WHAT IS RIGHT TO TRY?

Right to Try is a law that protects the right of terminally ill patients to pursue treatments that have passed Phase 1 of the FDA approval process but are not yet on pharmacy shelves. In essence, Right To Try allows doctors to prescribe to terminally ill patients medicines being safely used in clinical trials. 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 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 are required to report adverse events to the FDA (and data safety monitoring boards, site investigators, and others) whether they happen in a clinical trial or outside a clinical trial. Right to Try doesn’t change that; adverse events will still be reported to the FDA. All the law says is that this data alone cannot be used to stop a trial, or to delay or deny approval of the treatment. 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. The bottom line is that
Right to Try does not keep data from the FDA—it just says that the FDA must decide whether to approve or reject a treatment based on the clinical trial results and nothing else, just as the Agency would if no patient had accessed a treatment through a Right to Try law. In fact, the FDA will have more data about the drug with Right to Try than without it.

**Right to Try is a Last Resort:** Right to Try is only for patients whose doctors have determined are terminal, 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 or device 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 a year later are still with us and enjoying a robust quality of life.

*For more information about Right to Try in the states or the federal bills S. 204 or H.R. 878, please contact Starlee Coleman at (602) 758-9162 or scoleman@goldwaterinstitute.org.*