RIGHT TO TRY & THE FDA: PARTNERS IN HELPING PATIENTS

Right To Try laws allow terminally ill patients who have exhausted all approved treatments and who cannot participate in a clinical trial to work with their doctors to access promising treatments being used in clinical trials. These laws allow doctors, patients, and the drug or device manufacturer to work together directly to help the very sickest patients who don't have the time navigate the FDA's complex expanded access process.

This has raised concerns that the Right To Try laws cut the FDA out of the drug approval process and could put patients at risk. Nothing could be further from the truth.

The 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—what the FDA calls a "safety trial"—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, a patient cannot access it under Right To Try.

In some ways, Right To Try is even more protective of patient safety than the FDA's current regulations. The FDA currently allows some people to be treated with drugs that have not yet been tested in humans, as happened during the Ebola scare in 2014 The FDA also allows some patients to continue treatments with drugs that have been removed from clinical trials and are no longer working towards FDA approval. While we are supportive of the FDA's decision to allow these patients to be treated, drugs that fall into these categories would not be available under Right To Try.

The risk to a patient being treated under Right To Try is no greater than the risk to a patient in a clinical trial because they are the exact same treatments. Right To Try simply makes *all* terminal patients eligible to try a treatment currently in clinical trials. Ultimately, this means the drug or device manufacturer will have more data to report to the FDA and scientific community about the outcomes of people being treated.

Another backstop for safety is that Right To Try is completely voluntary. If a drug or device manufacturer doesn't believe a patient will be helped by their treatment or that it could be dangerous, the company does not have to participate. No one is forced to participate at all. It is simply a new option.

Right To Try doesn't circumvent the FDA's final approval process; on the contrary, it works in tandem with the FDA's safety testing and approval process and expands the small group of patients fortunate enough to qualify for clinical trials to all terminally ill patients with the same diseases.

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