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MARK WALKER, CHAIRMAN
RSC THE REPUBLICAN STUDY COMMITTEE

S. 204: Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (Sen. Johnson, R-WI)

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FLOOR SCHEDULE:

S. 204 is expected to be considered on May 22, 2018 under a closed rule.

The rule also provides for consideration of S. 2155, the Economic Growth, Regulatory Relief, and Consumer Protection Act, and initial consideration of H.R. 5515, the FY 2019 National Defense Authorization Act.

The rule would further provide that the motion to reconsider the vote on the question of passage of H.R. 2, the Agriculture and Nutrition Act of 2018, may continue to be postponed through the legislative day of Friday, June 22, 2018.

TOPLINE SUMMARY:

S. 204 would allow patients to gain access to experimental treatments if they have been diagnosed with a life threatening disease or condition and have exhausted approved treatment options.

COST:

A Congressional Budget Office (CBO) estimate is not available.

According to the Energy and Commerce Committee, "this legislation would not have a significant effect on direct spending or revenues."

CONSERVATIVE VIEWS:

- **Expand the Size and Scope of the Federal Government?** No, many conservatives may be pleased the bill would relieve government regulations in certain cases that could otherwise impede access to investigational treatments for patients with life threatening conditions.
- **Encroach into State or Local Authority?** No.
- **Delegate Any Legislative Authority to the Executive Branch?** No.
- **Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits?** No.

DETAILED SUMMARY AND ANALYSIS:

Federal law generally prohibits introducing or delivering new drugs in interstate commerce unless the drug is approved by Food and Drug Administration (FDA). Under current law, some patients can access an investigational medical product outside of a clinical trial through the FDA's Expanded Access program.

However, the program has been criticized because "To most patients, and many physicians outside of major institutions, the process of obtaining expanded access is excessively time-consuming and extremely difficult to navigate." Forty states have passed "Right to Try" laws. According to CRS, "These state laws do not alter federal requirements that restrict access to unapproved drugs. Additionally, because of the Supremacy Clause of the Constitution and the primacy of federal statutes, it seems unlikely that this type of state law could be construed so as to override federal drug regulation."

S. 204 would allow patients to gain access to certain experimental treatments if they have been diagnosed with a life threatening disease or condition and have exhausted approved treatment options. An eligible patient must be unable to participate in a clinical trial involving the eligible investigational drug. The eligible patient (or the legally authorized representative of the patient) must further provide the treating physician written informed consent regarding the eligible investigational drug.

Compared to the House-passed bill, H.R. 5247, the definition of an eligible patient eligible for the right to try under S. 204 is slightly broader. Under H.R. 5247, the eligible would have been required to have a disease or condition in which there is a reasonable likelihood that death will occur in a matter of months, or that the disease or condition will result in significant irreversible morbidity or severely premature death.

Eligible investigative drugs would include an experimental drug that has completed a Phase I clinical trial and has not been approved or licensed by the FDA but for which an active application has been filed, or an experimental drug that is under investigation in a clinical trial intended to form the primary basis of a claim of effectiveness in support of approval or licensure, that is the subject of an active investigational new drug application and active development or production is ongoing, has not been discontinued by a manufacturer, and is not the subject of a clinical hold.

Eligible investigative drugs provided to eligible patients under the bill would be exempt from certain current law provisions related to misbranded drugs and devices, labeling or packaging requirements for prescription drugs, and interstate commerce of new drugs. An eligible investigational drug would have to comply with existing FDA regulations related to the labeling, promotion, and recoverable costs of investigational drugs.

The Secretary would not be permitted to use clinical outcomes associated with use under the new alternative pathway to delay or adversely affect the eligible investigational drug's review or approval, unless the drug sponsor requests it or the Secretary makes a determination that use of the clinical outcome is critical to determining the drug's safety. The Secretary would be required to provide written notice of such a determination to the sponsor, including a public health justification, which would be made part of the administrative record, and the determination could not be delegated below the director of the agency center responsible for premarket review of the eligible investigational drug.

The manufacturer or sponsor would also be required to post an annual summary of any provision of an eligible investigational drug under the bill.

The Secretary would be required to post an annual summary of use of the right to try provided by the bill on the FDA website.

The bill would provide that the sponsor, manufacturer, prescriber, dispenser, or other entity shall not be liable with respect to any alleged act or omission related to an eligible investigational drug provided to an eligible patient pursuant to the bill, unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort.

The bill further provides that a sponsor manufacturer, prescriber, dispenser, or other entity shall not be liable for their determination to not provide access to an investigational drug under the bill.

The bill includes the sense of Senate that the bill: "does not establish a new entitlement or modify an existing entitlement, or otherwise establish a positive right to any party or individual; does not establish any new mandates, directives, or additional regulations; only expands the scope of individual liberty and agency among patients, in limited circumstances; is consistent with, and will act as an alternative pathway alongside, existing expanded access policies of the Food and Drug Administration; will not, and cannot, create a cure or effective therapy where none exists; 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 establishes national standards and rules by which investigational drugs may be provided to terminally ill patients."

OUTSIDE GROUP SUPPORT:

- **Americans for Prosperity** – **Key Vote**
- **FreedomWorks** – **Key Vote**

- Abigail Alliance for Better Access to Developmental Drugs
- American Commitment
- Americans for Limited Government
- Athletes for Care
- Campaign for Liberty
- Center for Individual Freedom
- Coalition for Access Now
- Competitive Enterprise Institute
- Cures Within Reach
- Digestive Disease National Coalition
- Dystrophic Epidermolysis Bullosa Research Association of America
- Federal Law Enforcement Officers Association Foundation
- Foundation to Open Access to Cancer Cures
- Freedom Partners
- Gastroparesis Patient Association for Cures and Treatments, Inc.
- Goldwater Institute
- G-PACT
- Have a Heart Foundation
- Hope Now for ALS
- Idaho Freedom Foundation
- Independent Women's Voice
- Institute for Justice
- KK125 Ovarian Cancer Research Foundation
- Libre Initiative
- Little Hercules Foundation
- METAvivor Research and Support, Inc.
- Mississippi Public Policy Center
- MyRightToTryNOW
- NAC Have a Heart Foundation
- One Woman Many Lakes
- Rare Disease United Foundation
- Rio Grande Foundation
- Sarcoidosis of Long Island
- Taxpayers Protection Alliance
- Teen Cancer America

COMMITTEE ACTION:

S. 204 was introduced on January 24, 2017, and referred to the Senate Health, Education, Labor, and Pensions Committee. The Senate passed the bill by unanimous consent on August 3, 2017.

The House considered and passed similar legislation, H.R. 5247, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2018, on March 21, 2018, by a 267 – 149 vote. H.R. 5247 had previously failed under suspension by a 259 – 140 vote on March 13, 2018.

The Energy and Commerce Committee held a hearing on the topic of patient access to investigational drugs on October 3, 2017, but no further Committee action has occurred.

ADMINISTRATION POSITION:

According to the Statement of Administration Policy, "If S. 204 were presented to the President in its current form, his advisors would recommend that he sign the bill into law."

President Trump and Vice President Pence have previously expressed support for "Right to Try" policies. In his State of the Union address, President Trump stated that "people who are terminally ill should not have to go from country to country to seek a cure. It is time for Congress to give these wonderful Americans the 'right to try.'" Vice President Pence recently stated that the policies are "about restoring hope and giving patients with life-threatening diseases a fighting chance."

CONSTITUTIONAL AUTHORITY:

Bills that originate in the Senate do not require a constitutional authority statement.

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