



September 12, 2017

Dear Members of the U.S. House:

As advocates for Americans facing terminal and life-threatening illnesses, we write to urge your support for S. 204, the Trickett Wendler, Frank Mongiello, Jordan McLinn & Matthew Bellina Right to Try Act of 2017, that was passed unanimously by the U.S. Senate. This bill will help protect the right of sick Americans to try to save their own lives. Fewer than 3 percent of cancer patients can participate in clinical trials, and for less common diseases like ALS and deadly Duchenne muscular dystrophy, the numbers are even lower. Right to Try gives people who cannot participate in trials a new path to access promising treatments.

Right to Try is Bipartisan: As of this writing, 37 states have adopted Right to Try laws with overwhelming bipartisan support. In half of those states the laws have passed with unanimous support in the state House and Senate; in Arizona, voters approved the measure with nearly 80% of the popular vote. The laws have been signed by 25 Republican Governors and 11 Democratic Governors.

Right to Try is Safe: The doctor-recommended treatments available to patients under Right to Try laws must have passed an FDA-approved Phase I clinical trial and be in an active Phase II or Phase III trial or under active consideration by the FDA. The risk for a patient trying an investigational treatment under Right to Try is the same as for those in clinical trials because they are the same treatments. Right to Try simply allows more patients to have access to treatments that are being safely used in clinical trials.

Right to Try Protects Clinical Trials & FDA-Authority: Right to Try laws rely on the FDA's approval process to determine which treatments in clinical trials terminal patients can access. Right to Try only applies to treatments that have successfully completed the FDA's first phase of trials and remain in ongoing FDA-sanctioned phase II or III trials where they are ultimately working towards approval. This alternative and limited pathway leaves the FDA trial system intact. Only treatments that the FDA itself has determined are worthy of continued investigation are eligible. If at any point or for any reason a treatment no longer remains in a clinical trial and is no longer working towards FDA approval, a patient cannot access it under Right to Try.

Right to Try Patient Data will be Collected & Reported: Drug manufacturers will be required to report adverse events to the FDA. But, this data alone cannot be used to stop a trial, or to delay or deny approval of the treatment, unless the FDA believes not using the data will create a significant public health risk. The FDA will still be allowed to have conversations with the manufacturer about the adverse events, request more

information, and even recommend changes in trial protocols. Simply put, the FDA will still decide whether to approve or reject a treatment based on the clinical trial results.

Right to Try is a Last Resort: Right to Try is only for patients whose doctors have determined are facing a life-threatening illness, who have exhausted all available treatments, and who cannot participate in a clinical trial. This law is aimed at helping a narrow set of patients who have truly run out of options, but who might be helped by a treatment that is helping people in clinical trials. Right to Try is the opposite of Right to Die: it is for people who are not ready to stop fighting. We owe them the opportunity to try treatments that are being given to the lucky few in clinical trials.

Right to Try is Voluntary: No patient, doctor, or drug manufacturer is required to seek or provide treatment under a state Right to Try law. If a patient wants to try an investigational treatment that his or her doctors and the manufacturer do not think will be helpful, they are under no obligation to provide that treatment. Right to Try can only be used in situations where the patient signs an informed consent document that fully explains all the risks the patient is assuming, and the doctor and manufacturer agree that the treatment could be helpful to the patient.

Right to Try is Working: While most state laws do not include central reporting requirements, we know the law is being used to successfully treat patients. Dr. Ebrahim Delpassand, an oncologist in Houston, and his colleagues at Excel Diagnostics, have used the Texas Right to Try law to treat nearly 100 terminal neuroendocrine cancer patients with a new compound that is under final review by the FDA. Many of these patients were given only months to live and two years later are still with us and enjoying a robust quality of life.

Right to Try provides a new path for people who are out of options to access promising and safe investigational treatments. We urge you to support this critical law that will help the Americans we represent at no cost to the government.

Sincerely,

Abigail Alliance for Better Access to Developmental Drugs
Athletes for Care
Coalition for Access Now
Cures Within Reach
Digestive Disease National Coalition
Dystrophic Epidermolysis Bullosa Research Association of America
Federal Law Enforcement Officers Association
Fire Fighters with Parkinson's Disease
Foundation to Open Access to Cancer Cures
Gastroparesis Patient Association for Cures and Treatments, Inc.

Right To Try Letter of Support

Hope Now for ALS

KK125 Ovarian Cancer Research Foundation

Little Hercules Foundation

METAvivor Research and Support, Inc.

Have a Heart Foundation

One Woman Many Lakes

Patients for Stem Cells

Rare Disease United Foundation

Teen Cancer America

Tomorrow's Cures Today Foundation