The Right to Try: Frequently Asked Questions

When a patient is suffering from a condition for which there is no known cure or approved treatment, the FDA’s traditional role of protecting patients from drugs and devices until efficacy is established has little meaning. These medications have received the FDA’s safety approval to be administered to hundreds, if not thousands of patients in clinical trials—so our government should not stand in the way of those terminally ill patients who have exhausted all other available options and want the right to try for the possibility that an effective treatment may exist beyond the red tape.

For Tennesseans and their families who are suffering from terminal illnesses, the FDA remains the arbiter of life and death.

★ These patients, with diseases ranging from ALS to Stage IV cancer, face little hope of recovery.

★ To access investigational and potentially life-saving or life-prolonging treatments, these patients must petition the government through a lengthy FDA exemption process or wait for the treatments to receive FDA approval—a process which can take a decade or more and cost hundreds of millions of dollars.

★ Tennesseans facing these devastating circumstances should have the option of accessing experimental drugs that have passed the FDA’s Phase I safety testing, provided there is a doctor’s recommendation, informed consent, and the willingness of the pharmaceutical manufacturer to make the drugs available.

There are many misconceptions about the role the FDA can and should play in the decisions facing terminally ill patients. Here are some frequently asked questions:

★ Does the “Right to Try” legislation claim that states can supersede federal law?
   Answer: No. In fact, Right to Try legislation has already passed in Colorado, Louisiana, Missouri, Michigan, and via a ballot initiative in Arizona. Because the legislation does not assert that pharmaceutical companies can sell experimental drugs in the open market, Right to Try poses no threat to the federal process.

★ Do insurance companies have to cover the cost of the experimental medication, or any treatment that may stem from taking the medication?
   Answer: No. Health insurance companies may cover a terminally ill patient that pursues experimental treatment under Right to Try, but are not obligated to provide coverage.

★ Are pharmaceutical companies required to provide their experimental drug to a patient requesting access under Right to Try?
   Answer: No. Pharmaceutical companies are not mandated to provide access to their investigational medicines. They may choose to make the drug available on their own volition.

★ Can a patient apply for access to experimental drugs without their doctor’s approval or involvement?
   Answer: No. A patient must obtain “informed consent” from their doctor before accessing an investigational treatment.

★ Can a doctor, drug company, or insurance company be sued by a patient or family member if desired results are not achieved?
   Answer: No. Physicians, pharmaceutical manufacturers, and insurance companies are protected from liability under Right to Try.