PATRICK SNYDER

STATE REPRESENTATIVE • 85th ASSEMBLY DISTRICT

Thank you Chairman Sanfelippo, Vice-Chair Bernier, and members of the committee for holding this public hearing today on Assembly Bill 69. I am honored to testify before you about this legislation, which is often known as Right to Try.

For the past four years, I have been a volunteer with Wausau Aspirus Comfort Care & Hospice. Throughout this experience, I have spent time in patients' homes and at the hospice house, having the opportunity to form unforgettable relationships with terminally ill patients and their loved ones. Far too many times, I have witnessed patients with a terminal illness exhaust all conventional treatment options and be told by their doctor that there are no other alternatives.

When a patient with a terminal illness reaches this devastating point, they have two options. They can attempt to enroll in a clinical trial, but typically the sickest individuals are ineligible. If enrollment in a clinical trial is not possible, a patient may ask the FDA for special permission through their expanded access (compassionate use) application. The expanded access process is complicated, expensive, and time-consuming. In 2015, the FDA reported granting a total of 1,256 expanded access applications. This number is miniscule compared to the millions of Americans that are dying from a terminal illness every year.

Right to Try is designed for those patients who run out of options.

In just a matter of 32 months, 33 states have passed similar legislation into law with overwhelming bipartisan support, including our neighboring states of Illinois, Indiana, Michigan, Minnesota and Ohio. A Texas doctor is on record testifying he alone has used Right to Try to prolong the lives of 78 patients with a terminal illness. We have crafted our legislation in the same vein as this movement that has taken off across the country. This bill gives certain people with a terminal illness access to investigational drug and treatment options that are not yet available on pharmacy shelves, but have passed Phase 1 basic safety testing by the FDA. Often times, these people do not have the luxury of waiting for these drugs to make it to the market. The average length of time for a drug to get approval for use by the general public is more than a decade long and costs over $2 billion dollars. Right to Try is an optional process for a patient and his/her doctor to close the gap between when this treatment is needed and when it's received. Far too often in our current system, by the time the drug is available, it's too late.

By putting these medical decisions back in the hands of the patient and their physician, we are ensuring that the patient has the right to explore every treatment option that is safe, legal, and available. Fortunately, I do not have a personal story to share with you today on how this legislation would have benefited a loved one of mine in the past, but I do know if the unspeakable were to happen I would want them to have the option to try a potentially life-saving drug or treatment if they chose to do so. They shouldn't have to wait for the government to grant them special permission. Even if these additional treatments don't save a person's life, at least their family will have peace of mind that every available option was pursued.

I ask for your support in my effort to bring Right to Try here to Wisconsin. It is common sense legislation that has been enacted by over half of the United States. These patients are already fighting for their lives, why make them fight the government for access to these potential lifesaving treatment options too?

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TERRY MOULTON
WISCONSIN STATE SENATOR
23RD SENATE DISTRICT

From: **Senator Terry Moulton**

To: **Assembly Committee on Health**

Re: **Testimony on Assembly Bill 69**
Relating to: access to investigational drugs, devices, and biological products and limitations on liability related to their use.

Date: **February 22, 2017**

Mr. Chairman and committee members, thank you for the opportunity to speak to you today about Assembly Bill 69, the Right to Try bill.

Every year in Wisconsin more than 11,000 Wisconsinites will be told that their cancer is terminal. 2,000 Wisconsin families will find out their loved has Alzheimer's, and 400 Wisconsinites will continue to battle with Lou Gehrig's Disease. Every year more and more people who have been diagnosed with a life-threatening condition undergo life-saving treatment. However, for those whose diagnosis is terminal, few options exist.

Only a handful of terminally ill patients qualify for clinical trials, and for those who do qualify, their access to potentially life-saving treatment ends when the clinical trial is over even if the treatment was successful and will be approved by the FDA. For those who aren't eligible, their only option is to apply for the FDA's compassionate use program, a process that is complicated, time-consuming, and can take months for an application to be approved.

Over the past few years 33 states, including our neighbors Minnesota, Michigan and Illinois, have passed Right to Try laws, giving terminally ill patients legal access to investigational drugs and treatment options. In Texas, a board certified nuclear medicine physician was kept from continuing life-saving treatment to his patients when the clinical trial he was conducting was completed. Although this drug was in the final stages of approval and was keeping his patients alive, approval was denied. Dr. Delpassand recently testified before the US Senate that under Texas' recent Right to Try laws, he was able to resume treatment, and today nearly 80 of patients diagnosed with terminal pancreatic cancer are still alive.

Assembly Bill 69 is modeled after other successful state models and allows a terminally ill patient who has exhausted all other treatment options to seek investigational treatment under the recommendation of a physician. Under this bill a manufacturer may choose to make an investigational drug that has completed FDA's phase 1 safety trials available to an eligible patient, and provides limited liability under state law for a manufacturer, distributor, pharmacist, or healthcare practitioner who provides this type of treatment while exercising reasonable care.

Put simply, this bill gives those who have no other alternative and are facing death, the ability to try and save their own lives. I ask you to please consider the passage of Assembly Bill 69. Thank you again for allowing me to submit testimony today.

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Wisconsin Medical Society
Your Doctor. Your Health.

TO: Assembly Committee on Health
Representative Joe Sanfelippo, Chair

FROM: Mark Grapentine, JD – Senior Vice President of Government and Legal Affairs

DATE: February 22, 2017

RE: Opposition to Assembly Bill 69

On behalf of more than 12,000 members statewide, the Wisconsin Medical Society thanks you for this opportunity to share our testimony opposing Assembly Bill 69, deemed "Right to Try" legislation.

Emotions surrounding the issue of terminal illness are powerful. Physicians understand all too well the tremendous toll a terminal illness can take on an entire family and how the desire to find a cure can become all-consuming. It is therefore understandable that someone suffering from a terminal illness or the family of that patient might want to turn to drugs that haven't yet made it through the typical U.S. Food and Drug Administration (FDA) review and approval process.

The Society's members certainly sympathize with this desire – besides family members, a patient's physician is often the most trusted person in a room where discussions take place about therapy options. Physicians also play an important role as patient advocates, including informing the patient and family members about what therapies and/or treatments are available in any particular case.

Physicians are also scientists, keeping abreast of the latest research and developments constantly abounding in the medical world. When serving as advocates, physicians rely upon the latest facts and data to make recommendations about treatments that could be effective for a patient's conditions. These data come from sophisticated clinical trials designed to weed out drugs that are dangerous, drugs that might be safe but don't work, drugs that might work but may have significant side effects for some, drugs that are "breakthroughs," seemingly beneficial to most patients with a minimum of negative impacts, and drugs that fall somewhere else in that spectrum.

The Society believes the FDA's current scientific methods and procedures are important for determining which drugs can serve the greatest good and which drugs should not be approved – even if a patient has a terminal illness. And while Assembly Bill 69 is genuinely promoted as a bill providing hope where little exists for an individual facing the worst circumstances, the Society believes the potential unintended negative consequences for society as a whole might outweigh supporting an individual's desires. The Society therefore respectfully opposes the bill.

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The FDA's Drug Development and Review Process is Scientifically Sound
Assembly Bill 69 allows access to drugs that have passed a Phase 1 clinical trial. While this may sound rigorous to the layperson, it is far from it. According to the FDA a Phase 1 trial is generally conducted with healthy volunteers to determine toxicity – that is, whether the drug is minimally safe, not whether it is effective.[1] The FDA describes the typical Phase 1 sample size as being between 20 and 80 people.

Drugs surpassing this relatively low hurdle – a drug fails a Phase 1 trial if it is shown to have unacceptable toxicity – can then proceed to a Phase 2 trial. The FDA describes a Phase 2 trial thusly:

> Phase 2 studies begin if Phase 1 studies don't reveal unacceptable toxicity. While the emphasis in Phase 1 is on safety, the emphasis in Phase 2 is on effectiveness. This phase aims to obtain preliminary data on whether the drug works in people who have a certain disease or condition. For controlled trials, patients receiving the drug are compared with similar patients receiving a different treatment--usually an inactive substance (placebo), or a different drug. Safety continues to be evaluated, and short-term side effects are studied. Typically, the number of subjects in Phase 2 studies ranges from a few dozen to about 300.[2]

If a drug shows signs of effectiveness, Phase 3 trials can be scheduled. This type of trial involves many more people than the first two phases – from several hundred to around 3,000 people – and study different populations and different dosages while also determining effects when the drug is combined with other drugs.

The FDA Has Worked to Accelerate the Drug Approval Process Where Appropriate
Critics of the FDA process cite the sometimes-lengthy process for new drug approval. In response the FDA in 2009 revised its regulations to allow for accelerated approval for drugs that can treat serious and life-threatening illnesses that don't currently have established medicines.[3] Often called the "compassionate use" or "expanded access" procedure, the FDA approves more than 99 percent of the applications it receives for such use.[4] Even then, the FDA continues to monitor effects of the drug, with the FDA holding the right to withdraw approval if the drug eventually proves ineffective or even harmful. Notably, the push for Right to Try predates the FDA's more recent "compassionate use" procedure, which pursues many of the same objectives in a more systematic and arguably safer manner.

Allowing an Experimental Drug Process Outside the FDA Could Harm Scientific Studies
Because science is so important in the development of potentially-lifesaving drugs, it is important to promote as many thorough, rigorous studies as possible when exploring potential new medicines. By creating and promoting an alternative route to a drug, the Right to Try effort could ironically slow down the process for finding potentially life-saving drugs by siphoning potential participants away from scientific trials. The New York University School of Medicine Working Group on Compassionate Use and Pre-Approval Access takes a dim view of both Right to Try and even Compassionate Use procedures due to this risk of impeding quality drug studies:

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[1] https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm
[2] Id.
[3] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm289601.htm
[4] https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm

How else could granting a dying person access to an unapproved medical product harm an ongoing clinical trial?
Several ways. If patients learn that pre-approval access is a possibility, they may not be willing to enroll in a clinical trial, fearing they'll receive a placebo or standard-of-care treatment instead of the desired product. If people had a choice to receive the investigational medical product they wanted through a compassionate use program or by entering a clinical trial, it is not surprising that they would choose the compassionate use program—after all, they would know for sure what they were receiving. While that may be the most rational choice for an individual, it could imperil the availability of patients for clinical trials, which would have dire consequences for the drug development process and for future patients.

Many manufacturers have limited supplies of their investigational products, and granting compassionate use access can threaten those supplies. If they run out of supplies, manufacturers may have to scale back or suspend clinical trials. Especially with biologics, it is no easy task to "just make more drug." Some biologics can take more than a year to produce, and there are limited numbers of manufacturing facilities that can perform these complex tasks. Other drugs are hugely costly to make.[5]

There are Unanswered Questions Regarding the Overall Cost of Expanded Experimental Drugs
One aspect of Right to Try expanded access to experimental drugs concerns insurance coverage. Simply put, if a patient suffers harm due to a drug taken via Right to Try, what are the implications for health care coverage of the additional costs borne due to taking the drug? While the bill provides extensive protections for a "manufacturer, distributor, pharmacists, practitioner, or other person who lawfully makes available, delivers, distributes, prescribes, dispenses, or administers an investigational drug, device, or biological product",[6] left unanswered is insurance company responsibility for any additional costs.

The Wisconsin Medical Society deeply appreciates the spirit behind Assembly Bill 69. Physicians join with policymakers in the desire to alleviate suffering and passionate pursuit of breakthrough drugs. Unfortunately, the bill's provisions could theoretically delay rather than promote those discoveries due to interference with current scientific standards, and questions remain about additional costs due to the potentially negative consequences caused by an experimental drug.

Thank you again for this opportunity to provide the Society's testimony on Assembly Bill 69. Please feel free to contact the Society on this and other health-related issues.

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[5] http://www.med.nyu.edu/pophealth/divisions/medical-ethics/compassionate-use/nyu-working-group-compassionate-use-pre-approval-access
[6] 2017 Assembly Bill 69, page 3, lines 22-24

AMERICANS FOR PROSPERITY
WISCONSIN

Memorandum

TO: Members of the Assembly Committee on Health

FROM: Eric Bott, Americans for Prosperity State Director

DATE: February 22, 2017

RE: Support Assembly Bill 69, Right to Try

Chairman Sanfelippo, Vice-Chair Bernier and Members of Committee, thank you for holding this hearing and for the opportunity to provide testimony. We also want to thank Representatives Snyder and Kleefisch and Senators Moulton and Risser for authoring.

On behalf of the more than 130,000 Americans for Prosperity activists in Wisconsin, I urge you to support proposed legislation (Assembly Bill 69) that will make Wisconsin a Right to Try state.

Americans for Prosperity-Wisconsin is the state's leading advocate for patient-centered, free market healthcare reforms aimed at increasing access to affordable, quality care for all Wisconsin families. Assembly Bill 69 will help advance these goals by increasing access to treatment options for Wisconsinites who are battling terminal illnesses.

Every year, thousands of terminally ill patients are not allowed to access treatment protocols that have passed phase one clinical trials because these treatments have not yet received final approval by the Food and Drug Administration. In many cases, these treatments have already been approved and are being used effectively in other countries. In other cases, patients here in the United States have achieved favorable results while using these treatments as part of a clinical trial, but find themselves cut off from a therapy that works when their clinical trial ends.

Currently, terminally ill patients in Wisconsin only have two options if they want to gain access to an experimental treatment: they can join a clinical trial or apply for a compassionate use approval from the FDA. Neither of these options work well for many terminally ill patients. When operating clinical trials, researchers look for patients who meet very specific criteria. If a patient does not fall within these criteria – and most don't – they won't be entered into the trial. And even if they do get accepted into a trial, as previously mentioned, their access to the treatment is cut off when the trial ends.

The odds are even slimmer on compassionate use approvals. A highly bureaucratic, expensive, and drawn out process, only around 1,200 people each year are able to obtain a compassionate

use approval. Some of the nation's leading medical research departments are only able to obtain one or two such approvals each year.

This bill does not place any unfunded mandates on government healthcare programs, nor does it create burdensome new regulations or requirements for healthcare providers or insurers. This bill does not require public or private insurers to cover the cost of these experimental treatments, nor does it require healthcare providers to offer experimental treatments. Providers and drug manufacturers are also not held liable for the results of experimental treatments.

In Right to Try states, providers and patients both enter willingly into a treatment agreement with an understanding of the potential risks. And with the regulatory hurdles cleared away, many terminally ill patients are able to access even very costly experimental drugs with the help of philanthropic donations and other sources of private funding.

Terminally ill patients in Wisconsin deserve to be able to fight for their own lives, and with reforms like Assembly Bill 69, they will have more available options to help them in their battle to extend their lives and improve their quality of life. This bill represents an important step forward in expanding access to potentially life-saving medical interventions for the Wisconsin patients who need it most. Americans for Prosperity strongly supports its passage, and we look forward to working with you in the future.

RIGHT TO TRY & THE FDA: PARTNERS IN HELPING PATIENTS

Right To Try laws allow terminally ill patients who have exhausted all approved treatments and who cannot participate in a clinical trial to work with their doctors to access promising treatments being used in clinical trials. These laws allow doctors, patients, and the drug or device manufacturer to work together directly to help the very sickest patients who don't have the time navigate the FDA's complex expanded access process.

This has raised concerns that the Right To Try laws cut the FDA out of the drug approval process and could put patients at risk. Nothing could be further from the truth.

The Right To Try laws rely on the FDA's approval process to determine which treatments in clinical trials terminal patients can access. Right To Try only applies to treatments that have successfully completed the FDA's first phase of trials—what the FDA calls a "safety trial"—and *remain* in ongoing FDA-sanctioned phase II or III trials where they are ultimately working towards approval.

This alternative and limited pathway leaves the FDA trial system intact. Only treatments that the FDA itself has determined are worthy of continued investigation are eligible. If at any point or for any reason a treatment no longer remains in a clinical trial, a patient cannot access it under Right To Try.

In some ways, Right To Try is even more protective of patient safety than the FDA's current regulations. The FDA currently allows some people to be treated with drugs that have not yet been tested in humans, as happened during the Ebola scare in 2014 The FDA also allows some patients to continue treatments with drugs that have been removed from clinical trials and are no longer working towards FDA approval. While we are supportive of the FDA's decision to allow these patients to be treated, drugs that fall into these categories would not be available under Right To Try.

The risk to a patient being treated under Right To Try is no greater than the risk to a patient in a clinical trial because they are the exact same treatments. Right To Try simply makes *all* terminal patients eligible to try a treatment currently in clinical trials. Ultimately, this means the drug or device manufacturer will have more data to report to the FDA and scientific community about the outcomes of people being treated.

Another backstop for safety is that Right To Try is completely voluntary. If a drug or device manufacturer doesn't believe a patient will be helped by their treatment or that it could be dangerous, the company does not have to participate. No one is forced to participate at all. It is simply a new option.

Right To Try doesn't circumvent the FDA's final approval process; on the contrary, it works in tandem with the FDA's safety testing and approval process and expands the small group of patients fortunate enough to qualify for clinical trials to all terminally ill patients with the same diseases.

For more information, please contact Starlee Coleman at scoleman@goldwaterinstitute.org.

Facts About "Right To Try"

For terminal patients who have exhausted their conventional treatment options, obtaining access to potentially life-saving investigational medications is often extremely difficult. The patient can attempt to enroll in a clinical trial, but many of the sickest individuals do not qualify. In fact, only 3 percent of cancer patients today are enrolled in clinical trials. For everyone else, their only hope for obtaining potentially life-saving medications is to ask the FDA for special permission.

Only about 1,200 people make it through the FDA's "compassionate use" application process each year. The process is complicated, time-consuming, and expensive. The first step in the process requires a doctor to complete a complex and time consuming application. After the doctor submits the application to the FDA, the manufacturer must also submit lengthy documentation requirements. The FDA then has a month to review the submission and either grant or deny the request, but if there are any questions the one-month clock starts over. After the FDA approves a request, a separate committee not affiliated with the FDA, called an Institutional Review Board, also must approve the patient's use of the drug. There is no time limit on when an Institutional Review Board must review and approve or deny an application. Sadly, there are many documented cases of patients dying while their application is being considered.

After a year and half of deliberation, the FDA recently shortened its application form. A shorter application for the first step is helpful, but it only addresses one part of the approval process. And ultimately, it's still an application to the government to ask permission to try to save your own life. If you have a terminal illness, you don't have time for a multi-step government process. If your child is dying from a terminal illness and you know there's an investigational medication that is already helping other children survive, a shorter form isn't good enough.

We need to remove barriers that limit doctors from providing the care they are trained to give—and this is exactly what Right To Try does.

Right To Try allows terminally ill Americans to try medicines that have passed Phase 1 of the FDA approval process but are not yet on pharmacy shelves. Right To Try expands access to potentially life-saving treatments years before patients would normally be able to access them.

Goldwater Institute
(602) 462-5000
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Under Right To Try, a terminal patient would be able to access an investigational medicine if:

- ✓ The patient has a terminal disease and has exhausted all conventional treatment options;
- ✓ The patient's doctor has advised the use of an investigational medication;
- ✓ The medication has successfully completed basic safety testing and is part of the FDA's on-going approval process;
- ✓ The patient has provided "informed consent" acknowledging the potential risk of the drug; and
- ✓ The company developing the medication is willing to make it available to the patient.

Right To Try includes important protections. The basic safety testing and informed consent requirements protect the patient. And doctors and the manufacturer are protected from liability if the investigational medication doesn't work. But this is not protection from medical malpractice.

Right To Try is already law in 33 states: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Louisiana, Maine, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia, and Wyoming. It has passed with overwhelming bipartisan support in each state and has been introduced in 16 additional states. Right To Try isn't a red or blue issue; it's a human dignity issue. That's why lawmakers from both sides of the aisle are coming together to protect their citizens' right to try to save their own lives.

The FDA says providing dying people with investigational medications should be an exception. We think it should be the rule. People fighting for their lives should have access to medicines that could save them without needing a permission slip from the government.

For more information about Right To Try visit RightToTry.org. Or contact Starlee Coleman at scoleman@goldwaterinstitute.org or (602) 758-9162.

Good morning.

My name is Peter Moe I am 59 yrs old been married to the same wonderful woman for 41 yrs and am the proud father of 4 fantastic children. And soon my second grandchild will be born. I appologize for the difficulty you may have understanding my speech but I will do my best to articulate as best I can. You see On may 2 2016 I was diagnosed with ALS commonly known as lou gerhigs disiese . This condition affects my ability to speak clearly. ALS was first recognised in the 1890's and as of today the cause is still unknown and there is no cure. It is a terminal condition with the average life expectensy of two –four years after diognosis. Als kills the motor neurons which causes the deteriation of the bodys muscles. I have lost 90% of the use of my hands, I am losing the ability to speak and swallow and soon will lose the ability to

walk. After some time I will loose the ability to breath and will eventually suffocate to death.

As of right now the FDA has approved only one drug to combate ALS this was in 1995 and it has shown to increase the life expectancy of als patients an average of 2 months. I am currently taking this drug but I may stop doing so, Im not sure if 2 months in the final stages of this condition is something that I want to do.

I have come to talk about the right to try bill that is being considered. For people like me it is our only Hope. The fda currently takes about 10-14 years to give final approval to new drugs. People like me don't have the luxory of that time. To apply for the FDA compasionate use programs is pardone my expresion but it's a joke, the application requires 100 hours to complete and multible

submisions to fda and institutional review boards.

There are currently 30 states that have inacted a right to try legislation and Wisconsin needs to join this group. If you do some research you will see that there are drugs out there that have shown great promise in stopping and slowing the progress of this disiese.
Japan,Australia,and the netherlands all have begun stage 3 clinical trials on promising new drugs. I tell you this to let you know that there is hope out there for me and others with ALS, hope but with no acsess because of the current laws and regulations.

I can only speculate as to the reasons some people are opposed to this legislation, maybe they see a need to protect me from the risk's of unknow drugs, maybe there is a concern about future litigation, maybe it's for monetary

considerations. I don't know but to all those opposed to this I remind you I am terminal you cant fix that or protect me. A wise man once said that time was our greatest commoditys. I am a perfect example of this. Time cannnot be replaced, there is no do overs.I believe I can make my own informed decision and wieght the risks/benefits of any treatment that I would choose to engage in. Just give me the opportunity to make that decision. Without that choice I have no hope I will die soon. I am not ready to leave my family, friends, my life.

I believe I have a constitutional right to make choices regarding my life liberty and the pursute of my happiness. Please give that ability.

In closing

I ask one small favor to those who would vote against this legislation. Please come

to my home sit at my dinner table and explain to my wife and children face to face why you think that this legislation is not in our best interest, because I wont be able to face them and explain that there is no hope on the horizan for me.

Thank you

02/18/2017

Good morning assembly members. I am honored to be here today to share my experiences and thoughts on the assembly bill 69, the Right to Try law before this committee. My name is Juran Cook and I am a lifelong Wisconsin resident currently residing in New Berlin, Wisconsin. I have been a registered nurse for 32 years and have cared for many people throughout my career as a critical care nurse. I have cried tears of joy as a witness to some miraculous recoveries against all hope and with tears of sadness I have held the hand of many patients and families as their journey on earth ended. My greatest challenge however is a personal one. I share this journey in honor of my husband Mitch Cook.

My husband was an avid outdoorsman. Fishing, golfing ,weather and music were his passions. He was hardworking and spent his entire life in retail management. 3 years ago he came home from helping a friend painting and said "I dropped the paintbrush 3 times today " Anyone married to a nurse knows you can't tell us these things and excpect us to ignore them. Mitch went through a series of doctor visits, testing and specialists and on June 12th , 2014 we were in the neurologist's office to get all the results. - He sat us down and somberly told us – You have ALS. It is also known as Lou Gehrig's disease. There is no treatment for it. There is no cure. There is 1 medication that may prolong your life by 3 or 4 months. Your life expectency with ALS is 3 to 5 years. The words hung in the air like in one of those cartoon balloons. He repeated it - you have ALS , there is no treatment , there is no cure and your life expectency is 3 to 5 years. Do everything you want to do while you still can. We left devastated, Mitch was only 55 years old.

After the shock began to wear off we were determined that we would beat the odds. We were so full of hope. Surely there are new treatments to try. Then the ice bucket challenge

came along . Surely now this under funded disease would now make great strides. I spent the next few months researching any treatment options I could find. We traveled to Northwestern memorial in Chicago for his care . Much to my suprise there was so little available. Either the studies were underway or with the flood of money into ALS research now they were just starting to develop studies. We went to hear Dr. Clive Svendson speak. He was at UW Madison for over a decade researching stem cell and gene therapy and had recently relocated to California to pursue his research . His treatment sounds quite promising, the first in the nation to combine stem cell and gene therapy for halting the progression of ALS. That was in June of 2014. We were hopeful again that Mitch would be able to particiapte in this very promising treatment.

8 months after diagnisis Mitch had a feeding tube placed for feeding as he could barely eat and had already lost 50 lbs. By now his speech was almost gone, he no longer had the use of his right arm , his left arm was getting weaker and walking was becoming a challenge without assistance. He needed to use a non invasive ventilation breathing machine at night.

11 months after diagnosis he could no longer walk, use his arms, very little speech, and breathing was worsening daily. He was now in a power wheelchair and depended on me for all of his needs. Yet he remained hopeful , his motto became "Never give up". I would come home from work and he would say please look into this new drug there talking about for ALS or please find out about this new breathing device for ALS. But by now his breathing had worsened and sadly he no longer qualified for most of the studies that were happening. Yet he never gave up hope, he said I won't go down without a fight.

2 years after disgnosis he was no longer eating, drinking, moving any extremeties , his speech was gone and he had to wear catheters. Pain and anxiety were his constant companions, fearful that at any moment he would stop breathing or I wouldn't hear his computer cries for help. All he had left was communication through his eye gaze computer ,his sense of humor and hope.

On October 8th 2016 we attended the ALS walk in Millwaukee, surrounded by family and friends and a beautiful day. We weren't sure if Mitch would be able to attend the walk but he insisted I get our team "Snappers Strutters" back together and fundraise. He told me that he knew it was too late for him but if he could raise money to help anyone else not have to suffer like he did then he was going to do it. We were there 3 hours and did the whole 2 mile walk in his power wheelchair and laughed and cried .This was the first time I realized he had given up hope for a cure. My heart broke as he told me he was at peace with dying.

One week later on October 17th 2016, my beloved MItch died peacefully in our bed in my arms. He fought a courageous battle for 2 1/2 years and was only 58 years old. Ironically this same week Dr. Clive Svendson got the FDA approval to begin clinical trails for the stem cell / gene therapy combination that 2 years prior we had pinned our hopes and dreams on, 13 years after it's inception. This study will begin to enroll patients later this year and I find myself wondering how many more people with ALS will die waiting for this trial to begin.

The Right to Try act is a call for compassion and reason. For rapidly fatal diseases like ALS and others that lack treatment options, there are promising therapies that are simply inaccessible. They are stuck in a drug approval process that dates back to 1962. In 2012 Congress directed the FDA to utilize their accelerated approval program for fatal diseases lacking treatments but they are still resisting this directive.

The Right to Try bill provides the necessary legal protections that only applies to products in the FDA approval pipeline and in the very specific case of a terminal illness lacking life saving treatments. Without these protections companies are largely unwilling to make their treatments available. There are already life saving treatments approved in Japan, Europe and elswhere that we cannot legally obtain here. A privileged few are taking up residence in foreign countries in an effort to save their own lives. We would have done this if we had the money. Mitch wanted to try promising treatments , knowing fully that there would be risk. He could

accept failure but he could not accept not trying. He wanted the right to try to save his own life.

We live in a country with extraordinary medical capabilities, I see this every day as a nurse. But we are being denied access to the only lifelines we have- therapies showing promising benefits in clinical trials. Unquestionably we need the FDA to protect public health, but we also deserve an FDA that is reasonable and responsive, especially in the case of fast moving fatal diseases that lack approved treatments.

Desmond Tutu said " Hope is being able to see that there is light despite all of the darkness" .

Please support this bill and be the hope that lights our darkness.

Thank you for your attention and consideration.