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 reelection 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, 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;

''(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 bill (S. 204), as amended, was ordered to be engrossed for a third reading, was read the third time, and passed.

The PRESIDING OFFICER. The Senator from Indiana.

Mr. DONNELLY. Mr. President, I want to talk about what a great moment this is. I want to thank Chairman ALEXANDER for all his help, Ranking Member PATTY MURRAY for all of her help, and to my colleague the Senator from Wisconsin, Mr. JOHNSON, for all he has done to spearhead this effort.

This gives folks a shot. It doesn't provide any guarantees, but it allows folks to be able to take their care into their own hands, to make judgments, and to decide: I want to take a shot at this.

For me, it was a wonderful family from Indiana who, by the way, this morning they are at Legoland down in Florida because their young boy is in good health, is getting along, but time is ticking. Young Jordan McLinn has Duchenne muscular dystrophy. His mom Laura and Jordan met with me and said: All we want is a shot. We don't want a guarantee. We want a chance to try to make Jordan better. That is what this Right to Try Act does. That is why I am so proud of all our colleagues coming together to support this, and to all the families Senator JOHNSON mentioned, we are so proud of you. We are so grateful to you for your advocacy because it was your words, your examples that have helped to get this done.

I want to say to everyone in Indiana and everyone in America how grateful we are that this Right to Try Act has passed, and to Chairman ALEXANDER and Ranking Member MURRAY, thank you for working together to make this happen.

I yield back.

EXECUTIVE SESSION

EXECUTIVE CALENDAR

The PRESIDING OFFICER. Under the previous order, the Senate will proceed to executive session to consider the following nomination, which the clerk will report.

The legislative clerk read the nomination of Dan R. Brouillette, of Texas, to be Deputy Secretary of Energy.

The PRESIDING OFFICER. There will now be 15 minutes of debate equally divided in the usual form.

The Senator from Washington.

FDA REAUTHORIZATION BILL

Mrs. MURRAY. Mr. President, I want to say I am really pleased we are moving forward on the FDA Reauthorization Act today. This is really a great example about how Congress can actually work together on health issues and compromise and solve challenges by putting patients and families first.

As my colleagues well know, these so-called user fee agreements are essential to supporting FDA's operation and mission. They allow FDA to meet the complex challenges of the 21st century technology and the movement toward precision medicine, and they help ensure that FDA upholds the gold standard of approval while evaluating new drugs and devices efficiently. Put simply, passing the FDA Reauthorization Act is absolutely necessary if Congress wants to advance safe, effective