February 14, 2017

Senator Ayer and Members of the Health Committee:

Thank you for allowing me to testify by phone last week on S. 37, Senator McCormack's Right to Try Act. I wanted to follow up today with a bit more information about some of the concerns that were raised during testimony is last week's hearing.

Safety

1. During last week's hearing, the bioethicist who testified erroneously stated that drugs tested in a Phase I clinical trial are "tested on healthy patients." A baby with spinal muscular atrophy who is receiving a safety dose in a Phase I trial is not healthy. SMA babies lose their ability to move any muscle in their bodies generally by the time they are 6 months old. They are basically only able to move their eyes. That is not a healthy baby. A person with ALS who is in a Phase 1 trial is not healthy. A woman with metastatic breast cancer is not healthy. Drugs in Phase I trials are given to very sick people with the express purpose of determining the proper dosage that will be used in later-stage trials and ensuring that the drug is not toxic to humans. Once a Phase I trial closes, the drugs are deemed safe enough by the FDA to be used in broader populations.
2. This same witness also raised concerns that patients would be using "unproven drugs" and could be subjected to "potential harm." It is important to remember that the only drugs that would be available under a Right to Try law are those that are being used in FDA-approved Phase II or III trials. That means that the FDA has already determined these drugs are safe enough to be used in broader patient populations. The risk for a Right to Try patient is the exact same as it is for one of the lucky few who is able to enroll in a clinical trial because they are the exact same drugs. If you determine that this is too risky, then what you are saying is that clinical trials are too risky.
3. We also heard a concern that an unscrupulous doctor could sell "snake oil" to a desperate patient. The fact is that this scenario would literally be impossible. Remember, a drug or device must have successfully concluded a Phase I FDA trial ***and*** be in an on-going Phase II or III trial that is being overseen by the FDA. It costs between $500 million and a billion dollars for a drug to complete a Phase I trial. A snake oil salesman is not going to have a billion dollars at his disposal and certainly is not going to be in an active FDA-approved and overseen Phase II or III trial. While we certainly understand not wanting very sick people and their families to be taken advantage of, this just simply cannot happen with the safety checks built into the law.

Impact on Clinical Trials

1. We also heard a concern that this law could hurt the clinical trial process. This law is specifically for patients who cannot enroll in a clinical trial. It will not be possible that this law pulls otherwise qualified patients away from trials, because they cannot qualify for a drug

under the law if they are also able to participate in a trial.

2. Furthermore, this law relies on the FDA's phased trial process to determine which drugs and devices are available. The law relies on the FDA to make a determination that a drug is safe enough to be used in a larger patient population and relies on the FDA's continuous oversight of those drugs throughout the trial process to determine that they continue to be safe and show enough promise to be under active study and consideration by the FDA. If for any reason the FDA shuts down a Phase II or II trial, or a drug or device company voluntarily shuts the trial down, the drug or device is no long available to Right to Try patients. This law ensures that if the FDA makes a decision at any point in the process that the treatment should not be under investigation, it is no longer available to patients under Right to Try.

Hospice Eligibility

1. Concerns were raised in testimony and also in the letter from Ms. Bateman-House that people could lose access to hospice care if they seek treatment under Right to Try. In fact, her letter refers to it as "morally reprehensible." Organizations that provide hospice care set their own criteria for who they will admit. This bill does nothing to change that. If a hospice organization wanted to admit a terminal patient who is also seeking treatment under Right to Try, they are perfectly within their right to do so.
2. But more to the point, hospice care is for people who have decided they are done seeking treatment. Right to Try is not for those people. Right to Try is for people who still have fight left and want to continue to seek treatment. If you drew a Venn diagram between those two patient populations, there would be no overlap. They are for different people.

What is "morally reprehensible" is for people who use expert credentials to raise demonstrably false claims in an official setting like a legislative hearing to scare people.

Government's Role

Lastly, I feel compelled to address a point the hospice care advocate raised. She said that she is concerned that with this law, the government will be encouraging people to seek continued treatment "when we should be encouraging them" to stop treatment. Put simply, it is not the government's role to encourage people to stop fighting for their life. There is no place for the government in the decision-making process that a terminal patient and his or her family must make in consultation with their doctor. If you don't want the government involved in other individual healthcare decisions a patient must make, then that same logic must extend to all healthcare questions.

Thank you again for considering this important bill. If you have any further questions, I would be happy to answer them in writing or by phone. I can be reached at scoleman@goldwaterinstitute.org or (602) 758-9162.

Kind regards,
Starlee Coleman