

Mr. ENZI. Mr. President, I yield back all time.

The ACTING PRESIDENT pro tempore. All time is yielded back.

CLOTURE MOTION

Pursuant to rule XXII, the Chair lays before the Senate the pending cloture motion, which the clerk will state.

The senior assistant legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, do hereby move to bring to a close debate on the motion to proceed to Calendar No. 174, H.R. 2430, an act to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and bi-similar biological products, and for other purposes.

Mitch McConnell, Steve Daines, Mike Crapo, James M. Inhofe, Lamar Alexander, Pat Roberts, Thom Tillis, Orrin G. Hatch, John Cornyn, Cory Gardner, Roy Blunt, James E. Risch, Roger F. Wicker, Tim Scott, John Thune, Mike Rounds, John Hoeven.

The ACTING PRESIDENT pro tempore. By unanimous consent, the mandatory quorum call has been waived.

The question is, Is it the sense of the Senate that debate on H.R. 2430, the FDA Reauthorization Act of 2017, shall be brought to a close?

The yeas and nays are mandatory under the rule.

The clerk will call the roll.

The legislative clerk called the roll.

Mr. CORNYN. The following Senators are necessarily absent: the Senator from North Carolina (Mr. BURR), the Senator from Oklahoma (Mr. INHOFE), and the Senator from Arizona (Mr. MCCAIN).

The PRESIDING OFFICER (Mr. SULLIVAN). Are there any other Senators in the Chamber desiring to vote?

The yeas and nays resulted—yeas 96, nays 1, as follows:

[Rollcall Vote No. 185 Leg.]

YEAS—96

Table listing Senators: Alexander, Baldwin, Barrasso, Bennet, Blumenthal, Blunt, Booker, Boozman, Brown, Cantwell, Capito, Cardin, Carper, Casey, Cassidy, Cochran, Collins, Coons, Corker, Cornyn, Cortez Masto, Cotton, Crapo, Cruz, Daines, Donnelly, Duckworth, Durbin, Enzi, Ernst, Feinstein, Fischer, Flake, Franken, Gardner, Gillibrand, Graham, Grassley, Harris, Hassan, Hatch, Heinrich, Heitkamp, Heller, Hirono, Hoeven, Isakson, Johnson, Kaine, Kennedy, King, Klobuchar, Lankford, Leahy, Lee, Manchin, Markey, McCaskill, McConnell, Menendez, Merkley, Moran, Murkowski, Murphy, Murray, Nelson, Paul, Perdue, Peters, Portman, Reed, Risch, Roberts, Rounds, Rubio, Sasse, Schatz, Schumer, Scott, Shaheen, Shelby, Stabenow, Strange, Sullivan, Tetter, Thune, Tillis, Toomey, Udall, Van Hollen, Warner, Warren, Whitehouse, Wicker, Wyden, Young.

NAYS—1

Sanders

NOT VOTING—3

Burr Inhofe McCain

The PRESIDING OFFICER. On this vote, the yeas are 96, the nays are 1.

Three-fifths of the Senators duly chosen and sworn having voted in the affirmative, the motion is agreed to.

The Senator from Tennessee.

ORDER OF PROCEDURE

Mr. ALEXANDER. Mr. President, I ask unanimous consent that after the disposition of the Brouillette nomination, the Senate resume consideration of the motion to proceed to H.R. 2430, that all postcloture time be expired, and the motion to proceed be agreed to; further, that there be no amendments in order to H.R. 2430, that there be 10 minutes of debate equally divided in the usual form, and that following the use or yielding back of that time, the bill be read a third time and the Senate vote on passage of the bill with no intervening action or debate.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

JESSIE'S LAW

Mr. ALEXANDER. Mr. President, I ask unanimous consent that the Committee on Health, Education, Labor, and Pensions be discharged from further consideration of S. 581 and the Senate proceed to its immediate consideration.

The PRESIDING OFFICER. Without objection, it is so ordered.

The clerk will report the bill by title. The legislative clerk read as follows:

A bill (S. 581) to include information concerning a patient's opioid addiction in certain medical records.

There being no objection, the Senate proceeded to consider the bill.

Mr. ALEXANDER. Mr. President, I ask unanimous consent that the Manchin-Capito substitute amendment be agreed to, the bill, as amended, be considered read a third time and passed, and the motion to reconsider be considered made and laid upon the table.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

The amendment (No. 752) in the nature of a substitute was agreed to, as follows:

(Purpose: In the nature of a substitute)

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as "Jessie's Law".

SEC. 2. INCLUSION OF OPIOID ADDICTION HISTORY IN PATIENT RECORDS.

(a) BEST PRACTICES.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with appropriate stakeholders, including a patient with a history of opioid use disorder, an expert in electronic health records, an expert in the confidentiality of patient health information and records, and

a health care provider, shall identify or facilitate the development of best practices regarding—

(A) the circumstances under which information that a patient has provided to a health care provider regarding such patient's history of opioid use disorder should, only at the patient's request, be prominently displayed in the medical records (including electronic health records) of such patient;

(B) what constitutes the patient's request for the purpose described in subparagraph (A); and

(C) the process and methods by which the information should be so displayed.

(2) DISSEMINATION.—The Secretary shall disseminate the best practices developed under paragraph (1) to health care providers and State agencies.

(b) REQUIREMENTS.—In identifying or facilitating the development of best practices under subsection (a), as applicable, the Secretary, in consultation with appropriate stakeholders, shall consider the following:

(1) The potential for addiction relapse or overdose, including overdose death, when opioid medications are prescribed to a patient recovering from opioid use disorder.

(2) The benefits of displaying information about a patient's opioid use disorder history in a manner similar to other potentially lethal medical concerns, including drug allergies and contraindications.

(3) The importance of prominently displaying information about a patient's opioid use disorder when a physician or medical professional is prescribing medication, including methods for avoiding alert fatigue in providers.

(4) The importance of a variety of appropriate medical professionals, including physicians, nurses, and pharmacists, to have access to information described in this section when prescribing or dispensing opioid medication, consistent with Federal and State laws and regulations.

(5) The importance of protecting patient privacy, including the requirements related to consent for disclosure of substance use disorder information under all applicable laws and regulations.

(6) All applicable Federal and State laws and regulations.

The bill (S. 581), as amended, was ordered to be engrossed for a third reading, was read the third time, and passed.

BETTER EMPOWERMENT NOW TO ENHANCE FRAMEWORK AND IMPROVE TREATMENTS ACT OF 2017

Mr. ALEXANDER. Mr. President, I ask unanimous consent that the Committee on Health, Education, Labor, and Pensions be discharged from further consideration of S. 1052 and the Senate proceed to its immediate consideration.

The PRESIDING OFFICER. Without objection, it is so ordered.

The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 1052) to strengthen the use of patient-experience data within the benefit-risk framework for approval of new drugs.

There being no objection, the Senate proceeded to consider the bill.

Mr. ALEXANDER. Mr. President, I ask unanimous consent that the bill be considered read a third time and passed and the motion to reconsider be considered made and laid upon the table.

The PRESIDING OFFICER. Without objection, it is so ordered.

The bill (S. 1052) was ordered to be engrossed for a third reading, was read the third time, and passed, as follows:

S. 1052

*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 “Better Empowerment Now to Enhance Framework and Improve Treatments Act of 2017” or the “BENEFIT Act of 2017”.

**SEC. 2. STRENGTHENING THE USE PATIENT-EXPERIENCE DATA WITHIN BENEFIT-RISK FRAMEWORK.**

Section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-8c) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (A), by striking “; and” and inserting a semicolon;

(B) in subparagraph (B), by striking the period and inserting “; and”; and

(C) by adding at the end the following:

“(C) as part of the risk-benefit assessment framework in the new drug approval process described in section 505(d), considering relevant patient-focused drug development data, such as data from patient preference studies (benefit-risk), patient reported outcome data, or patient experience data, developed by the sponsor of an application or another party.”; and

(2) in subsection (b)(1), by inserting “, including a description of how such data and information were considered in the risk benefit assessment described in section 505(d)” before the period.

The PRESIDING OFFICER. The Senator from Wisconsin.

**TRICKETT WENDLER RIGHT TO TRY ACT OF 2017**

Mr. JOHNSON. Mr. President, in about 5 minutes, I am going to be asking for consent to pass the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Belina Right to Try Act of 2017.

I wish to take a few moments, though, to tell the story of how that right-to-try bill, which has been passed by 37 States, obtained that name. I believe it was probably March of 2014 that I met Trickett Wendler, a young mom with three children, who came to Washington, DC, with a group of other individuals advocating for those patients and their families with people suffering from ALS, or Lou Gehrig’s disease—an incurable and devastating disease.

A week before meeting Trickett, I met with the Goldwater Institute, which was talking about its right-to-try legislation. They were beginning to pass through State legislatures. Just mentioning the fact that I supported the right to try brought tears streaming down Trickett Wendler’s face. Unfortunately, Trickett Wendler lost her battle to ALS on March 18, 2015. She has inspired something that I think is going to give so many thousands—maybe tens of thousands, maybe millions—of Americans hope when they face a similar type of disease, where there is no hope, where there are no

further options, other than potentially an experimental drug that has been proven safe, according to the FDA.

In our press conference announcing the introduction of this bill, we had met Matthew Belina, a naval aviator and lieutenant commander—one of the finest among us—also stricken with ALS. We had little Jordan McLinn, a little boy with Duchenne muscular dystrophy, and his mother Laura was speaking at that press conference. Remarkably, a man also stricken with ALS, Frank Mongiello, his wife Marilyn, and their children asked to speak. He made such an impression on our gathering, which encapsulated that press conference, particularly his speech in a video that I showed to my colleagues, which resulted in so many cosponsorships of this bill.

These are real people facing their mortality with no hope. This right-to-try piece of legislation will give those individuals and their families hope.

I want to truly thank my lead cosponsor from across the aisle, Senator JOE DONNELLY, who is in the Chamber here today, and also Senator KING and Senator MANCHIN, who decided not to play any politics whatsoever and also were willing to cosponsor a bill offered by somebody who was in a tough re-election fight. I want to thank my 43 Republican cosponsors, particularly Senator MCCONNELL. As leader, he was one of the first cosponsors who helped me to get those other 42 cosponsors. I want to particularly thank Chairman ALEXANDER and Ranking Member MURRAY, who have worked so cooperatively with me and my staff to make this moment possible. I would like to thank Vice President PENCE, who also met Frank Mongiello and became a real advocate for this, and President Trump, who after meeting these types of victims—these individuals—also supported this piece of legislation.

I wish to thank the Goldwater Institute and Darcy Olson for their tireless efforts at promoting the right to try and the 37 States and the 97.7 percent of the legislators who, when given a chance to vote to give people the right to try and the right to hope, voted yes.

I would also like to thank a very special person, Dr. Delpassand, who really demonstrated why this is such an important piece of legislation. Dr. Delpassand is an oncologist from Houston, TX. He was engaged in an FDA trial on an aggressive form of endocrine cancer with 150 patients. It was working. The drug was working. He petitioned the FDA to allow another 78 patients to participate in the trial. The FDA said no, but Dr. Delpassand said yes, putting his career at risk.

It is that kind of courage that we want to reward today by passing this right-to-try bill.

In conclusion, I want to thank the thousands of patients and their families who have taken their wheelchairs and gone to their State capitals and have come here to Washington, DC, to advocate for their personal freedom,

for their personal liberty, for their right to try, for their right to hope, and for the right to hope of millions of other Americans faced with these incurable diseases.

Mr. President, I ask unanimous consent that the Committee on Health, Education, Labor, and Pensions be discharged from further consideration of S. 204 and the Senate proceed to its immediate consideration.

The PRESIDING OFFICER. Without objection, it is so ordered.

The clerk will report the bill by title.

The legislative clerk read as follows:

A 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.

There being no objection, the Senate proceeded to consider the bill.

Mr. JOHNSON. Mr. President, I ask unanimous consent that the Johnson-Donnelly amendment at the desk be considered and agreed to, and the bill, as amended, be considered read a third time and passed, and the motion to reconsider be considered made and laid upon the table.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment (No. 753) in the nature of a substitute was agreed to, as follows:

(Purpose: In the nature of a substitute)

Strike all after the enacting clause and insert the following:

**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;