Good morning Chairwoman Ayer and members of the committee. Thank you for allowing me to be call in this morning to talk about the Vermont Right To Try Act. I am Starlee Coleman, the vice president for communications at the Goldwater Institute. We are the organization that crafted the language on which your bill is based.

Right now, if you are diagnosed with a terminal illness and you have exhausted all approved options, there are three paths to accessing promising investigational treatments.

The first path is for the lucky: those are clinical trials. Fewer than 1 percent of terminal patients nationwide are able to enroll in clinical trials.

The second path is for the rich: those are people who can afford to travel overseas to access drugs that aren't available in the U.S.

The third path is for the connected: those are the people who are able to get through the FDA's complicated expanded access program. Only about 1,000 people a year can make it through this process.

For everyone else, there's no path and that is why we created the Right to Try.

Every year a million Americans with terminal diagnoses will hear from their doctor that there are no options left, and it's time to get their affairs in order. What their doctors really mean is that in their toolbox of approved medicines, there's nothing left. But the truth is there are more than 500 treatments just for cancer in the FDA's pipeline right now; many already available and saving lives in Europe. The Right to Try gives patients access to many of those medicines.

Right to Try allows patients with a terminal illness, who have tried all existing treatments with no success and who cannot enroll in clinical trials, with their doctor's recommendation and help, to access new treatments that are being safely used in government-approved clinical trials but have not yet been fully approved.

33 states have adopted Right To Try and it has been introduced in the other 17. This has caught the attention of Washington, where bipartisan bills to protect the state-passed laws from

federal interference have been introduced in the House and Senate.

Let's be clear about what kind of treatments we're talking about. We're not talking about pimple cream for healthy teens. This is about people with Lou Gehrig's disease, brain cancer, and spinal muscular atrophy which kills babies by the time they are two years old. If you were on a sinking ship, would you pass on the only available lifeboat because the government hadn't finished certified it yet? No, you'd say, put the lifeboat in the water. Right To Try gets the lifeboats in the water.

You may wonder if trying an investigational treatment is risky. The risks for someone who takes a drug under Right To Try are exactly the same as they are for patients who get into government-sanctioned clinical trials. These are the same medicines the FDA is allowing a lucky few to take in clinical trials.

Another question you may have is why more people don't just sign up for a clinical trial. The answer is that it's really hard to be selected for a clinical trial. You have to be sick enough, but

not too sick. They cannot have other conditions that could skew the trial results.

Earlier I mentioned a disease called spinal muscular atrophy. SMA is the number one genetic killer of children and it is fatal 100 percent of the time. There is one drug under development for SMA and only 8 children were chosen to enroll. Eight. Even though this is the number one genetic disease that kills children. It will take approximately 5-7 more years for this drug to make it all the way through its approval process. That means that every baby with SMA that is alive today and born with the disease for the next three years will die before they have a chance to take a drug that is showing tremendous promise in FDA-approved clinical trials. For the two years that this drug has been in trial, the children who are treated are seemingly unaffected by the disease. They are normal babies.

Fewer than 3 percent of cancer patients are selected for clinical trials. That means 97 percent of cancer patients must rely on drugs that are already on the market, even if drug in a clinical trial could save their life.

40,000 women with breast cancer will hear from their doctor this year that there are no treatment options left for them. But there are 22 pioneering breast cancer treatments waiting for the FDA's green light and being safely used in clinical trials; some of them are already available and saving lives in Europe. If you're facing a death sentence, trying a drug that could save you is not a risk. It would be a risk not to try.

Five years ago, a little boy in Phoenix, named Diego Morris was diagnosed with osteosarcoma, a rare and deadly bone cancer. Diego was treated by experts at St. Jude's and they quickly exhausted all available treatment options. His doctors recommended his family find a way to relocate to another country to access a successful treatment that was not yet available in the US. Diego's parents are both lawyers and they could afford to move their family to England for a year where Diego was able to be treated with a drug that has been given Europe's most prestigious prize for breakthrough medicines. Diego is a healthy teenage boy today.

If you're rich, you can afford to access promising treatments in other countries. But what about all the other people in this country who can't afford to move to England and pay out of

pocket for an expensive treatment? Right to Try gives these people a path to try these drugs at home.

Now let's talk about the lucky few who are able to get help through the FDA's expanded access process. As I mentioned earlier, about 1000 people a year make it through this application process. By comparison, 25,000 people a year get help through a similar program in France. If a country 1/5 our size can help 2000 percent more people, we clearly have a problem.

We talked to a doctor named Razelle Kurzrock, who used to run clinical trials for MD Anderson Cancer Center in Houston. Her trial center was the largest in the world and she said that she was able to get one person a year through the FDA expanded access process. She calls the FDA's inflated numbers of approving 99% of the expanded access requests that come in a "self-fulfilling prophecy" because doctors only submit applications after they get a verbal commitment from the FDA that it's worth spending the time to apply. She called the idea that only one of her patients a year needing access to a drug they couldn't qualify for "laughable."

So, if only one patient a year at the largest cancer trial center in the world can get access to a drug through the FDA, imagine what it is like for a person in Vermont who is seeing an oncologist who has never run a trial before and doesn't even know who to call at the FDA. The chances are not good that they will be helped.

As we've worked on this issue across the country, I've met hundreds of patients and their families and they all say the same thing. No one expects that being able to take a drug because of a state Right To Try will save their life. But they want to try. They just want the choice to take the same medications that are being used in clinical trials. They want to be able to say they tried everything they could. We owe dying people and their families that opportunity.

The good news is that we know Right To Try is working and saving lives today. A doctor in Texas has successfully treated nearly 100 patients with a treatment in clinical trials in the U.S. that has been available in Europe for decades. These patients came to the doctor with deadly neuroendocrine cancer—that's what killed Apple founder Steve Jobs. More than a year later, many of them are still with us.

We believe that the right to save your own life is a fundamental human right. And when you're fighting for your life, you shouldn't have to fight the government too. That is why we hope that you will support S. 37.