

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

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

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

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

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

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

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

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

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

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

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

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

Providing clarity on how negative side effects will be accounted for dur-

ing drug approvals is helpful. Giving manufacturers, sponsors, physicians, hospitals, and clinical investigators certainty on liability protections is meaningful. Taken together, these improvements to the existing expanded access program could lead to enhanced manufacturer and sponsor participation and increased patient access.

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

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

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

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

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

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

There was no objection.

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

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

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

The yeas and nays were ordered.

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

RECESS

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

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

□ 2115

AFTER RECESS

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

COMMUNICATION FROM THE CLERK OF THE HOUSE

The SPEAKER pro tempore laid before the House the following commu-

nication from the Clerk of the House of Representatives:

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

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

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

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

With best wishes, I am
Sincerely,

KAREN L. HAAS.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

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

Votes will be taken in the following order:

The motion to recommit on H.R. 5247;

Passage of H.R. 5247, if ordered; and Agreeing to the Speaker's approval of the Journal, if ordered.

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

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

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

The Clerk will redesignate the motion.

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

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

[Roll No. 120]

YEAS—182

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