

Testimony of the Honorable Ian C. Calderon

Majority Leader

California State Assembly

Before the

United States Senate

Committee on Homeland Security and Governmental Affairs

“Exploring a Right to Try for Terminally Ill Patients”

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Thank you Chairman Johnson, Ranking Member Carper, and Members of the Committee for inviting me here today. I am honored to testify before you about Right to Try for terminally ill patients.

As Majority Leader of the California State Assembly, I am fortunate to work on a variety of public policy issues every year. This year alone I've sent bills to the Governor dealing with issues ranging from ensuring that financial literacy is part of the high school curriculum, to setting minimum fines for piracy violations. While each bill I work on is a piece of policy I believe strongly in, my work on Right to Try legislation over the last two years has truly given me purpose as an elected official. The fight to allow terminally ill patients to seek investigational drugs and treatments not yet approved by the FDA is something I'm immensely proud to be a part of in California, and I thank you for giving me the opportunity to talk about it today.

In January of 2015, much of the policy conversations in California centered around "Death with Dignity." If you recall, this was mere months after Brittany Maynard, the young woman diagnosed with brain cancer, had moved from California to Oregon, in order to utilize Oregon's Death with Dignity law. While researching Oregon's law and its possible application in California, it struck me that this conversation needed to include policy prescriptions to make it easier for these terminally ill patients to fight to save or extend their lives as well. It was then that I came across the Right to Try movement, and subsequently introduced Assembly Bill 159. For me, Right to Try was a logical companion to Death with Dignity. I never saw the two issues as incompatible. I didn't want to limit the options for those diagnosed with a terminal illness, to

only death, albeit a more controlled one. I felt strongly that if we were going to pass Death with Dignity, and thus make it easier for terminally ill patients to die in California, that we should also make it easier for these terminally ill patients to fight to live, by giving them access to potentially life-saving drugs and treatments, that have been deemed safe, but not yet approved by the FDA.

As the first iteration of California's Right to Try legislation made its way through the legislative process, I had the privilege of meeting David Huntley. David was a Professor Emeritus at San Diego State University, an accomplished ironman triathlete, and an obviously loved husband and father. David was also diagnosed with ALS, more commonly known as Lou Gehrig's Disease. It's a death sentence given our current lack of understanding of the disease, but there are ways to combat the speed at which it progresses, and the pain it causes. Shortly after his diagnosis, David learned that there was a promising new drug called GM604, that was still in the clinical trial process at the FDA, and thus had not yet been approved. He sought access to this drug, but was denied. So David spent the latter part of his life fighting to give patients like himself a chance. David agreed to fly up to Sacramento in April of last year to testify with me before the California Assembly Health Committee. This was the first committee hearing on Right to Try in California. David's testimony and clear understanding of the pitfalls of the current experimental drug access paradigm was instrumental in getting us past that first legislative hurdle.

It was evident that David was in a tremendous amount of pain, yet he was determined that he be there to help Right to Try legislation pass in his home state. Just three months after testifying, on July 4th, 2015, David Huntley succumbed to ALS and passed away. He came to Sacramento to testify, for a measure he knew would be too late to help himself, but to ensure that future

terminally ill patients have the access to potentially life-saving medication he had been denied. That kind of selflessness is rare, and I'll never forget his dedication.

With David's help, Right to Try passed the Assembly Health Committee, but it still faced intense scrutiny from five more Committees in the Assembly and Senate. Though this was only last year, it was early in the Right to Try movement. The bill went through a rigorous public hearing process, where we sought to improve upon the Right to Try legislation that had been introduced in other states. Each Committee, in concert with the myriad of stakeholder groups, and in deference to concerns that felt unique to California, included amendments to the legislation. Throughout the Committee process we worked on, and eventually added, several amendments to alleviate concerns about having proper oversight patient protections. We added Institutional Review Board Oversight of a physician's recommendation, in order to ensure that patients are fully aware of the potential side-effects of any investigational drugs they may consume. We also added a requirement that a consulting physician confirm the primary physicians' diagnosis that the patient is terminally ill, and inserted reporting requirements to the California Department of Public Health, to further increase oversight. And, similar to the difference I see in Senator Johnson's Right to Try bill versus the House's version, we clarified that the legislation would not create a private cause of action against the prescribing physician or drug manufacturer – this was instrumental in removing the opposition of the California Medical Association.

While we weren't able to completely remove all opposition to the California's Right to Try bill, through the public hearing process we did work to address many of their concerns, without compromising the strong intent of my bill. When my Right to Try bill reached the Governor's

desk last year, I was satisfied that due to its strong patient protections and robust oversight requirements, it was one of the most comprehensive versions of Right to Try legislation in the country.

The governor vetoed my bill. In his veto message, he acknowledged that the FDA was in the process of streamlining its Expanded Access application, and wanted to grant the agency the time to do so, with the hope that this new application would make a state process unnecessary. As 31 other states have passed Right to Try legislation, I'm happy to have been a part of the impetus that spurred the FDA to streamline the application. However, these new regulations, announced in June of this year, only deal with streamlining the physician's portion of the application. This is an improvement, but the new process does nothing to shorten the manufacturer's portion and the data required by the application or reduce the 30 days the FDA has to decide. According to statistics furnished by the FDA, roughly 1,000 terminally ill patients make it through the costly and cumbersome application process each year. Considering the fact that 564,000 Americans are expected to die from cancer alone this year, the small number of people navigating the FDA's Expanded Use program speaks to the program's failure to actually help terminally ill patients obtain access to life saving treatment. These patients do not have the luxury of waiting for an onerous, bureaucratic process. This is one of the chief reasons Right to Try Legislation is so important. In the midst of a battle with a life-threatening illness, it is much easier for a patient to deal with their own doctor than a large and impersonal government agency.

At the beginning of this year, I re-introduced Right to Try legislation in California. Fortunately, with all of the protections added via last year's comprehensive public hearing process, Assembly

Bill 1668 had a much smoother path through the State Assembly and Senate. It now sits on the Governor's desk, and I'm hopeful will merit his signature, adding California as the 32nd state to enact Right to Try legislation.

Mr. Chairman, members of the Committee, thank you for giving me the opportunity to share my effort to bring Right to Try to California. I applaud any effort at the Federal level to do the same nationwide. I hope the federal government doesn't stop there. We need federal legislation that expedites the FDA's drug approval process. It should not take 10 to 15 years to approve new, life-saving treatments. In the meantime, I commend the federal effort to encourage states to essentially adopt methods to work around the FDA.

Right to try, at its core, is very simple and speaks to a basic human right. If your parent, your child, or even you are faced with a terminal illness, there should be a process in place for you to seek potentially life-saving treatments, and the government should not impede that. Thank you very much for your time.