Cosmetic Act and in compliance with such section, no liability in a cause of action shall lie against—

(A) a sponsor or manufacturer; or

(B) a prescriber, dispenser, or other individual entity (other than a sponsor or manufacturer), unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort under any applicable State law.

(2) DETERMINATION NOT TO PROVIDE DRUG.—No liability shall lie against a sponsor manufacturer, prescriber, dispenser or other individual entity for its determination not to provide access to an eligible investigational drug under section 561B of the Federal Food, Drug, and Cosmetic Act.

(3) LIMITATION.—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 under any State or Federal product liability, tort, consumer protection, or warranty law.

SEC. 3. SENSE OF THE SENATE.

It is the sense of the Senate that section 561B of the Federal Food, Drug, and Cosmetic Act, as added by section 2—

(1) does not establish a new entitlement or modify an existing entitlement, or otherwise establish a positive right to any party or individual;

(2) does not establish any new mandates, directives, or additional regulations;

(3) only expands the scope of individual liberty and agency among patients, in limited circumstances;

(4) is consistent with, and will act as an alternative pathway alongside, existing expanded access policies of the Food and Drug Administration;

(5) will not, and cannot, create a cure or effective therapy where none exists;

(6) recognizes that the eligible terminally ill patient population often consists of those patients with the highest risk of mortality, and use of experimental treatments under the criteria and procedure described in such section 561A involves an informed assumption of risk; and

(7) establishes national standards and rules by which investigational drugs may be provided to terminally ill patients.

The SPEAKER pro tempore. The bill shall be debatable for 1 hour equally divided and controlled by the chair and ranking minority member of the Committee on Energy and Commerce.

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 have 5 legislative days to revise and extend their remarks and to insert extraneous material into the RECORD on the bill.

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, here in the people's House, we reflect the will of the American people. When the Right to Try Act is law in 40 States, it may no longer just be a grassroots movement. It is a call to action from Americans from coast to coast—many of the over 1 million Americans who die from a terminal illness every year—to return choice and control over treatment options to where it is most effective: with the patient, with the doctor.

Today, the House is taking up the Right to Try Act for the third time. But the reason we are here again debating this issue is because of the Senate Democrats' refusal to take up the revised right-to-try legislation that passed this House by a bipartisan vote 2 months ago.

That revised bill, H.R. 5247, was more narrowly crafted than this version of S. 204.

This version, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, is before us today. S. 204 was authored by Senator RON JOHNSON of Wisconsin and passed by unanimous consent in the Senate last August.

I think it is important, so let me take a moment to lay out the efforts by the Energy and Commerce Committee since that time.

First, the Energy and Commerce Health Subcommittee, which I chair, held a hearing last October to consider right-to-try bills, including this bill, S. 204, where Members heard from Dr. Scott Gottlieb, the Commissioner of the Food and Drug Administration, from patients and other groups that either support or oppose the concept of right to try.

For several months, our committee engaged in conversations with patients, advocates, the administration, particularly the Food and Drug Administration, and stakeholders on all sides of this complex topic.

Our aim was to open the door to innovative, experimental drugs for terminally ill patients without necessarily compromising the vital work and mission of the Food and Drug Administration. The product of that aim was H.R. 5247, the revised House right-to-try bill.

Sadly, Senate Democrats said ''thanks, but no thanks'' to the House bill. Frankly, I am perplexed by their decision, because not a single Senate Democrat expressed any reservation when S. 204 passed their Chamber by unanimous consent last August.

So House Republicans will show the American people that we hear you. We will act to deliver on a promise made by the President in this House before the joint session of the House and Senate during the State of the Union address. He told us that we would pass the right-to-try legislation. Well, today, we are doing just that.

You know, this was kind of a bold statement by the President, to stand up in the State of the Union and say that he wanted to sign this bill into law. So I am proud to boldly stand with him and stand with the American people.

Mr. Speaker, we live in the greatest Nation in the world. An unprecedented amount of innovation and scientific breakthrough is the norm. We have innovative treatments at our fingertips because of the valuable contributions of researchers in academia and the private sector.

Despite these achievements, I still hear from patients with serious, life-threatening conditions, including constituents from north Texas, who remain frustrated with the current regulatory processes that prevent them from trying or experimenting with new therapies when everything else has failed them.

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 terminal conditions.

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

Mr. Speaker, I am proud to support H.R. 5247, the House right-to-try bill that currently remains in the Senate.

However, the right-to-try legislation before the House today is the Senate bill, S. 204, so I am pleased that we are considering this right-to-try bill so that terminally ill patients have a chance, 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 and give them renewed hope.

S. 204 establishes an alternative pathway for terminally ill patients to access certain investigational drugs that have successfully completed a phase one clinical trial and have an active application at the Food and Drug Administration. They also must be under active development or production by the manufacturer.

It is important to note that, for these patients, they have exhausted all FDA-approved treatment options and are unable to participate in a clinical trial involving these investigational drugs.

The bill we will be voting out soon is about patients. It is about having more

time with their loved ones. In the words of Vice President MIKE PENCE, ''It's about restoring hope and giving patients with life-threatening diseases a fighting chance.''

With hundreds of thousands of Americans with a terminal illness and their families looking for us to act, I urge Members of this House, the people's House, to support restoring hope and giving them a fighting chance at life.

I urge a vote in support of S. 204. Let us send this groundbreaking legislation to the President's desk for his signature, and let it become the law of the land.

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

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

Mr. Speaker, I rise today in strong opposition to S. 204, the Federal Right to Try Act. This is dangerous legislation that threatens FDA's authority over ensuring that medical treatments are safe and effective. This bill needlessly exposes vulnerable patients to the risks of unproven medications.

□ 1600

We heard last night in the Rules Committee from my Republican colleagues that we must accept and pass this legislation because the Senate is unable to pass a bill that passed the House earlier this year. That House bill was bad enough, but this Senate bill is much worse. I cannot fathom why my Republican colleagues are surrendering to the Senate and agreeing to pass a more dangerous version of the right-to-try legislation.

The Senate bill, like the House bill, establishes an alternative pathway for experimental treatments that eliminates any review from the Food and Drug Administration and scientific and medical experts of an independent review board. This will provide fly-by-night physicians and clinics the opportunity to peddle false hope and ineffective drugs to desperate patients.

At a hearing before our committee, FDA Commissioner Scott Gottlieb cautioned that S. 204 risked ''exposing people to unwanted side effects from experimental therapies.''

Now, supporters of this bill would have you believe that this legislation is targeted at those with terminal illnesses, but this is simply not the case. S. 204 would, in fact, apply to a much broader range of patients diagnosed with life-threatening diseases or conditions. And the term ''life-threatening disease or condition'' could include chronic and often manageable diseases, such as diabetes or chronic heart failure.

If all patients with diabetes and other chronic but manageable illnesses were eligible, it would greatly expand the scope of the legislation well beyond the scope of most State laws and FDA's expanded access program. This exposes an even greater number of patients to risk and undermines our clinical trial program by diverting patients from trials that could support full approval to the alternate pathway.

Commissioner Gottlieb also cautioned Congress that this legislation risked ''undermining a regulatory process that has been carefully crafted over many years to strike a very careful balance.'' The Commissioner noted that S. 204 would not subject all participants to the alternate pathway to critical regulatory requirements, such as labeling products as investigational, charging limitations, and restrictions on promotion and commercialization of such treatments.

S. 204 could also impede the FDA from taking action against manufacturers and others that violate other provisions of the Federal Food, Drug, and Cosmetic Act. Under this bill, if a bad actor is not in compliance with good manufacturing practices or does not protect against intentional alteration—adulteration, I should say—or allows dishonest or misleading labeling, the FDA will not be able to take any enforcement action.

But, more importantly, Mr. Speaker, this Federal right-to-try bill simply is not necessary, in my opinion. FDA has an expanded access program and has an approval rate of nearly 100 percent.

To be clear, FDA's high approval rate is not just a rubberstamp for these applications. Of the applications FDA receives and approves, it also adjusts applications for 11 percent of patients to improve patient safety protections. This could include modifying the dosing, strengthening informed consent, or improving safety monitoring.

We must protect patients from bad actors or from dangerous treatments that might make their lives worse. Without this critical review, there will not be any oversight to ensure that patients are not being taken advantage of or put in harm's way.

The main reason this bill is being pushed is to chip away at FDA's authority to ensure the safety and effectiveness of our drugs.

FDA oversight of access to experimental treatment exists for a reason: it protects patients from potentially snake oil salesmen or from experimental treatments that might do more harm than good.

By removing the FDA oversight, you are counting on physicians and manufacturers to serve as the gatekeeper and protector of our patients. I simply don't buy that that is going to work.

Supporters of this bill want to blindly believe that there are no bad actors out there, but imagine someone like Martin Shkreli promising a dying patient a cure that could save their life. Under this bill, FDA would play no role in determining whether or not Martin Shkreli could provide that drug to that dying patient.

If S. 204 is signed into law, patients will be taken advantage of and will be harmed. Bad actors exist, and this Republican bill gives them the opportunity to prey on desperate people who are, understandably, looking for any treatment that may help save their lives.

Now, let me also point out that the supporters of this bill claim to be helping desperate patients who are looking for hope. If this is such a patient-centered bill, why does every major patient organization overwhelmingly oppose it? Where is the call from patients for this legislation?

More than 100 patient organizations, including the National Organization for Rare Disorders, Friends of Cancer Research, and American Cancer Society Cancer Action Network, sent a letter to Congress just yesterday opposing this legislation. In the letter, they stated: ''The Senate version of the legislation is less safe than the pathway proposed in the House version and is dangerous compared to the current expanded FDA access process.''

Four former FDA Commissioners from both parties also oppose this Republican legislation, noting: ''There is no evidence that either bill''—that is the House or the Senate—''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, S. 204, I know, is a key agenda item for the President and the Vice President; but I think it is dangerous for our patients, and it is an unprecedented attempt to roll back FDA's oversight of investigational treatments.

Mr. Speaker, 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 5 minutes to the gentleman from Oregon (Mr. WALDEN), the chairman of the full committee.

Mr. WALDEN. Mr. Speaker, today represents the third time this year that the House has considered legislation to deliver hope to patients who are battling terminal diseases. Twice already, a bipartisan majority of Members has supported increasing patient access to investigational drugs through a new pathway outside of the existing expanded access program, and the bill before us today is deserving of that same support.

Thirty-nine States have right-to-try laws, including my home State of Oregon. While the State policies vary, they have a common goal: helping vulnerable patients. President Trump praised the movement during the State of the Union. He said: ''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.'' Those are the President's words. Since this time, he has continued to feverishly advocate for this legislation.

For today's debate, I believe it is important to understand that it is both

the background of this issue as well as the politics that have brought us back to this floor.

Today, there is an existing process for patients to access unapproved drugs. The FDA oversees the expanded access program, commonly known as compassionate use. This program has been critical in helping patients access experimental or investigative drugs.

As I previously said before in this Chamber, Commissioner Gottlieb and the agency should be commended for their continued work to improve the expanded access program for patients.

To improve this successful program, the bill this Chamber previously passed 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 the legislation. That provision removes one of the biggest hurdles patients face, as identified by the Government Accountability Office, in gaining access to experimental therapies: manufacturer hesitancy to participate. That is the obstacle. That same bill creates a new alternative pathway for patients who do not qualify for a clinical trial.

It is my view that the House-passed bill strengthens patient protections with clearer informed consent and adverse event reporting. The bill also ensures that the FDA is notified when a patient receives an unapproved drug through the new alternative pathway to ensure proper oversight.

But when a strong bipartisan majority of this Chamber, of the U.S. House of Representatives, Mr. Speaker, delivered for patients and answered President Trump's call to give Americans the right to try, leaders in the Senate on the other side of the aisle objected, blocking terminally ill patients from increasing access to investigational drugs. But we will not allow them to play politics to delay this effort any longer. That is why we are here today.

Mr. Speaker, across our great country, men, women, children, and parents are desperately seeking a beacon of hope, and the Senate bill we have before us today will provide it.

Mr. Speaker, I thank President Trump and Vice President PENCE for continuing to weigh in on this important issue; and the sponsors of past and current legislation, including Senator JOHNSON and Representatives FITZPATRICK and BIGGS, who are here with us today. They have all been tireless in their advocacy and their efforts for this worthy cause. I am glad to see that, together, we are once again going to deliver.

But, most importantly, I would like to acknowledge the individuals this bill is named after: Trickett, Frank, Jordan, and Matthew. Jordan was here on the House floor the first time we considered right-to-try legislation, and Matthew testified at our hearing last fall. Jordan is back with us today. It is through their advocacy and hope to find a treatment or a cure that we have this chance to give patients the right to try.

Mr. Speaker, it is time for the House to do what the entire United States Senate did and pass this legislation. It is time to send a right-to-try bill to President Trump's desk, where he is eager to sign it.

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

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentlewoman from Florida (Ms. CASTOR), the vice ranking member of the Energy and Commerce Committee.

Ms. CASTOR of Florida. Mr. Speaker, I thank the ranking member for his leadership and for yielding me time.

Mr. Speaker, S. 204 is harmful legislation that offers a false hope of access to investigational therapies and endangers patients who have serious and life-threatening diseases. The bill establishes a dangerous and unnecessary alternative pathway that is void of any FDA review or oversight. It is opposed overwhelmingly by the patient community.

Mr. Speaker, I include in the RECORD a letter to the Speaker and minority leader from 104 patient advocacy groups. It includes such groups as the American Cancer Society Cancer Action Network, the American Lung Association, the Cystic Fibrosis Foundation—all opposed to this bill—the Leukemia & Lymphoma Society, and about 100 more.

MAY 21, 2018.

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

The Hon. NANCY PELOSI,
Minority Leader, House of Representatives, Washington, DC.

DEAR SPEAKER RYAN AND LEADER PELOSI: The undersigned organizations collectively represent millions of patients with serious and life-threatening diseases. We write to express our strong opposition to the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act (S. 204).

On March 21st, The House of Representatives passed a version of the Right to Try Act (H.R. 5247), that incorporated important patient safeguards such as more robust informed consent and public reporting requirements, additional Food and Drug Administration (FDA) oversight, and a narrower definition of eligibility for this pathway. The Senate version does not include these safeguards and therefore could greatly increase the likelihood of our patients being harmed by unsafe and ineffective experimental therapies. Therefore, this version is substantially worse for patients.

We reiterate our concern with creating a secondary pathway for accessing investigational therapies outside of clinical trials. This pathway removes FDA approval and consultation and would not increase access to promising therapies for our patients because it does not address the primary barriers to access.

FDA's expanded access program, though imperfect, facilitates access to investigational therapies for over a thousand patients facing serious and life-threatening conditions each year. FDA repeatedly approves over 99 percent of requests while sometimes making important dosing and safety improvements to proposed expanded use. Conversely, it is often times the pharmaceutical company that denies access to its investigational therapy outside of its clinical trials for any number of reasons.

The Senate version of the legislation is less safe than the pathway proposed in the House version and is dangerous compared to the current expanded access process. The Senate's bill would allow unproven therapies to be given to patients without FDA notification for up to a full year and would not establish any standards for informed consent.

Additionally, both versions prohibit FDA from halting access to these experimental therapies short of placing a clinical hold on all clinical research on the therapy in question. Both House and Senate versions would also remove FDA's consultation on dosing, route of administration, dosing schedule, and other important safety measures available under FDA's current expanded access program.

While we did not support the recent House passed version of this legislation, the House legislation includes improved patient safeguards compared to the Senate version. The Senate version would negatively impact patient safety substantially, and our collective organizations are strongly opposed. We appreciate past efforts in the House to consider stakeholder perspectives and desire to continue the dialogue, but returning to the Senate version is simply not the way forward.

Sincerely,

A Twist of Fate-ATS; ADNP Kids Research Foundation; Adult Polyglucosan Body Disease Research Foundation; AIDS Action Baltimore; Alliance for Aging Research; Alliance of Dedicated Cancer Centers; American Cancer Society Cancer Action Network; American Lung Association; American Society of Clinical Oncology; American Syringomyelia and Chiari Alliance Project; Amyloidosis Support Groups; APS Type 1 Foundation; Association for Creatine Deficiencies; Association of American Medical Colleges; Benign Essential Blepharospasm Research Foundation; Bonnie J. Addario Lung Cancer Foundation; Bridge the Gap-SYNGAP Education and Research Foundation; CancerCare; Charlotte and Gwenyth Gray Foundation to Cure Batten Disease; Children's Cardiomyopathy Foundation.

Congenital Hyperinsulinism International; cureCADASIL; CurePSP; Cutaneous Lymphoma Foundation; Cystic Fibrosis Foundation; Defeat MSA; The Desmoid Tumor Research Foundation; The Disability Rights Legal Center; Dupl5q Alliance; Dysautonomia Foundation; Dyskeratosis Congenita Outreach, Inc.; Equal Access for Rare Disorders; Fight Colorectal Cancer; FORCE: Facing Our Risk of Cancer Empowered; Friedreich's Ataxia Research Alliance (FARA); Friends of Cancer Research; The Global Foundation for Peroxisomal Disorders; Glutl Deficiency Foundation; The Guthy-Jackson Charitable Foundation; Hemophilia Federation of America.

HLRCC Family Alliance; Hope for Hypothalamic Hamartomas; Hyper IgM Foundation, Inc.; Incontinentia Pigmenti International Foundation; Indian Organization for Rare Disorders; 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; Li-Fraumeni Syndrome Association (LFS Association/LFSA); LUNGevity Foundation; Lymphangiomatosis

& Gorham's Disease Alliance; 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 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 PKU Alliance; National PKU News; Neurofibromatosis Northeast; The Oley Foundation; Operation ASHA; Organic Acidemia Association.

PSC Partners Seeking a Cure; Platelet Disorder Support Association; PRP Alliance, Inc.; Pulmonary Fibrosis Foundation; Rare and Undiagnosed Network (RUN); Rothmund-Thomson Syndrome Foundation; The Snyder-Robinson Foundation; Sofia Sees Hope; SSADH Association; Susan G. Komen; TargetCancer Foundation; Tarlov Cyst Disease Foundation; Team Audrey; Treatment Action Group; The Turner Syndrome Society; United Leukodystrophy Foundation; United Mitochondrial Disease Foundation (UMDF); Vasculitis Foundation; Veterans Health Council; Vietnam Veterans of America; VHL Alliance; Wilhelm Foundation; Worldwide Syringomyelia & Chiari Task Force; The XLH Network, Inc.

Ms. CASTOR of Florida. Mr. Speaker, this bill is a bill in search of a problem. FDA has approved 99 percent of the expanded access requests it receives. FDA's expanded access program approves nearly all requests for investigational drugs or biologics it receives.

Physicians at the FDA are available 24 hours a day to approve any emergency expanded access requests that the agency receives, and it typically grants those 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 this entire process.

The process of clinical trials at FDA is vital to the protection of the health of all of our neighbors and the folks we represent. In 11 percent of expanded access applications, FDA has raised a red flag and said: Do you know what? You have got to change this.

That is who we are trying to protect here: the actual patients. The patient groups across the country agree with us.

Many States have tinkered with right-to-try laws, but this is different. Forty States have enacted right-to-try laws, but there is no evidence that anyone has obtained the type of therapy via these laws that couldn't have been obtained through the FDA's expanded access program.

Right-to-try laws do not compel companies to provide patient access to these treatments. Therefore, under these laws, patients still do not have a right to try, only the right to request it from the company.

Sometimes those insurance companies will say: Do you know what? We are not going to pay for it.

So that is going to be another barrier.

Mr. Speaker, in the end, these right-to-try laws put patients at higher risk by prohibiting and weakening the FDA oversight, leaving our neighbors on the hook to cover the cost of unproven treatments.

For all of these reasons, I urge a ''no'' vote on the bill. Join with the patient advocates across America, who, in this letter, called this a dangerous proposal.

Mr. BURGESS. Mr. Speaker, I am pleased to yield 3 minutes to the gentleman from Texas (Mr. BARTON), the vice chairman of the full committee and chairman emeritus of the Energy and Commerce Committee.

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

Mr. BARTON. Mr. Speaker, when I was a little boy, I used to read comic books, and one of them I read was Superman. In the Superman comic books, way back in the 1960s, Superman had an alterego that lived on Bizarro World.

□ 1615

In Bizarro World, everything was a little bit off-kilter. When I listen to my sincerely good friends on the minority side, I think they are on Bizarro World. I know they mean well, but they are not seeing the same planet I am seeing.

I have told this story a number of times about my brother John at the age of 40 having liver cancer. He had exhausted all conventional therapy. He was given less than 3 months to live.

Being a Member of Congress and on the Energy and Commerce Committee, I had access to the National Institutes of Health and the FDA. I called, and I said: Are there any experimental programs that you could get my brother into that might help him?

They checked, and they had a clinical trial, I believe, in San Antonio, Texas. We called down, and they got him into it. But they told him: This is experimental. It has helped a lot of people so far, but it doesn't help everybody. And if it doesn't help you, it accelerates your disease.

He and his wife prayed about it, and his mother and myself and his brother and sister, and we all decided, why not?

They put John in the trial, and it didn't help him, but we were at peace because we had used every available remedy that we could to try to help him.

This bill—which has passed the Senate, and if we pass it today, it goes to the President and it is going to be signed this week—gives patients, if their doctors approve, the right to try.

It has to be an investigational drug that is in an FDA clinical trial that has passed phase one, which has proved that it is nontoxic.

It gives them the right to try. There is no downside to this. This could become law. It would give a statutory right to try at the Federal level.

Why in the world my friends on the minority side have a problem with—it passed the Senate unanimously, which means, under the current Senate, 49 Democrats voted for it by a voice vote.

There is no downside to it. The FDA is still in control of what drugs are passed through this phase one clinical trial. And the doctor has to recommend it, and the patient has to accept it.

So I hope we will vote ''yes.''

The SPEAKER pro tempore (Mr. DONOVAN). The time of the gentleman has expired.

Mr. BURGESS. Mr. Speaker, I yield an additional 30 seconds to the gentleman from Texas.

Mr. BARTON. Mr. Speaker, the bill has already passed the House on a bipartisan vote. I think I am right that it passed with 261 votes the last time we sent it.

The House bill is a little bit better bill than the Senate, but the Senate bill is better than no bill. So please vote ''yes'' when the time comes this afternoon.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentleman from California (Mr. MCNERNEY).

Mr. MCNERNEY. Mr. Speaker, I thank the gentleman for yielding, and I thank the Members of the House for talking about this issue.

Mr. Speaker, I rise in opposition to S. 204, the Right to Try Act. I don't agree with my friend from Texas that there is no downside, and I will go over that here in these 2 minutes.

The House took up this issue before, and I voted against it then. This version is worse, so of course I am going to oppose it.

It would weaken the FDA's authority and provide broad access to unproven treatments. The FDA's oversight of experimental treatment plays a critical role in protecting patients from bad actors with malicious intent or from drugs that are grossly untested. The FDA's oversight protections protect patients from experimental treatments that might do more harm than good.

Chipping away at the FDA's authority would put patients in my district and around the country in great danger by providing liability protections for manufacturers and weaken the FDA's oversight ability. This legislation would leave patients with no recourse in the case of harmful side effects.

This legislation is even more flawed, as I said, than the House bill that I voted against back in March. Like the earlier bill, the Senate bill contains the same dangerous, unnecessary pathways to experimental treatments, but it exposes a much larger number of patients to serious risk—not just terminal patients, but patients that would like to try something that is not even tested. In fact, it is so broad, that it exposes patients of all chronic conditions to the risk of experimental treatments.

More than 100 major patient safety groups have voiced their strong opposition to this bill.

Moreover, this bill is not even necessary. The FDA has an expedited approval process for terminal patients.

Mr. Speaker, I urge my colleagues to stand up for patient safety and vote against this flawed legislation.

Mr. BURGESS. Mr. Speaker, I yield 2 minutes to the gentleman from Georgia (Mr. CARTER), a valuable member of the Health Subcommittee.

Mr. CARTER of Georgia. Mr. Speaker, I thank the gentleman for yielding.

Mr. Speaker, I rise today in support of S. 204, the Right to Try Act, because this legislation will enhance access to potentially lifesaving treatments for patients with terminal diseases or conditions.

Currently, patients can only receive drugs that are undergoing FDA clinical trials through compassionate use or expanded access. At this time, patients and their physicians can acquire unapproved treatments through the FDA, not directly 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 new alternative pathway must have an active application that is not the subject of a clinical hold.

Mr. Speaker, I want to thank the Speaker and the majority leader for recognizing the importance of right-to-try legislation and making sure that we fulfill our duty to patients looking for any chance to survive deadly conditions.

This is a great step forward toward ensuring our patients get to take advantage of the incredible pharmaceutical therapies that are being researched and developed in the United States.

Mr. Speaker, I urge my colleagues to support this legislation.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentleman from New York (Mr. TONKO).

Mr. TONKO. Mr. Speaker, I thank the gentleman from New Jersey for yielding.

Mr. Speaker, I rise in strong opposition to the so-called Right to Try Act.

This ideologically driven legislation is trying to solve a problem that simply doesn't exist.

Every single Member of this body supports allowing terminally ill individuals to seek access to experimental treatments that could be potentially lifesaving. However, we have to do so in a structured way that won't undermine the role of the FDA in guaranteeing that the medications we all use are safe and are effective.

I believe the FDA's current expanded access program meets that test by ensuring proper informed consent and adverse event reporting and establishes the appropriate safeguards around access to experimental drugs.

The legislation before us would take the FDA out of the process completely and would allow a black market of snake oil salesmen to emerge, with unscrupulous companies selling untested drugs to a broad array of individuals, including those with manageable chronic conditions like diabetes.

Make no mistake about it: this legislation offers false hope to seriously ill individuals and will put patients at risk.

Mr. BURGESS. Mr. Speaker, I yield 2 minutes to the gentleman from Arizona (Mr. BIGGS).

Mr. BIGGS. Mr. Speaker, before giving my remarks, I include in the RECORD a statement by Senator JOHNSON explaining the intent of S. 204.

STATEMENT OF LEGISLATIVE INTENT

(By Sen. Ron Johnson on S. 204 (as considered by the House of Representatives))

In a recent article about pending right to try legislation, FDA Commissioner Scott Gottlieb was quoted as saying: ''In terms of making sure that it balances [access to experimental drugs] against appropriate patient protections . . . with [S. 204], we'd have to do a little bit more . . . in guidance and perhaps in regulation to achieve some of those goals, and I think those are the goals that Congress wants us to achieve.'' The article went on to quote Commissioner Gottlieb as saying: ''We felt that there were certain aspects of [S. 204] that could be modified to build in additional patient protections, but if you weren't able to do that legislatively, that there [was] a pathway by which you do that administratively and still remain consistent with the letter and the spirit of this law.''

In response to this article, Commissioner Gottlieb tweeted the ''FDA . . . stands ready to implement [right to try] in a way consistent with the intent of Congress.''

As S. 204's primary author and lead sponsor, I want to make this legislation's intent absolutely clear and remove any ambiguity that the FDA could use to implement right to try in a way contrary to its aim.

S. 204, as originally introduced, applied to patients ''with a terminal illness,'' as defined by State law. In discussion with the FDA, the agency suggested it would prefer a uniform federal definition, especially one that already existed in federal statute or regulation, because an existing federal definition would facilitate implementation of the law. The FDA suggested defining terminal illness as an ''immediately life-threatening disease or condition.'' The FDA disclosed that its suggested definition would exclude, for example, patients with Duchenne muscular dystrophy—an illness explicitly intended to be covered by the legislation.

To be clear, I rejected this proposed definition because I believed it would inappropriately exclude patients with certain diseases from accessing treatments. By contrast, the legislation instead defines terminal illness as ''life-threatening disease or condition'' (which exists in current federal regulation), which the FDA confirmed would include patients diagnosed with Duchenne muscular dystrophy.

Contrary to the preference of FDA official Dr. Janet Woodcock, who expressed the FDA's desire to draft the legislation ''to make sure we don't include patients we (the FDA) doesn't intend to include,'' I replied and rejected that notion by stating my intent was completely opposite hers:

''I wanted to make sure we didn't exclude any one we didn't intend to exclude.'' My aim from the beginning was to be as inclusive as possible such that as many patients as possible who are facing no available alternatives could potentially qualify.

S. 204 is fundamentally about empowering terminally-ill patients and their doctors who, together with the cooperation of the developers of potentially life-saving therapies, should be in charge of making a determination about their own course of treatment. The bill is not intended to further empower any federal agency, including the FDA, to limit in any way the ability of an individual facing a life-threatening disease or condition from accessing treatment. S. 204 is about preserving a right to hope and about expanding individual freedom. It is not meant to empower the FDA to limit the right to hope by regulation or guidance.

S. 204 includes a provision ensuring the Secretary may not use a clinical outcome associated with the use of an eligible investigational drug to delay or adversely affect review or approval of the drugs, unless use of such clinical outcome is critical to determining safety. This language is in no way intended to enable the FDA to expand the scope of existing safety determinations regarding investigational drugs.

S. 204 requires, in certain circumstances, that an eligible investigational drug be under investigation in a clinical trial that is intended to form the primary basis of a claim of effectiveness in support of approval or licensure. According to the FDA, this language simply incorporates the standard definition of a clinical trial. This language is not in any way intended to enable the FDA to exclude any clinical trial as a basis for precluding access to treatments under right to try.

Mr. BIGGS. Mr. Speaker, I rise today in strong support of the Right to Try Act and on behalf of the patients who are fighting each and every day to try to save their own lives.

It has been a long ride, but we are in sight of our destination.

Mr. Speaker, I would like to take a brief moment to thank my friend and colleague, Representative FITZPATRICK, for working with me on this cause from the moment we both entered office last year, and to extend my appreciation to Senator JOHNSON, whose efforts on behalf of right to try have been extraordinary.

Mr. Speaker, I also thank Chairman WALDEN for his efforts and the leadership of President Trump and Vice President PENCE.

Mr. Speaker, I acknowledge and thank my predecessor, Congressman Matt Salmon, for his tireless efforts to pass right to try.

But it is the patients themselves and their tireless advocates who deserve the most recognition. I have said this before and I will continue to say it: when the Right to Try Act passes this Chamber and is signed into law by the President, it will be them, not us, who deserve the most credit for this remarkable victory.

Everyone here has heard me speak about the Right to Try Act more than a few times already and everyone here is aware of the widespread support that this legislation has garnered. Forty States have already passed right-to-try legislation, often with unanimous or overwhelming support from Republicans and Democrats alike.

If we can't come together to support a commonsense cause such as this one, I am not sure what effort we can unite behind.

Those on the other side of this debate—and they are a shrinking minority—argue that this legislation is unnecessary. Well, if it is so unnecessary, why do I receive phone calls and letters from patients each week urging me to do everything in my power to get this legislation passed?

I have no doubt the FDA's expanded access program helps patients, but I also know that the agency's personnel, including Director Gottlieb himself, want to help as many patients as possible, but their efforts simply are not enough.

The Right to Try Act doesn't eliminate the expanded access program. Far from it. We are merely providing another, more direct avenue for patients to acquire potentially lifesaving medications from pharmaceutical companies that don't require them to ask permission from a bureaucratic middleman.

Another argument I hear from the naysayers, one that makes me angry, is that we are peddling false hope. False hope? What is that?

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. BURGESS. Mr. Speaker, I yield an additional 30 seconds to the gentleman from Arizona.

Mr. BIGGS. Mr. Speaker, to this tired argument, I respond that there is no such thing as false hope. You either have hope or you don't.

I, for one, want those brave men and women who are fighting every day against terrible illnesses and almost insurmountable odds to have a choice, even if it is the last choice many of them will ever have the opportunity to make. I trust them to weigh the pros and cons and choose for themselves whether they wish to take a risk to try to save their own lives.

Make no mistake: it is a choice. We are not offering a mandate, merely an option.

Mr. Speaker, I urge all of my colleagues to vote ''yes'' on this legislation.

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

Mr. Speaker, I just want to respond briefly to the previous speaker on the Republican side.

I don't understand how the gentleman can say that the expanded access program will continue even under right to try.

The problem is, sure, on paper it will continue, but there wouldn't be any reason for anyone to go to the FDA. If the FDA is now out of the picture and all you have to do is find somebody who manufactures a drug or treatment and get the doctor to say, ''Okay, I will administer it,'' then you don't need to go to the expanded access program.

You see, the problem is that the gentleman assumes that people will go to the FDA and they will know that the expanded access program exists. I think the very nature of this legislation, which basically says that you don't have to go to the FDA, is going to mean that people won't even know that that is an option. And if they can get somebody to give them the drug without going to the FDA, they will just do it.

Let me just say this. I know the gentleman referred to the FDA's bureaucrats. I guess you could say that the people at the FDA are bureaucrats, but the FDA existed because, for many years before then, in the 19th century and early 20th century, all kinds of snake oil and things were advertised and promoted in the papers and in magazines, saying that this is going to cure that, this is going to cure that, and people demanded that there be some kind of Federal oversight as to whether drugs or treatments actually are effective, whether they have harm, whether they are toxic. That is why the FDA was started.

So I guess I just don't understand, because the bottom line is there is very little evidence that there is any significant number of people who are denied treatment or drugs because of the expanded access program. At least then they know that some agency has looked at this to see whether it is harmful, whether it has some negative impact.

The great concern that those of us on the other side of this issue have is that without the FDA, there is no guarantee that what somebody gets as a form of treatment is actually going to be meaningful, not be harmful.

So I don't want to prolong my response to the gentleman, but I do think that you have to understand that those of us on this side of the aisle actually think that the FDA has a purpose and actually performs an important function, and I don't think we should deny that. I think it is unfortunate that there are those who think that somehow the FDA is not doing its job.

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

□ 1630

Mr. BURGESS. Mr. Speaker, I yield 2 minutes to the gentleman from Pennsylvania (Mr. FITZPATRICK), another principal author of the bill.

Mr. FITZPATRICK. Mr. Speaker, today is long overdue; long, long overdue. I want to thank Leader MCCARTHY, Chairman WALDEN, Dr. BURGESS, Mr. GRIFFITH, my friend and colleague, ANDY BIGGS, Senator RON JOHNSON, and all of the advocates who have had a relentless fight to see right to try debated, passed, and signed into law once and for all.

And I want to thank the overwhelming bipartisan majority of my colleagues here in the House who we had to work on, many of them, back in March, who 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.

For those patients caught in between traditional drug delay approvals, a clinical trial process for which they do not qualify, and limited time, the Right to Try Act.

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 saving their life.

Mr. Speaker, I want to acknowledge the Wendler, Bellina, Mongiello, McLinn families, all who are here with us in this Chamber today to see history be made.

Although the FDA has a program that allows terminal patients to apply for early access to promising treatments, the Right to Try Act is needed because the FDA's compassionate use process does not help enough people.

While 99 percent of expanded access applications are approved, the application process is complicated, it is time consuming, and it is expensive.

Moreover, only about 1,200 people a year can make it through the application process. By contrast, Mr. Speaker, in 2014, more than 12,000 people in France were using investigational treatments through that government's equivalent program.

How is it, pray tell, that a country one-fifth the size of the United States can help 900 percent more people? The FDA program clearly is not working.

Mr. Speaker, the Right to Try Act gives people hope. And let me be clear: This bill requires robust informed consent between the patient, the doctor, and the manufacturer, while requiring notification be given to the FDA after an unapproved drug becomes available to an eligible patient, and requiring doctors and the manufacturers to report adverse events.

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. BURGESS. Mr. Speaker, I yield an additional 30 seconds to the gentleman from Pennsylvania.

Mr. FITZPATRICK. Mr. Speaker, when life hangs in the balance, the Federal Government must not stand in the way of this process. We have to get this done once and for all.

Mr. Speaker, today, I urge my colleagues on both sides of the aisle, appeal to the better angels of your nature. All the groups that they say are opposed to this bill, I will tell you who is in favor of this bill: Over 80 percent of the American people, and they are the ones who have the power in this country, and they are the ones we have to listen to.

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

Mr. Speaker, again, I would like to respond to the previous Republican speaker. He made three comments that disturb me.

One, he said that people should be able to try things, try the drugs or the treatment, when the benefits outweigh the risks. But how are they going to know that when the FDA isn't involved?

When the FDA goes through various phases of clinical trial, not only phase

one, which determines whether something is toxic, but beyond, to determine whether it is effective or whether it has harmful effects, then you do know. The FDA basically will tell you: Yes, the benefits outweigh the risk, and that is why we have an approval process in general for drugs, and that is why we have the expanded access, so that the FDA can look at it and say: Okay. Maybe you are going to risk this, but we want to make sure that you have some protection.

The gentleman said that the FDA process is complicated or time consuming. First of all, there is an emergency process where you can simply get on the phone or the doctor gets on the phone, and within 24 hours you can be approved.

But on the other hand, if it is not an emergency, the average approval time is 4 days. So I don't know how he can say that this is time consuming.

And then the last thing he said is that there is consent, that the doctors and the manufacturers have to agree. But who is going to enforce this?

Right now, because the FDA has to go through the expanded access process, the FDA has the enforcement. They can say: We are going to grant this; we are not; we are going to provide some safety or other protections.

But if the doctor and some fly-by-night manufacturer decide that they want to give you this drug or treatment, who is going to enforce that? How do we know that the doctor is legitimate? How do we know that the manufacturer is not selling snake oil?

Once the FDA is out of the picture, there is no way for the patient to know whether the doctor is unscrupulous, whether the manufacturer is unscrupulous. There is no review. There is no enforcement whatsoever.

So, again, this is the problem once you take the FDA out. I understand there are some that don't like the FDA, don't think maybe they should be involved. But in the absence of the FDA, I don't know how you possibly could know whether this thing is going to help you, whether the benefits outweigh the risk, whether there is a bad actor involved, either with the doctor or the manufacturer.

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

Mr. BURGESS. Mr. Speaker, I yield myself 1 minute.

Mr. Speaker, I want to read from the Statement of Administration Policy that was put out by the Executive Office of the President.

The last paragraph:

Since the late 1980s, the Food and Drug Administration has facilitated access to investigational drugs, devices, and biological products for the treatment of seriously ill patients. Families in these situations have sometimes found this process challenging, and the Food and Drug Administration is constantly striving to make improvements to its expanded access program. Some patients and their families, however, still have challenges accessing investigational treatments. The administration believes that the treatment decisions for those facing terminal illnesses are best made by the patients with the support and the guidance of their treating physicians. This legislation will advance those principles.

Mr. Speaker, that is from the Statement of Administration Policy, and I reserve the balance of my time.

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

Mr. Speaker, I want my colleagues on the other side to understand why so many of us over here have been so upset by this proposal today.

As I think I said before, the House bill was bad enough. The Senate bill is worse for at least two reasons.

One is our concern, on the one hand, that rather than these drugs or treatments without FDA approval would be handed to just terminally ill patients, that the Senate bill says that it would apply to people who have life-threatening situations.

And the FDA and the commissioner of the FDA have stated quite clearly that they are concerned about the expansion from terminal to life-threatening, because it could be that people who have diseases like diabetes, severe diabetes, or chronic heart disease, for example, could make the argument that their situation is life-threatening, and, therefore, they can go and get these experimental drugs without FDA approval.

So that is a huge loophole that is very disconcerting.

The second thing is that the prohibition, if you will, on promotional activity with these investigational drugs is taken out by the Senate bill.

So the worst thing of all, we talk about snake oil and advertising, is now is some unscrupulous doctor or manufacturer now going to promote this and say: Well, if you take this, this may save your life?

So that is why the Senate bill is worse.

But I want to go back to the whole idea. The problem that I have with all this is that once you take out the FDA, and the FDA is not involved anymore, the way this bill is set up, how do I know, if I am the patient and I hear from some doctor or through some promotion or whatever, that there is something that might help me, and I am desperate, how do I know that the doctor that I go to or the manufacturer who is promoting this drug, that this is actually not a bad actor, not somebody who is taking advantage of the situation because there is no FDA approval?

In other words, who is going to determine whether this person's life is threatened or whether they are terminally ill? There is no FDA. Who determines that?

Who is going to determine whether this drug has any effectiveness at all?

Well, some of my Republican colleagues say: Well, it has to go through phase one, but phase one clinical trials could have 20 or 30 people. They are sometimes very small.

The FDA doesn't really have any ability to control those clinical trials. Sure, they have some oversight over clinical trials, but there are clinical trials that take place all over the country with very few people, and sometimes the drug manufacturers who are experimenting with these trials, with these small groups, are not necessarily known manufacturers or large ones that we know will be safeguarding these drugs or treatments.

So I just think the problem is, when we talk about snake oil and bad actors, it is almost as if the Republicans assume there are no bad actors.

Because if you assume that there are, which I do, and there are bad actors who are going to promote something that is not going to be effective or is going to harm somebody, and that there is a manufacturer who is not someone we know, who is going to determine whether or not they are a bad actor or what they are doing?

You need to have some kind of enforcement. You need to have somebody who is supervising this. Otherwise, it is any man for himself decides: I will try this drug. It went through phase one. Maybe it is not toxic.

So I really worry that this debate on the other side of the aisle is not taking into consideration that there always are going to be people who want to take advantage of the situation and sell something that they are going to make a buck on that is not necessarily going to have any real oversight in this situation.

So that is my fear. That is my fundamental fear about this bill, that these situations are going to arise, nobody is going to be in charge, nobody is going to know what is going on, and then the person is going to either die earlier or have some awful impact, and then they are going to say: Oh, how come the FDA didn't approve it? Or maybe they are going to assume the FDA approved it, and there is no FDA. They are gone.

Mr. Speaker, in any case, I would urge my colleagues to oppose what I consider very harmful legislation, and I yield back the balance of my time.

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

Mr. Speaker, on January 30 of this year, the President of the United States came to this House and addressed a joint session of the House and Senate in the State of the Union address, and he said, right from that podium, ''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 right here at home. It is time for Congress to give these wonderful Americans the right to try.''

Mr. Speaker, I couldn't say it any better than the President has already put it. The Right to Try Act is before us. It is a good bill. The House needs to support it, and it will go to the President for his signature.

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

Ms. MATSUI. Mr. Speaker, this proposed ''Right to Try'' legislation will make it possible for bad actors to take advantage of desperate families.

The pill would allow companies to completely circumvent the FDA if they claim to have a new drug or cure for a patient. And it dogs not require the doctor or the company to even report to FDA, so we will have no way of knowing who is trying which experimental drug. This legislation really does encourage snake oil salesmen.

Currently, legitimate companies may have new experimental drugs that have not yet been approved, but that could be helpful for patients who have no other options . . . but this bill is not limited to that situation. And, FDA does have an existing process to allow for patients with life-threatening conditions to try experimental drugs before they are approved.

And, this bill is not limited only to patients with a life-threatening condition. FDA has testified that the process under this bill would be available much more broadly to patients with chronic conditions such as diabetes.

That is a large population with a condition that is managed with currently available treatments. Under this bill, bad actors could see the dollar signs to market ineffective drugs to these patients.

The bill before us today does not require FDA or Institutional Review Boards (or IRB's) to review any request for experimental therapy, and rescinds any requirement to report adverse effects of a drug immediately.

This means that if someone loses their eyesight or dies from taking an unproven experimental treatment, then no one is required to report it immediately. This puts other patients taking the same drug in danger.

Additionally, if a patient does have a success with a drug, but it is not reported or considered in a clinical trial, that success will not translate to other patients that could be saved by the treatment.

I am also incredibly concerned that in 19 states, taking experimental treatment will result in the loss of people's hospice care, and in 4 states it will result in the loss of their insurance, completely.

To rake matters worse, this legislation does not stipulate that patients must be informed of this loss of coverage or hospice coverage in advance.

This legislation, therefore, puts patients' care network, financial stability, and safety at risk—without any legal recourse.

If we open this loophole, a surge of bad actors who may claim to have experimental drug therapies could make money peddling dangerous therapies to unsuspecting patients with no system of oversight, safety, and accountability.

The unfortunate victims will be families and their loved ones. I strongly urge my colleagues to vote no on this bill.

Mr. GENE GREEN of Texas. Mr. Speaker, I rise in opposition to S. 204, the so-called ''Right to Try'' bill that offers false hope for patients and families while circumventing FDA's role in overseeing drugs.

Two months ago, our chamber debated the House Republican version of this legislation, H.R. 5247. I spoke out in opposition to that bill due to my serious concerns over the lack of oversight and protections for terminally ill patients and their families, particularly by excluding the U.S. Food and Drug Administration from any role in ensuring the safety and efficacy of experimental therapies.

Instead of addressing our concerns, the Majority has double-downed on this unnecessary legislation with an even broader proposal that would expose a great number of patients to unproven medical treatments and unwanted side effects.

S. 204 eliminates critical patient protections, such as a review by a third party of clinical protocols and informed consent, and eliminates the requirement that treating physicians and manufacturers report adverse events to the FDA in real time.

Under this legislation, insurers and pharmaceutical companies are not required to cover the cost, or reduce the cost, of these often-expensive treatments—meaning the full cost of these experimental drugs would fall on patients and their families.

All the while, we already have a proven Right-to-Try system already in place through the FDA. This program, popularly known as Compassionate Use, has been helping seriously ill Americans have access to experimental therapies still under clinical trials for 31 years.

FDA approves nearly all requests for investigational drugs. For the past five years, FDA's approval rate for expanded access requests is over 99 percent. In fact, FDA physicians are available 24 hours a day to approve emergency requests.

My daughter, an infectious disease expert at the University of Nebraska, used FDA's Compassionate Use pathway to provide an experimental therapy for an American missionary who had contracted ebola while in Africa in 2014. FDA approved the request for the experimental treatment over the telephone in less than 24 hours.

The new pathway created in S. 204 is not necessary and, in fact, may well endanger the health and safety of seriously ill patients by bypassing FDA's oversight and expertise.

This is an unnecessary and dangerous bill that offers false hope to seriously ill patients and families. I ask my colleague to oppose this legislation and work with me to advance proven measures that will help Americans facing life-threatening diseases.

The SPEAKER pro tempore (Mr. KELLY of Pennsylvania). All time for debate has expired.

Pursuant to House Resolution 905, the previous question is ordered on the bill.

The question is on the third reading of the bill.

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

MOTION TO RECOMMIT

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

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

Ms. SCHAKOWSKY. Mr. Speaker, I am opposed in its current form.

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

The Clerk read as follows:

Ms. Schakowsky moves to recommit the bill S. 204 to the Committee on Energy and Commerce with instructions to report the same back to the House forthwith, with the following amendment:

Strike all after section 1 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. ELIGIBLE 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 eligible 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 eligible 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 eligible 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 eligible investigational drug under subsection (b) or (c) of section 561; and

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

''(c) DEFINITION.—In this section, the term 'eligible investigational drug' means an investigational drug (as such term is used in section 561)—

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

''(2) 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;

''(3)(A) for which an application has been filed under section 505(b) of this Act or section 351(a) of the Public Health Service Act; or

''(B) 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

''(4) the active development or production of which is ongoing and has not been discontinued by the manufacturer or placed on clinical hold under section 505(i); and''.

(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.—

''(1) IN GENERAL.—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 eligible 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.

''(2) DEFINITION.—In this subsection, the term 'eligible investigational drug' has the meaning given to such term in section 561B(c).''.

(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 eligible 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 eligible 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 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 eligible 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 eligible 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.

''(2) DEFINITION.—In this subsection, the term 'eligible investigational drug' has the meaning given to such term in section 561B(c).''.

Ms. SCHAKOWSKY (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 gentlewoman from Illinois?

There was no objection.

The SPEAKER pro tempore. The gentlewoman from Illinois is recognized for 5 minutes in support of her motion.

Ms. SCHAKOWSKY. Mr. Speaker, this that I am proposing today would be 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 improve FDA's expanded access program that allows patients access to experimental drugs that can possibly save their lives, which is the goal of all of us.

□ 1645

The FDA ensures that expanded access requests are safe, and it approves nearly 100 percent of all the requests that are made, and most in a matter of hours, if necessary.

The right-to-try legislation we are considering today presents a huge risk to patients and is much worse than the House bill we passed in March, as our ranking member explained.

If this bill is so good, why are 104 patient groups—these are the groups that represent the sick and dying people—opposed? And PhRMA, the big pharmaceutical companies, are not supportive because this gives open license to snake oil salesmen.

This bill exposes far more patients to serious risks through a dangerous and unnecessary pathway for experimental treatment.

FDA Commissioner Gottlieb noted this legislation is not limited to patients with terminal illness anymore: ''We are certainly going to be exposing patients with potentially less severe conditions to a risk.''

It is troubling that, in some States, patients using an investigational drug can lose their hospice coverage and, in other States, that they can be denied home care. These are the very people who need this care.

Why should we put more patients at risk when the current process does work? FDA already approves, as I said, nearly 100 percent of the requests for experimental therapies through the expanded access program. If a person is denied treatment, it is because the manufacturer will not provide it. It also isn't going about giving the terminally ill hope.

If that were true, then why would these 104 patient groups, including the American Cancer Society, the Cystic Fibrosis Foundation, and the Vietnam Veterans of America also oppose this bill?

The main reason that this bill is being pushed is to remove FDA oversight of the safety and effectiveness of our drugs. It allows manufacturers to serve as the gatekeeper and protector of patients. It opens the door for bad actors to prey on people desperate to save their lives or the lives of their children.

Imagine if someone like Martin Shkreli, the infamous pharmaceutical bad actor, promised a cure to save a child's life provided that the parents pay whatever price he might charge, under this bill, FDA would play no role in determining if that drug were safe and effective.

Bad actors do exist, and this Republican bill gives them the opportunity to prey on desperate people who are looking for any treatment that might help to save their lives.

Unlike S. 204, this motion to recommit is not based on the false premise that the FDA approval is a barrier to investigational treatments; rather, it provides clarification of the liability and how FDA will utilize clinical outcomes.

With this motion to recommit, the FDA would provide manufacturers guidance to clarify how FDA will consider clinical outcomes associated with treatments under expanded access when making a decision about whether or not the drug should be granted full approval. It also provides transparency as to how many patients are making expanded access requests and how often these requests are granted or denied by the FDA and manufacturers. It also offers to provide manufacturers or sponsors liability protection if they comply with the requirements of the expanded access program.

I believe that these legislative fixes facilitate patient accessing of experimental treatments while ensuring critical FDA oversight to protect public health.

In conclusion, patients already have the right to try. Rather than creating an unnecessary pathway that puts patients at risk by allowing the sale of

snake oil, I would urge my colleagues to join the over 100 patient groups, organizations that care about their neighbors and their friends and people who have these diseases, in support of the expanded access program.

These targeted improvements are one way to achieve that goal, so I urge my colleagues to support my motion to recommit and oppose the dangerous Republican proposal.

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

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

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

Mr. BURGESS. Mr. Speaker, while the motion to recommit may be well intentioned, it has a practical effect of killing this bill because the Senate has rejected House attempts to refine the Senate bill that was passed by unanimous consent last August. So if you want to provide that right to try for patients, this is the vehicle.

Now, interestingly enough, the Food and Drug Administration Administrator, this morning, Dr. Gottlieb, put out a statement. He said that he is: ''. . . ready to implement it in a way that achieves Congress' intent to promote access and protect patients; and build on FDA's longstanding commitment to these important goals.''

Mr. Speaker, I urge people to vote against the motion to recommit and vote for the underlying bill. Let's give patients that expanded access, and 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.

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

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 and clause 9 of rule XX, this 15-minute vote on the motion to recommit will be followed by 5-minute votes on:

Passage of S. 204, if ordered;

The motion to suspend the rules on H.R. 5682; and

Passage of S. 2155.

The vote was taken by electronic device, and there were—yeas 187, nays 231, not voting 9, as follows:

[Roll No. 213]

YEAS—187

Adams
Aguilar
Barragán
Bass
Beatty
Bera
Beyer
Bishop (GA)
Blumenauer
Blunt Rochester
Bonamici
Boyle, Brendan F.
Brady (PA)
Brown (MD)
Brownley (CA)
Bustos
Butterfield
Capuano
Carbajal
Cárdenas
Carson (IN)
Cartwright
Castor (FL)
Castro (TX)
Chu, Judy
Cicilline
Clark (MA)
Clarke (NY)
Clay
Cleaver
Clyburn
Cohen
Connolly
Cooper
Correa
Costa
Courtney
Crist
Crowley
Cuellar
Cummings
Davis (CA)
Davis, Danny
DeFazio
DeGette
Delaney
DeLauro
DelBene
Demings
DeSaulnier
Deutch
Dingell
Doggett
Doyle, Michael F.
Ellison
Engel
Eshoo
Espaillat
Esty (CT)
Evans
Foster
Frankel (FL)
Fudge
Gabbard
Gallego
Garamendi
Gomez
Gottheimer
Green, Al
Green, Gene
Grijalva
Gutiérrez
Hanabusa
Hastings
Heck
Higgins (NY)
Himes
Hoyer
Huffman
Jackson Lee
Jayapal
Jeffries
Johnson (GA)
Johnson, E. B.
Keating
Kelly (IL)
Kennedy
Khanna
Kihuen
Kildee
Kilmer
Kind
Krishnamoorthi
Kuster (NH)
Lamb
Langevin
Larsen (WA)
Larson (CT)
Lawrence
Lawson (FL)
Lee
Levin
Lewis (GA)
Lieu, Ted
Lipinski
Loebsack
Lofgren
Lowenthal
Lowey
Lujan Grisham, M.
Luján, Ben Ray
Lynch
Maloney, Carolyn B.
Maloney, Sean
Matsui
McCollum
McEachin
McGovern
McNerney
Meeks
Meng
Moore
Moulton
Murphy (FL)
Nadler
Napolitano
Neal
Nolan
Norcross
O'Halleran
O'Rourke
Pallone
Panetta
Pascrell
Payne
Pelosi
Perlmutter
Peters
Peterson
Pingree
Pocan
Price (NC)
Quigley
Raskin
Rice (NY)
Richmond
Rosen
Roybal-Allard
Ruiz
Ruppersberger
Rush
Ryan (OH)
Sánchez
Sarbanes
Schakowsky
Schiff
Schneider
Schrader
Scott (VA)
Scott, David
Serrano
Sewell (AL)
Shea-Porter
Sherman
Sires
Smith (WA)
Soto
Suozzi
Swalwell (CA)
Takano
Thompson (CA)
Thompson (MS)
Titus
Tonko
Torres
Tsongas
Vargas
Veasey
Vela
Velázquez
Visclosky
Wasserman Schultz
Waters, Maxine
Watson Coleman
Welch
Wilson (FL)
Yarmuth

NAYS—231

Abraham
Aderholt
Allen
Amash
Amodei
Arrington
Babin
Bacon
Banks (IN)
Barletta
Barr
Barton
Bergman
Biggs
Bilirakis
Bishop (MI)
Bishop (UT)
Blackburn
Blum
Bost
Brady (TX)
Brat
Brooks (AL)
Brooks (IN)
Buchanan
Buck
Bucshon
Budd
Burgess
Byrne
Calvert
Carter (GA)
Carter (TX)
Chabot
Cheney
Coffman
Cole
Collins (GA)
Collins (NY)
Comer
Comstock
Conaway
Cook
Costello (PA)
Cramer
Crawford
Culberson
Curbelo (FL)
Curtis
Davidson
Davis, Rodney
Denham
DeSantis
DesJarlais
Diaz-Balart
Donovan
Duffy
Duncan (SC)
Duncan (TN)
Dunn
Emmer
Estes (KS)
Faso
Ferguson
Fitzpatrick
Fleischmann
Flores
Fortenberry
Foxx
Gaetz
Gallagher
Garrett
Gianforte
Gibbs
Gohmert
Gonzalez (TX)
Goodlatte
Gosar
Gowdy
Granger
Graves (GA)
Graves (LA)
Graves (MO)
Griffith
Grothman
Guthrie
Handel
Harper
Harris
Hartzler
Hensarling
Herrera Beutler
Hice, Jody B.
Hill
Holding
Hollingsworth
Hudson
Huizenga
Hultgren
Hunter
Hurd
Issa
Jenkins (KS)
Jenkins (WV)
Johnson (LA)
Johnson (OH)
Johnson, Sam
Jones
Jordan
Joyce (OH)
Kaptur
Katko
Kelly (MS)
Kelly (PA)
King (IA)
King (NY)
Kinzinger
Knight
Kustoff (TN)
Labrador
LaHood
LaMalfa
Lamborn
Lance
Latta
Lesko
Lewis (MN)
LoBiondo
Long
Loudermilk
Love
Lucas
Luetkemeyer
MacArthur
Marchant
Marino
Marshall
Massie
Mast
McCarthy
McCaul
McClintock
McHenry
McKinley
McMorris Rodgers
McSally
Meadows
Messer
Mitchell
Moolenaar
Mullin
Newhouse
Noem
Norman
Nunes
Olson
Palazzo
Palmer
Paulsen
Perry
Pittenger
Poe (TX)
Poliquin
Polis
Posey
Ratcliffe
Reed
Reichert
Renacci
Rice (SC)
Roby
Roe (TN)
Rogers (AL)
Rohrabacher
Rokita
Rooney, Francis
Rooney, Thomas J.
Ros-Lehtinen
Roskam
Ross
Rothfus
Rouzer
Royce (CA)
Russell
Rutherford
Sanford
Scalise
Schweikert
Scott, Austin
Sensenbrenner
Sessions
Shimkus
Shuster
Simpson
Sinema
Smith (MO)
Smith (NE)
Smith (NJ)
Smith (TX)
Smucker
Stefanik
Stewart
Taylor
Tenney
Thompson (PA)
Thornberry
Tipton
Trott
Turner
Upton
Valadao
Wagner
Walberg
Walden
Walker
Walorski
Walters, Mimi
Weber (TX)
Webster (FL)
Wenstrup
Westerman
Williams
Wilson (SC)
Wittman
Womack
Woodall
Yoder
Yoho
Young (AK)
Young (IA)
Zeldin

NOT VOTING—9

Black
Frelinghuysen
Higgins (LA)
Mooney (WV)
Pearce
Rogers (KY)
Speier
Stivers
Walz

□ 1717

Ms. STEFANIK, Messrs. WALKER, MCCAUL, BILIRAKIS, and AUSTIN SCOTT of Georgia changed their vote from ''yea'' to ''nay.''

Ms. SÁNCHEZ, Mr. VISCLOSKY, and Ms. HANABUSA changed their vote from ''nay'' to ''yea.''

So the motion to recommit was rejected.

The result of the vote was announced as above recorded.

The SPEAKER pro tempore (Mr. BERGMAN). The question is on the passage of the bill.

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

RECORDED VOTE

Mr. PALLONE. Mr. Speaker, I demand a recorded vote.

A recorded vote was ordered.

The SPEAKER pro tempore. This is a 5-minute vote.

The vote was taken by electronic device, and there were—ayes 250, noes 169, not voting 8, as follows:

[Roll No. 214]

AYES—250

Abraham
Aderholt
Allen
Amash
Amodei
Arrington
Babin
Bacon
Banks (IN)
Barletta
Barr
Barton
Bergman
Biggs
Bilirakis
Bishop (GA)
Bishop (MI)
Bishop (UT)
Blackburn
Blum
Bost
Brady (TX)
Brat
Brooks (AL)
Brooks (IN)
Buchanan
Buck
Bucshon
Budd
Burgess
Byrne
Calvert
Carson (IN)
Carter (GA)
Carter (TX)
Chabot
Cheney
Coffman
Cole
Collins (GA)
Collins (NY)
Comer
Comstock
Conaway
Cook
Cooper
Correa
Costa
Costello (PA)
Cramer
Crawford
Cuellar
Culberson
Curbelo (FL)
Curtis
Davidson
Davis, Rodney
Denham
DeSantis
DesJarlais
Diaz-Balart
Donovan
Duffy

Duncan (SC)
Duncan (TN)
Dunn
Emmer
Estes (KS)
Faso
Ferguson
Fitzpatrick
Fleischmann
Flores
Fortenberry
Foxx
Gabbard
Gaetz
Gallagher
Garrett
Gianforte
Gibbs
Gohmert
Goodlatte
Gosar
Gottheimer
Gowdy
Granger
Graves (GA)
Graves (LA)
Graves (MO)
Griffith
Grothman
Guthrie
Handel
Harper
Harris
Hartzler
Hensarling
Herrera Beutler
Hice, Jody B.
Hill
Holding
Hollingsworth
Hudson
Huizenga
Hultgren
Hunter
Hurd
Issa
Jenkins (KS)
Jenkins (WV)
Johnson (LA)
Johnson (OH)
Johnson, Sam
Jones
Jordan
Joyce (OH)
Katko
Kelly (MS)
Kelly (PA)
Kind
King (IA)
King (NY)
Kinzinger
Knight
Kuster (NH)
Kustoff (TN)
Labrador
LaHood
LaMalfa
Lamborn
Lance
Larson (CT)
Latta
Lawson (FL)
Lesko
Lewis (MN)
Lieu, Ted
LoBiondo
Long
Loudermilk
Love
Lucas
Luetkemeyer
Lynch
MacArthur
Maloney, Sean
Marchant
Marino
Marshall
Massie
Mast
McCarthy
McCaul
McClintock
McHenry
McKinley
McMorris Rodgers
McSally
Meadows
Messer
Mitchell
Moolenaar
Mooney (WV)
Mullin
Newhouse
Noem
Norman
Nunes
O'Halleran
O'Rourke
Olson
Palazzo
Palmer
Paulsen
Perlmutter
Perry
Peterson
Pittenger
Poe (TX)
Poliquin
Polis
Posey
Ratcliffe
Reed
Reichert
Renacci
Rice (SC)
Roby
Roe (TN)
Rogers (AL)
Rohrabacher
Rokita
Rooney, Francis
Rooney, Thomas J.
Ros-Lehtinen
Roskam
Ross
Rothfus
Rouzer
Royce (CA)
Russell
Rutherford
Sanford
Scalise
Schweikert
Scott, Austin
Sensenbrenner
Sessions
Shimkus
Shuster
Simpson
Sinema
Smith (MO)
Smith (NE)
Smith (NJ)
Smith (TX)
Smucker
Stefanik
Stewart
Taylor
Tenney
Thompson (PA)
Thornberry
Tipton
Trott
Turner
Upton
Valadao
Veasey
Wagner
Walberg
Walden
Walker
Walorski
Walters, Mimi
Weber (TX)
Webster (FL)
Wenstrup
Westerman
Williams
Wilson (SC)
Wittman
Womack
Woodall
Yoder
Yoho
Young (AK)
Young (IA)
Zeldin

NOES—169

Adams
Aguilar
Barragán
Bass
Beatty
Bera
Beyer
Blumenauer
Blunt Rochester
Bonamici
Boyle, Brendan F.
Brady (PA)
Brown (MD)
Brownley (CA)
Bustos
Butterfield
Capuano
Carbajal
Cárdenas
Cartwright
Castor (FL)
Castro (TX)
Chu, Judy
Cicilline
Clark (MA)
Clarke (NY)
Clay
Cleaver
Clyburn
Cohen
Connolly
Courtney
Crist
Crowley
Cummings
Davis (CA)
Davis, Danny
DeFazio
DeGette
Delaney
DeLauro
DelBene
Demings
DeSaulnier
Deutch
Dingell
Doggett
Doyle, Michael F.
Ellison
Engel
Eshoo
Espaillat
Esty (CT)
Evans
Foster
Frankel (FL)
Fudge
Gallego
Garamendi
Gomez
Gonzalez (TX)
Green, Al
Green, Gene
Grijalva
Gutiérrez
Hanabusa
Hastings
Heck
Higgins (NY)
Himes
Hoyer
Huffman
Jackson Lee
Jayapal
Jeffries
Johnson (GA)
Johnson, E. B.
Kaptur
Keating
Kelly (IL)
Kennedy
Khanna
Kihuen
Kildee
Kilmer
Krishnamoorthi
Lamb
Langevin
Larsen (WA)
Lawrence
Lee
Levin
Lewis (GA)
Lipinski
Loebsack
Lofgren
Lowenthal
Lowey
Lujan Grisham, M.
Luján, Ben Ray
Maloney, Carolyn B.
Matsui
McCollum
McEachin
McGovern
McNerney
Meeks
Meng
Moore
Moulton
Murphy (FL)
Nadler
Napolitano
Neal
Nolan
Norcross
Pallone
Panetta
Pascrell
Payne
Pelosi
Peters
Pingree
Pocan
Price (NC)
Quigley
Raskin
Rice (NY)
Richmond
Rosen
Roybal-Allard
Ruiz
Ruppersberger
Rush
Ryan (OH)
Sánchez
Sarbanes
Schakowsky
Schiff
Schneider
Schrader
Scott (VA)
Scott, David
Serrano
Sewell (AL)
Shea-Porter
Sherman
Sires
Smith (WA)
Soto
Suozzi
Swalwell (CA)
Takano
Thompson (CA)
Thompson (MS)
Titus
Tonko
Torres
Tsongas
Vargas
Vela
Velázquez
Visclosky
Wasserman Schultz
Waters, Maxine
Watson Coleman
Welch
Wilson (FL)
Yarmuth

NOT VOTING—8

Black
Frelinghuysen
Higgins (LA)
Pearce
Rogers (KY)
Speier
Stivers
Walz

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). The Chair will remind all persons in the gallery that they are here as guests of the House and that any manifestation of approval or disapproval of proceedings is in violation of the rules of the House.

□ 1725

So the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

FORMERLY INCARCERATED REENTER SOCIETY TRANSFORMED SAFELY TRANSITIONING EVERY PERSON ACT

The SPEAKER pro tempore. The unfinished business is the vote on the motion to suspend the rules and pass the bill (H.R. 5682) to provide for programs to help reduce the risk that prisoners will recidivate upon release from prison, and for other purposes, as amended, 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 Virginia (Mr. GOODLATTE) that the House suspend the rules and pass the bill, as amended.

This is a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 360, nays 59, not voting 8, as follows:

[Roll No. 215]

YEAS—360

Abraham
Adams
Aderholt
Aguilar
Allen
Amash
Amodei
Arrington
Babin
Bacon
Banks (IN)
Barletta
Barr
Barragán
Barton
Bass
Beatty
Bera
Bergman
Beyer
Biggs
Bilirakis
Bishop (GA)
Bishop (MI)
Bishop (UT)
Blackburn
Blum
Blunt Rochester
Bost
Brady (TX)
Brat
Brooks (AL)
Brooks (IN)
Brownley (CA)
Buchanan
Buck
Bucshon
Budd
Burgess
Butterfield
Byrne
Calvert
Carbajal
Cárdenas
Carson (IN)
Carter (GA)
Carter (TX)
Cartwright
Castor (FL)
Castro (TX)
Chabot
Cheney
Cicilline
Clark (MA)
Clarke (NY)
Clay
Cleaver
Clyburn
Coffman
Cohen
Cole
Collins (GA)
Collins (NY)
Comer
Comstock
Conaway
Connolly
Cook
Cooper
Costa
Costello (PA)
Courtney
Cramer
Crawford
Crist
Crowley
Cuellar
Culberson
Curbelo (FL)
Curtis
Davidson
Davis (CA)
Davis, Rodney
DeFazio
Delaney
DelBene
Demings
Denham
DeSantis
DesJarlais
Diaz-Balart
Dingell
Donovan
Doyle, Michael F.
Duffy
Duncan (SC)
Duncan (TN)
Dunn
Ellison
Emmer
Engel
Eshoo
Espaillat
Estes (KS)
Esty (CT)
Evans
Faso
Ferguson
Fitzpatrick
Fleischmann
Flores
Fortenberry
Foster
Foxx
Frankel (FL)
Fudge
Gabbard
Gaetz
Gallagher
Gallego
Garamendi
Garrett
Gianforte
Gibbs
Gohmert
Gonzalez (TX)
Goodlatte
Gosar
Gottheimer
Gowdy
Granger
Graves (GA)
Graves (LA)
Graves (MO)
Griffith
Grothman
Guthrie
Gutiérrez
Hanabusa
Handel
Harper
Harris
Hartzler
Hastings
Heck
Hensarling
Herrera Beutler
Hice, Jody B.
Higgins (NY)
Hill
Himes
Holding
Hollingsworth
Hoyer
Hudson
Huffman
Hultgren
Hunter
Hurd
Issa
Jeffries
Jenkins (KS)
Jenkins (WV)
Johnson (LA)
Johnson (OH)
Johnson, E. B.
Johnson, Sam
Jones
Jordan
Joyce (OH)
Kaptur
Katko
Keating
Kelly (IL)
Kelly (MS)
Kelly (PA)
Kildee
Kilmer
Kind
King (NY)
Kinzinger
Knight
Kuster (NH)
Kustoff (TN)
Labrador
LaHood
LaMalfa
Lamb
Lamborn
Lance
Langevin
Larson (CT)
Latta
Lawrence
Lawson (FL)
Lesko
Lewis (MN)
Lieu, Ted
Lipinski
LoBiondo
Loebsack
Lofgren
Long
Loudermilk
Love
Lowey
Lucas
Luetkemeyer
Lujan Grisham, M.
Luján, Ben Ray
Lynch
MacArthur
Maloney, Sean
Marchant
Marino
Marshall
Massie
Mast
Matsui
McCarthy
McCaul
McClintock
McCollum
McEachin
McHenry
McKinley
McMorris Rodgers
McNerney
McSally
Meadows
Meeks
Meng
Messer
Mitchell
Moolenaar
Mooney (WV)
Moore
Moulton
Mullin
Murphy (FL)
Newhouse
Noem
Nolan
Norman
Nunes
O'Halleran
O'Rourke
Olson
Palazzo
Palmer
Panetta
Pascrell
Paulsen
Pelosi
Perlmutter
Perry
Peters
Peterson
Pingree
Pittenger
Pocan
Poe (TX)
Poliquin
Posey
Price (NC)
Ratcliffe
Reed
Reichert
Renacci
Rice (NY)
Rice (SC)
Richmond
Roby
Roe (TN)
Rogers (AL)
Rohrabacher
Rokita
Rooney, Francis
Rooney, Thomas J.
Ros-Lehtinen
Rosen
Roskam
Ross
Rothfus
Rouzer
Royce (CA)
Ruiz
Ruppersberger
Russell
Rutherford
Ryan (OH)
Sánchez
Sanford
Scalise
Schiff
Schneider
Schrader
Schweikert
Scott (VA)
Scott, Austin
Sensenbrenner
Serrano
Sessions
Sewell (AL)
Shea-Porter
Sherman
Shimkus
Shuster
Simpson
Sinema
Smith (MO)
Smith (NE)
Smith (NJ)
Smith (TX)
Smucker
Soto
Stefanik
Stewart
Suozzi
Swalwell (CA)
Taylor
Tenney
Thompson (CA)
Thompson (MS)
Thompson (PA)
Thornberry
Tipton
Tonko
Trott
Tsongas
Turner
Upton
Valadao
Veasey
Vela
Velázquez
Visclosky
Wagner