The Trickett Wendler Right to Try Act (S.204) aims to establish a new pathway for terminally ill patients to access experimental drugs not yet approved by the FDA. These patients are often extremely ill and not able to participate in clinical trials, or have no treatment options. Under current law, companies can already provide access to investigation drugs to patients outside of clinical trials under a pathway at FDA called expanded access.

Often times if drugs are requested under expanded access, companies will refuse for a variety of reasons, including insufficient quantity of the drug, and fear that FDA will use these patients' outcomes against them during the approval process. Some companies cite that the reason they do not give out the drug under expanded access is the fear of liability in case something unexpected goes wrong in an uncontrolled patient population.

S. 204 aims to specifically address the issues associated with use of outcomes and liability in order to incentivize companies to provide greater access to investigational drugs for patients without treatment options.

The substitute amendment, now entitled the Trickett Wendler, Frank Mongiello, and Jordan McLinn Right to Try Act of 2017 addresses concerns with the previous version of the bill by -

- **Applying all laws, including the Food Drug and Cosmetic Act and the Controlled Substances Act, to entities utilizing Right to Try.**
- **Limiting the Right to Try pathway to drugs.**
- **Requiring that the price charged to patients cannot exceed the cost to produce the drug.**
- **More accurately defining a terminal patient.**
- **Requiring that patients exhaust approved treatment options and clinical trials before becoming eligible for Right to Try.**
- **Allowing FDA to use clinical outcomes when necessary for patient safety.**
- **Assuring appropriate liability for patient harms.**
- **Eliminating the state by state approach, consistent with federal drug regulation.**
- **Requiring companies to report on the use of the Right to Try pathway to FDA, including serious adverse events.**
- **Requiring FDA to publish a public annual summary report of the use of Right to Try.**

<u>Ranking Member Murray Supports the substitute amendment to S.204, The Trickett Wendler, Frank Mongiello, and Jordan McLinn Right to Try Act of 2017.</u>