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RSC THE REPUBLICAN STUDY COMMITTEE

H.R. 5247 – Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2018 (Fitzpatrick, R-PA)

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FLOOR SCHEDULE:

Expected to be considered on March 21, 2018, under a closed rule.

TOPLINE SUMMARY:

H.R. 5247 would create an alternative pathway for patients to gain access to experimental treatments if they 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.

COST:

No Congressional Budget Office (CBO) score is currently available. Rule 28(a)(1) of the Rules of the Republican Conference prohibit measures from being scheduled for consideration under suspension of the rules without an accompanying cost estimate. Rule 28(b) provides that the cost estimate requirement may be waived by a majority of the Elected Leadership.

CONSERVATIVE CONCERNS:

- **Expand the Size and Scope of the Federal Government?** No.
- **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:

H.R. 5247 would create an alternative pathway for patients to gain access to experimental treatments if they 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. Specifically, the bill would allow patients to gain access to any experimental drug that has completed a Phase I clinical trial and has not been approved or licensed by the Food and Drug Administration (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.

As long as certain conditions specified in the bill are met, investigational drugs obtained under the new pathway 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. First, the

eligible investigational drug would have to comply with existing FDA regulations related to the labeling, promotion, and recoverable costs of investigational drugs. Second, the drug sponsor would be required to notify the Secretary of any provision of an eligible investigational drug within seven business days, as correspondence to the investigational new drug application. Third, as a condition of providing the eligible investigational drug to a physician for use under this bill, the drug sponsor or manufacturer must require that the physician immediately report any serious adverse events to the sponsor or manufacturer. 21 CFR 312.

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's new alternative pathway, to be posted on the same public Internet website that the manufacturer is required to maintain in order to participate in FDA's current law Expanded Access program.

Finally, the bill includes several provisions related to liability. It would ensure that manufacturers and sponsors would not be held liable for any alleged act or omission related to providing eligible investigational drugs to single patients or small groups of patients under FDA's current law Expanded Access program or the new alternative pathway established under this bill. It also ensures that no licensed physician, clinical investigator, or hospital would be held liable for any alleged act or omission related to providing eligible investigational drugs to single patients or small groups of patients in accordance with FDA's current law Expanded Access program or the new alternative pathway established under this bill, unless such act or omission constitutes willful or criminal misconduct, reckless misconduct, gross negligence, or an applicable tort under applicable state law. In addition, it would ensure that no manufacturer, sponsor, licensed physician, clinical investigator, or hospital would be held liable for determining not to provide access to an investigational drug or for discontinuing access it initially determined to provide.

COMMITTEE ACTION:

H.R. 5247 was introduced in the House on March 13, 2018, and failed to pass under suspension of the rules by a vote of 259-140 the same day. 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. The Senate passed a similar bill, S. 204, by unanimous consent on August 3, 2017.

OUTSIDE GROUP SUPPORT:

Americans for Prosperity
Freedom Partners
FreedomWorks – ***Key Vote***
Generation Opportunity
Taxpayers Protection Alliance
The Libre Initiative

ADMINISTRATION POSITION:

No Statement of Administration Policy is available at this time. 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:

According to the bill sponsor, Congress has the power to enact this legislation pursuant to Article I, Section 8.

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