H.R. 5247, To authorize the use of eligible investigational drugs by eligible patients who have been diagnosed with a stage of a disease or condition in which there is reasonable likelihood that death will occur within a matter of months, or with another eligible illness, and for other purposes.

Section-by-Section

Section 1. Short Title.

This section provides that the Act may be cited as the "Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2018."

Section 2. Use of Unapproved Investigational Drugs by Patients Diagnosed with a Terminal Illness.

Section 2 would amend Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (FFDCA) by adding section 561B, Investigational Drugs for Use by Eligible Patients.

Definitions: The section would define the terms "eligible patient"; "eligible investigational drug"; "phase 1 trial"; and "eligible illness."

Alternative pathway for eligible patients with a terminal illness. The section would exempt "eligible investigational drugs" provided to "eligible patients" from sections 502(f), 503(b)(4), 505(a), and 505(i) of the FFDCA and section 351(a) of the Public Health Service Act (PHSA).

[Sections 502(f) and 503(b)(4) of the FFDCA pertain to labeling; sections 505(a) and 505(i) of the FFDCA pertain to new drugs; and section 351(a) of the PHSA relates to the regulation of biological products.]

Such exemption is conditioned upon satisfying specified labeling, promotional, and charging requirements in the Code of Federal Regulations; notifying Secretary of Health and Human Services that an "eligible investigational drug" has been provided to an "eligible patient"; and providing for the immediate reporting of an serious adverse events associated with the use of the "eligible investigational drug" by the providing physician.

The section also would provide that 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 the drug. However, such outcomes may be used if the Secretary determines that use of such clinical outcome is critical to determining the safety of the "eligible investigational drug" or if the sponsor requests use of such outcomes.

Clinical outcomes. If the Secretary determines that the use of such clinical outcome is critical to determining the safety of the "eligible investigational drug," the Secretary shall

provide written notice of such determination to the sponsor, including a public health justification.

The manufacturer or sponsor that provides an "eligible investigational drug" pursuant to this section shall post on a specified website an annual summary of such provision. The summary shall include the number of requests received, the number of requests granted, the number of patients treated, the therapeutic area of the drug made available, and any known or suspected serious adverse events associated with the use of the eligible investigational drug.

Liability. The section would provide that no manufacturer or sponsor of an investigational drug and no licensed physician, clinical investigator, or hospital shall be liable for any alleged act or omission related to the provision of an investigational drug for treatment use in accordance with this section. This would not apply to an act or omission by a licensed physician, clinical investigator, or hospital that was willful or criminal conduct, reckless misconduct, gross negligence, or an intentional tort under applicable State law.

No manufacturer, sponsor, licensed physician, clinical investigator, or hospital shall be liable for determining not to provide access to an investigational drug under this section or for discontinuing any such access that it initially determined to provide.

Nothing in the section would affect the right of a person to bring a private action against a manufacturer or sponsor (or their agent or representative), physician, clinical investigator, hospital, prescriber, dispenser, or other entity under any State or Federal product liability, tort, consumer protection, or warranty law. Nor would the section affect the authority of the Federal Government to bring suit under any Federal law.