



## RIGHT TO TRY FACT VS. FICTION

*While there should be a robust debate on any policy change that impacts terminal patients, some of the criticisms against Right to Try are simply not factual. This resource intends to provide clarity to decision-makers as they consider this important issue.*

Fictitious Claim	Fact
<p><b>Right to Try would cut the FDA out of the process</b></p>	<p>Right to Try not only recognizes the FDA's important and valued role in providing for patient safety, but it also <b>works in tandem with the FDA human safety requirements, payment rules, and reporting requirements.</b></p> <p>Right to Try requires treatments to have passed FDA Phase 1 trials, and that the treatment remains under FDA investigation. Following FDA rules, manufacturers may only charge for the <i>direct</i> costs of making the treatment available, and any adverse outcomes must be reported to the FDA. In fact, nothing in the Right to Try law affects FDA's role in drug development or the current approval process.</p>
<p><b>No patients have been helped by Right to Try</b></p>	<p>Right to Try is providing <b>hope, patient treatment, and extending the length and quality of patients' lives.</b></p> <p>Terminal patients like Mark Angelo of Florida credit Right to Try for not only allowing him to continue an investigational treatment that would otherwise be available but also for saving his life.</p> <p>A Houston physician has now treated nearly 100 terminal cancer patients under the Texas Right to Try law. Some had only three months to live when they began treatment. Today, years later, most are doing very well.</p> <p>The harsh reality is that terminal patients with means are already seeking these and similar treatments overseas. Right to Try reduces that obstacle for those Americans who can't afford to do so.</p>

<p><b>Right to Try threatens the clinical trial process</b></p>	<p>Only terminal patients who are <b>unable to participate in a clinical trial</b> are eligible for Right to Try under the proposed legislation.</p> <p>Patients who are accepted into clinical trials must generally be just sick enough, but not too sick. As a result, many terminal patients are excluded from clinical trials because they are too sick.</p>
<p><b>The FDA's expanded access program is sufficient</b></p>	<p>While the FDA does approve almost all of the compassionate use applications it receives, it is beyond comprehension that <b>fewer than one out of every one-thousand terminal patients</b> would wish to do so. Something is clearly amiss in a system that is so bureaucratic and time-consuming that fewer than one-tenth of one percent of terminal patients can take advantage of the FDA's compassionate use exception.</p> <p>The FDA granted fewer than 1,300 compassionate use requests in 2015. That same year, more than 1.3 million died from the three leading disease killers of heart disease, cancer, and chronic obstructive pulmonary disease (COPD), alone. That does not include other devastating diseases, such as Alzheimer's, ALS, and Parkinson's. And for every single terminal patient that accesses compassionate use in the U.S., there are dozens who obtain access in countries like France and Australia under their countries' compassionate access programs.</p> <p>Federal Right to Try legislation would make compassionate use the rule, not the exception.</p>