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Right to Try Testimony HB 290

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Good morning Madam Chair, members of the Committee. My name is Kurt Altman. I'm the Director of National Affairs and Special Council to the Goldwater Institute. We are based in Phoenix, Arizona. First I'd like to express my appreciation for the invitation to speak to this Committee today on this very important issue. I'd like to share a brief background of myself and my involvement in the Right to Try legislation that is currently sweeping the nation. I am one of the original drafters of the model legislation that is the basis for most, if not all the state legislation running around the country. I have been to and testified before committees in approximately 22-27 states. I have had the opportunity to meet with stakeholders throughout the our country, including patients and patient groups, physicians, researchers, medical associations and various representatives of the pharmaceutical industry. I have participated in scientific and legal panels and debates, which included representatives of the legal and medical community, some even with FDA representatives and physicians. I give you these details only to let you know that I am able to answer any questions you may have regarding Right to Try laws, why they are needed, how they work, why most criticisms are unfounded, how the laws were designed to take into account and rely on the current FDA approval process, to compliment current clinical trials and not jeopardize them, and why they will eventually help give terminally ill patients the control they so desire and one last opportunity to fight for more time with their loved ones, another year, another day, another hour, should they so choose.

What is Right to Try and what does HB 290 do? Right to try laws give terminally ill patients an opportunity, with the recommendation of their treating physician, the opportunity to access Investigational New Drugs (INDs), that have passed Phase I of the FDA approval process, if their doctor believes at this stage of the disease, the IND is the patients last and best chance. Importantly, to be eligible under RTT, a drug must not only have passed Phase I, the safety testing phase, but must REMAIN in ongoing clinical trials, Phase II or III, moving toward ultimate approval. This ensures that the drug is considered legitimated by its sponsor company, showing promise, oft times getting very positive results. It also means that a manufacturer is

willing to continue to invest significant amounts of money in the clinical testing process, typically resulting in a final price tag near 1 billion dollars.

These laws are designed for patients who are ineligible or unable to access current clinical trials for the needed IND. Clinical trials accept only about 3% of given patients afflicted with the condition the therapy is being tested for. That leaves 97% of folks in this situation unable to access therapies that could potentially benefit them. I like to say that a patient has to be sick enough to qualify for the trial but not too sick. They cannot have other conditions that could skew the trial results. As a result, many patients are left without an option to access these medications other that the current, arduous and largely unworkable FDA Compassionate Use/Expanded Access program. I say largely unworkable when I reference expanded access, not because the FDA refuses to grant approvals though the program. In fact, nearly 99% of requests are approved. I say largely unworkable because it is a time consuming process for patients, doctors and manufacturers to navigate. Time consuming at a period in a person's life where time is truly of the essence. Each year only approximately 1000 people are able to navigate the FDA's program. Compare that to last years cancer death in the U.S., which topped 450,000, and that is cancer alone. That does not account for other terminal illnesses. That 1000 number is too small and that is why Right to Try laws have taken off in the States, and hopefully will be successfully voted on here in the State of Ohio. Finally, Right to Try is no mandate. It does not require doctors, manufacturers or even insurance companies to participate, however it does create the avenue and the opportunity for each; an opportunity that does not currently exist for most.

I often like to end by talking about what Right to Try is not. It is certainly no guarantee. It is not something a patient can do on their own without the recommendation from their doctor. It is not something that can financially benefit a manufacturer or take advantage of a desperate patient. And it is not something that can damage the current FDA approval process. But I have had the district honor of speaking with patients and doctors all across our nation and consistently heard a single theme that Right to Try laws preserve. That theme is control. Patients, at this stage of their lives want to feel some semblance of control over their destiny. They hold no grand illusions that the passage of this law will be the cure all end all. But they do know that Right to Try laws give them a little more control over how they choose to fight to see a graduation, maybe a walk down the aisle, or even just one more sunrise. Not too long ago that theme was echoed by my side before the Assembly Health Committee in the State of California, by a man named Dr. David Huntley and his wife. Dr. Huntley was a College professor at the University of San Diego. Just two years ago he participated in and finished an iron man triathlon. Shortly thereafter ALS struck him. His wife Linda and he became huge advocates of giving patients opportunities to access medications that could be beneficial when there was

nothing else left. ALS has nothing. They agreed to testify by my side in California because they believed Right to Try represented that control, that freedom, that choice that patients in his situation so desperately needed. Sadly, in July, Dr. Huntley succumbed to his ALS as he knew he would, without an opportunity to try to help himself with investigational therapies. His hope was that others like him would not have to die without that chance.

I could go on and on with the importance of Right to Try laws but I'm mindful of this Committee's time. I would now like to offer myself for any questions you may have. Please address anything that may not be clear about Right to try: Why is it needed? Is the FDA changing its program? Legalities? Practical application? Access? I would be happy to answer these and any other questions today or at any time in the future.

Thank you again for your time and consideration of this very important bill.