STATEMENT OF

REPRESENTATIVE BRIAN FITZPATRICK OF PENNSYLVANIA'S EIGHTH DISTRICT

BEFORE THE SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES

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I want to start by thanking Chairman Burgess, Ranking Member Green, Vice-Chairman Guthrie and other members of the Energy and Commerce Subcommittee on Health for holding this hearing on Right to Try. Thank you to my colleague, Rep. Biggs, for your steadfast leadership on this issue.

Each year more Americans receive the devastating news of a terminal diagnosis. Even with the amazing work done in American medical research and development, for too many families, access to these potentially lifesaving treatments will come too late, or not at all.

Thousands of terminally ill patients suffer needlessly while awaiting final approval for drugs, therapies, and other medical technologies. While the Food and Drug Administration carries out its three-phase approval process – which can take years and cost billions of dollars – many patients simply want the chance to try treatments that are already demonstrated to be safe.

Mr. Chairman, it is my hope to come together with federal regulators and industry leaders to clear the path forward to care for those who are fighting just for a shot at living. A bill unanimously passed by the Senate will offer them a chance to extend their lives.

The *Right to Try Act* would ensure that terminally ill patients - together with their physicians, and pharmaceutical manufacturers - can administer investigational treatments where no alternative exists. In fact, this bipartisan idea is already law in 37 states. A federal Right-to-Try would prevent the government from blocking access to potentially lifesaving medications. It would require patients to first try all other available treatments and be unable to participate in clinical trials.

Mr. Chairman, I want to note that these provisions only apply to terminally-ill patients. It does not undo the FDA approval process, but provides a potential lifeline for those who cannot wait. It requires physician certification that other options to be exhausted or unavailable. This maintains the incentive for patients to seek out and join clinical trials. This bill requires that a product meet a demonstrated level of safety by attaining FDA Phase I approval. We've worked with drug companies to ensure adverse outcomes are not used against the ongoing application for approval. Additionally, patients, doctors, and manufacturers do not assume any additional liability under this act.

For those patients caught between the traditional drug approval delays, a clinical trial process for which they do not qualify, and limited time, Right to Try simply establishes the freedom for patients and their doctors to try therapies where the benefits far outweigh the risks. It gives them the option of trying to save their life.

Whether it's a father courageously battling ALS or a brave child living with Duchene Muscular Dystrophy, they deserve the right to try.

Thank you all for your time and consideration. I look forward to working with you.