''(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

and innovative medical products for patients and families across the country.

I would add, when we pass this reauthorization today, more than 5,000 employees at FDA will be able to continue their critical work without worry of interruption, employees that worked every day to protect the health and families and advance medical innovations to patients.

So I am really pleased to have worked alongside the chairman of our HELP Committee, the Senior Senator from Tennessee, and all of our colleagues on and off the committee to bring to the floor these finalized agreements.

They truly reflect years of negotiations between FDA and the industry, incorporate input from patient and consumer groups, and support some of our most urgent priorities: restructuring the generic drug user fees, building up the Biosimilars Program, making sure patients' perspectives are considered in drug and device development, and advancing many of the policies we passed as part of the 21st Century Cures Act.

In addition to those agreements, the FDA Reauthorization Act includes priorities and provisions from Members across the political spectrum, so I again want to thank Chairman ALEXANDER and all my colleagues, in particular, Senators CASEY, FRANKEN, and WARREN, on their work to improve medical device safety; Senators HASSAN and YOUNG on their provision to get better information to providers about opioids; Senators MCCASKILL, FRANKEN, and COLLINS for their commitment to improving the generic drug market; and Senators BENNET, VAN HOLLEN, and RUBIO for their drive to get new medicine for kids with cancer.

I really want to thank my staff and Chairman ALEXANDER's staff who worked so well together over months of hard work to get this done.

Mr. President, this bill advances several significant bipartisan priorities I am proud to support. As many know, the HELP Committee has a strong tradition of bipartisan success in these user fee agreements, and I am very proud to say we have kept it this way. I think this bill not only improves FDA, but it also shows that when we work together with a common goal, we can get things done and make progress.

I thank the chair and my partner, Senator ALEXANDER.

I yield the floor.

The PRESIDING OFFICER. The Senator from Tennessee.

Mr. ALEXANDER. Mr. President, I see Senators ISAKSON and TESTER are here. I think they want to make remarks before the vote.

Let me say a few words following up on Senator MURRAY, and then I will place the rest of my comments in the RECORD.

This is very important legislation. Last year, we passed the 21st Century Cures Act to move these modern medical miracles into medicine cabinets and doctors' offices more rapidly. This is funding that pays for one-quarter of the Food and Drug Administration, which has a critical role in approving the safety and effectiveness of drugs, treatments, and devices. As with most things in the Senate that actually are important and work well and get a result, a lot of hard work has gone into this.

It started 2 years ago with Republicans and Democrats; Senator MURRAY and I and our staffs working together with the House of Representatives at the same time, working with manufacturers, the FDA, many others, working out many differences of opinion. So now we are going to get to a result within a few minutes. We are probably going to adopt this by voice vote almost unanimously. Everyone will say that must have been easy. It wasn't that easy, but it is how work gets done in the U.S. Senate when we do it well.

I want to comment on our colleagues and the staff and the House of Representatives on what they have done. We will continue to focus our attention on the 21st Century Cures Act. A piece of legislation is not worth the paper it is printed on unless it is implemented properly, but this funding today, done in a timely way, says to the men and women who work at the Food and Drug Administration and to their leader, Dr. Gottlieb: We value what you do.

In the 21st Century Cures Act, we gave the Commissioner more authority to hire and pay talented people to work at FDA and approve these medical miracles that are coming. We are reauthorizing the user fees in a timely way so the FDA's work will not be interrupted.

I thank Senator MURRAY for the way she worked on this. This is typical of our committee when we work well, which we most always do.

I will make remarks in the RECORD concerning the staff. They are almost too numerous to mention. Senator MURRAY's staff, my staff, Chairman WALDEN's staff, Ranking Member PALLONE's staff, Food and Drug Administration staff, Congressional Budget Office legislative counsel, and Senator MCCONNELL's staff—they have all been critical to the success we are about to have today.

I would like to thank the staff who have been devoted to reauthorizing these important programs. Some of them have been working on this bill for over 2 years. I am deeply grateful to them. I have deep appreciation for their hard work, their ingenuity, and their skill in helping us come to this result. Without their hard work and tireless effort, we wouldn't have been able to pass this before the deadline, ensuring the FDA can continue its important mission.

On Senator MURRAY's exceptional staff, I would like to thank Evan Schatz, John Righter, Nick Bath, Andi Fristedt, and Remy Brim.

On my hard-working and dedicated staff, I would like to thank David Cleary, Lindsey Seidman, Allison Martin, Mary-Sumpter Lapinski, Grace Stuntz, Margaret Coulter, Curtis Vann, Lowell Schiller, Bobby McMillin, Liz Wolgemuth, Margaret Atkinson, Taylor Haulsee, Elizabeth Gibson, and Anthony Birch.

On Chairman WALDEN's staff, I would like to thank Ray Baum, Paul Edattel, and John Stone.

On Ranking Member PALLONE's staff, I would like to thank Jeff Carroll, Tiffany Guarascio, and Kimberlee Trzeciak. I would also like to thank much of the hard-working staff from the Food and Drug Administration who provided great help in getting this bill completed and working out the user fee agreements in a timely manner. From legislative counsel from the House and Senate, I would like to thank Warren Burke, Michelle Vanek, Kim Tamber, and Katie Bonander.

From the Congressional Budget Office, I would like to thank Darren Young, Andrea Noda, Chad Chirico, Holly Harvey, Ellen Werble, and Rebecca Yip.

On Senator MCCONNELL's staff, I would like to thank Scott Raab.

On Speaker RYAN's staff, I would like to thank Matt Hoffman.

Finally, I would like to thank all the patients, doctors, researchers, innovators, thought leaders, and experts who dedicated time and expertise to helping improve the legislation and supporting its approval.

To reiterate, today the Senate will take up and I expect it will pass the Food and Drug Administration Reauthorization Act of 2017 to speed cures and treatments into patients' medicine cabinets.

Last year, 94 Senators voted to pass 21st Century Cures and send $4.8–billion to spur medical research at the National Institutes of Health.

Leader MCCONNELL called it the ''most important piece of legislation'' that year.

Today's passage of the FDA user fees will help ensure advancements in research supported by 21st Century Cures actually make it to patients who are waiting.

The Food and Drug Administration is the agency responsible for making sure promising research supported by 21st Century Cures can turn into lifesaving treatments and cures.

This legislation we will vote on today includes four FDA user fee agreements—which are set to expire on September 30—and will speed the agency's ability to review new prescription drugs, generic drugs, biosimilar drugs, and medical devices and bring those treatments and cures to patients more quickly.

This legislation will reauthorize the authority for the FDA to accept user fees—paid by manufacturers of drugs and medical devices—that account for $8 to $9 billion over 5 years and is over a quarter of all FDA funding.

The reauthorizations are based on recommendations from industry and FDA after a thorough public process.

FDA posted meeting minutes after every negotiation and held public meetings before discussion began and to hear feedback on the draft recommendations last fall.

We began almost 2 years ago working in a bipartisan way to reauthorize and update the user fee agreements. We held 15 bipartisan Senate health committee briefings, including several with the House Energy and Commerce Committee.

In the Senate HELP Committee, we held two bipartisan hearings on these agreements—one in March and one in April of this year.

We heard from the FDA, witnesses representing the manufacturers of drugs and medical devices, and witnesses representing the patients who rely on the products they make.

Throughout this process, we have worked closely with the House. In April, the leaders of the Senate and House health committees released a discussion draft of bipartisan legislation to reauthorize and update the user-fee agreements and which reflected the recommendations sent to Congress by the FDA in January.

In May, the Senate HELP Committee overwhelmingly approved this legislation reauthorizing the user fees by a vote of 21 to 2. This also included over 20 provisions that were adopted in committee and were priorities for HELP members.

The bill includes provisions from Senators ISAKSON and BENNET to improve the medical device inspection process; Senators HASSAN and YOUNG to improve communication about abuse-deterrent opioid products; Senators ENZI and FRANKEN to encourage medical device development for children and make sure FDA has appropriate expertise to review devices for children; Senators ROBERTS, DONNELLY, and BURR to allow more appropriate classification of accessories used with medical devices; Senators COLLINS, FRANKEN, MCCASKILL, and COTTON to improve generic drug development and help lower prescription drug costs; Senators HATCH, BENNET, BURR, and CASEY to improve access to clinical trials for all patients; and Senators BENNET, RUBIO, VAN HOLLEN, and GARDNER to increase the development of new drugs to treat pediatric cancers and other diseases.

The House passed this user fee legislation on July 12 by voice vote.

Now it is our turn to pass this bipartisan legislation that is integral to helping patients and families who rely on the lifesaving medical innovation that FDA is responsible for reviewing.

The goal of getting this to the President's desk is an important one. If we do not pass this legislation before the end of September, FDA will begin sending layoff notices to more than 5,000 employees to notify them that they may lose their job in 60 days.

If we do not pass this bill, a FDA reviewer who gets started reviewing a cancer drug submitted to the agency in April could be laid off before the reviewer is able to finish his or her work.

A delay in reauthorizing the user fees would not only harm patients and families who rely on medical innovation, but it would threaten biomedical industry jobs and jeopardize America's global leadership in biomedical innovation.

I am glad the Senate is taking the step of voting on this legislation today. I look forward to supporting this important bipartisan bill and sending it to the President's desk. I urge my colleagues to support it as well.

The PRESIDING OFFICER. The Senator from Georgia.

VETERANS LEGISLATION

Mr. ISAKSON. Mr. President, I rise for a moment to reflect on what was a great night for the U.S. Senate, the U.S. Government, for the population of our country but most importantly for those who served as veterans in the military.

Last night, the Senate agreed to significant legislation on three fronts to make the VA better and more responsive to our veterans.

Ranking Member TESTER and I have spent the entire year working toward making sure we dealt with the needs the VA has so all these stories we see on the front page of papers, stories about there being unsafe conditions, stories about people being mistreated, stories of people having to wait so long for their appointments—we want to put an end to all this, and we have given the Secretary the tools to do exactly that.

I was telling the ranking member this is called ''no excuses day.'' Secretary Shulkin will have no excuses for any mistakes to be made. Every tool he needs in his toolbox to see that the Veterans' Administration is responsible to the veterans of the United States of America passed in this Senate, passed in the House. There were six major bills the first 7 months of this year, a remarkable achievement, a testimony to teamwork, to staff, and to the leadership of the Republican and the Democratic Parties. The majority and minority leaders of this Senate made it possible for that to happen last night. I am eternally grateful to both of them for their support and help.

I am not going to read all the names of the staff now because we are in limited time.

I ask unanimous consent that the names of every staff member who worked with the VA Committee to make it the best year ever be printed in the RECORD.

Credit is given to captains, Presidents, and people with titles. Senator TESTER and I have the titles, when it comes to the VA Committee, but the reason the VA Committee was successful in accomplishing every single goal, was because of every ranking file member, Republican or Democratic. We took our labels off, we put our armor on, and we plowed ahead. We didn't say no to problems that looked like they were too hard. We said yes to solutions that looked like they made sense.

Veterans of the United States of America have better healthcare, better educational benefits, and a modern VA to deal with in the years ahead. I am proud to have been a part of it. I want to commend Senator TESTER for his contribution.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

Staff on the Senate Committee on Veterans' Affairs:

Tom Bowman, staff director, soon-to-be Deputy Secretary of VA; Amanda Meredith, deputy staff director, soon-to-be judge on the U.S. Court of Appeals for Veterans Claims; Leslie Campbell; Gretchan Blum; Maureen O'Neill; Adam Reece; David Shearman; Jillian Workman; Kristen Hines; Thomas Coleman; John Ashley; Mitchell Sylvest; Joan Kirchner; Trey Kilpatrick; Jay Sulzmann; Ryan Evans; Salvador Ortega; and Amanda Maddox.

Mr. ISAKSON. I yield to Senator TESTER.

The PRESIDING OFFICER. The Senator from Montana.

Mr. TESTER. Thank you, Mr. President.

I want to thank Chairman ISAKSON for his work on the VA Committee. We have gotten a lot of work done the first part of this Congress because we communicated. We haven't put up artificial barriers. We sat down and all realized taking care of our veterans is the cost of war. We need to do it and live up to the promises of these folks when they signed up. We have done pretty good work.

It is not only JOHNNY. It is not only myself. It is also the people who have served on that committee, many in the Chamber right now. I want to thank them for their commitment to making sure we live up to the promises we made our veterans, but it is about working together. It is about talking to folks. It is about compromise. It is about not digging in but moving together. This is a great country, and it was built by people working together.

The VA Committee is a prime example of people working together. We set aside our differences. We listened to the veterans service organizations. We let them drive the bus, to an extent. We worked with Secretary Shulkin and other leaders within the VA. We have been transparent. We have been honest when we disagreed. We haven't embarrassed one another. Quite frankly, this is the way it can work in this body when we start from a point of agreement rather than disagreement.

We have two bills already signed into law: an accountability bill, which holds VA employees accountable to the veterans, fires bad employees, protects whistleblowers; and the Veterans Choice Improvement Act, which makes VA the prime payer and reduces out-of-pocket expenses for veterans. Then, the bills passed last night to take care of the disability appeals, some 470,000—we are going to expedite that process and bring it down from 3 years to 1 year.