

United States Senate

WASHINGTON, DC 20510

September 28, 2016

The Honorable Scott Walker
Governor
State of Wisconsin
115 East Capitol
Madison, WI 53702

Dear Governor Walker:

I write today regarding an issue of great importance to millions of terminal patients and families across Wisconsin and the nation: providing potentially life-saving therapies and treatments to persons with life-threatening and severely-debilitating illnesses.

In 2014, I had the honor of meeting Trickett Wendler, a mother-of-three from Waukesha, Wisconsin. At the time, Trickett was battling amyotrophic lateral sclerosis (ALS) and receiving the same treatment that her father did when he was diagnosed with ALS decades ago. When I was talking with Trickett and her husband, Tim, I mentioned the idea of the “right to try” laws that were being considered in states at the time. Tears began flowing down Trickett’s cheeks. She was moved by a powerful and emotional idea—that terminal patients deserve the chance to try to save their lives.

While Trickett lost her battle to ALS in 2015, the fight to give terminal patients hope was just beginning. As Chairman of the Homeland Security and Governmental Affairs Committee of the United States Senate, I have written several letters to the FDA this year asking questions about its drug approval process, its expanded access program, and its consideration of a new drug application to treat patients suffering from Duchenne muscular dystrophy.¹ My Committee also held a hearing on February 25, 2016, to examine strategies to connect terminal patients with potentially life-saving treatments.² My examination of the FDA’s processes of drug approvals and the expanded access program is based on the basic premise that I believe that terminal patients like Trickett deserve a right to hope—a chance to save their own lives without the need to obtain the FDA’s permission.

With that idea in mind, thirty-two states have enacted laws to provide patients the right to try to save their own lives by using investigational treatments that have passed Phase I of the FDA’s clinical trials that demonstrate safety, to date. These laws have passed with overwhelming

¹ Letter from Chairman Johnson to Acting Commissioner Dr. Stephen Ostroff, February 18, 2016; Letter from Chairman Johnson, Ranking Member Tom Carper, Senator Dan Coats, and Senator Joe Donnelly to Dr. Janet Woodcock, March 16, 2016; Letter from Chairman Johnson and Senator Coats to the Honorable Robert M. Califf, M.D, Commissioner of Food and Drugs, May 20, 2016; Letter from Chairman Johnson and Chairman Lamar Alexander to the Honorable Robert M. Califf, M.D, Commissioner of Food and Drugs, September 17, 2016.

² U.S. Senate, Committee on Homeland Security and Governmental Affairs. *Connecting Patients to New and Potentially Life Saving Treatments*, February 25, 2016.

bipartisan support, and bicameral legislation in Wisconsin has similarly received bipartisan support.

My oversight of the FDA and the strong bipartisan support of the state movement led me to introduce S. 2912, *The Trickett Wendler Right to Try Act of 2016*. The bill is designed to resolve potential questions about the legality of state right to try laws under federal law. It would clarify that the federal government cannot prohibit doctors from treating terminal patients in accordance with state law if certain requirements are met. The bill includes liability protections for doctors and manufacturers who provide treatment under federal and state right to try laws. It also prohibits the FDA from using adverse outcomes of treatments used under right to try laws when reviewing extant Investigational New Drug applications. To date, 42 of my colleagues in the Senate—both Republicans and Democrats—have joined me in co-sponsoring S. 2912.

The right to try movement has shown the beauty of our federalist system and the wisdom of our founding fathers. What started with one state has transformed into thirty-one states enacting right to try laws. In order for those patients, doctors and manufacturers in those thirty-one states to fully utilize the capabilities granted in these laws, certainty must be provided to clarify that the federal government cannot interfere with state right to try laws. That is why *The Trickett Wendler Right to Try Act of 2016* is of the upmost importance, and why witnesses spoke to that reality last Thursday, at a hearing of my Committee titled “Exploring a Right to Try for Terminally Ill Patients.”

The reality is that in America, people should have the right to try and save their lives. As Lieutenant Governor Kleefisch so eloquently stated in her February letter to me, “on the hope that just one patient, left alone after every effort by conventional medical logic, might be that miracle, shouldn’t those with little hope have a right to try?”³ I could not agree more and I look forward to continued efforts in Wisconsin to give patients the freedom and access they need to have the chance to try to save their lives.

Sincerely,



Ron Johnson
Chairman

cc: The Honorable Thomas R. Carper
Ranking Member

The Honorable Rebecca Kleefisch
Lieutenant Governor, Wisconsin

³ Letter from Lieutenant Governor Rebecca Kleefisch to U.S. Senator Ron Johnson, February 26, 2016.