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United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

January 9, 2017

The Honorable Mike Pence
Vice President-Elect
Presidential Transition Office
1800 F Street NW
Washington, DC 20006

Dear Vice President-Elect Pence:

As President-Elect Trump and you prepare to take office, we write to thank you for your commitment to pursue changes to federal policies that have the effect of denying access to potentially life-saving medical treatments to terminally ill patients.

An individual suffering from these policies is a man named Frank Mongiello. A father of six who resides in Bucks County, Pennsylvania, Frank is suffering from amyotrophic lateral sclerosis, better known as ALS. As you may recall, you spoke with Frank and his sons Eric and Zack at an event in Lancaster, Pennsylvania on August 9. When asked whether you would commit to supporting a federal right to try law, you noted how proud you were to sign right to try into law as Governor of Indiana and promised to take that message to Washington and open the doors to treatment. We write today to thank you for that commitment.

Last May, I introduced S. 2912, the Trickett Wendler Right to Try Act of 2016. I was honored to have Frank Mongiello at the press conference and his powerful testimony moved everyone in attendance that day. I am even more honored to have Frank join me in writing this letter today. Frank and I believe there are incremental steps the federal government can take to remove barriers to treatment that will help patients with no other options. One step is right to try. Right to try laws have been enacted in 33 states with the overwhelming bipartisan support of state legislators. But patients, doctors, and manufacturers in those states lack the legal certainty necessary for the laws to work effectively. To date, the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA) have ignored my attempts to establish clarity—requests made in letters, staff briefings, as well as direct questions during a hearing of my Committee.

Frank and I believe that this refusal to provide clarity is completely unacceptable. It is not Congress who suffers, but ALS patients like Frank, and his friend and former Naval aviator, Matt Bellina, who do not have time to wait 14 years for a treatment to be approved by the FDA. It is boys with Duchenne, like Jordan McLinn from Indianapolis, whom you know, who suffer.

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Jordan may not benefit from today's exon-skipping treatment, but perhaps he could from the next iteration of the treatment. Jordan should have the opportunity to try potentially life-saving treatments.

For Frank and other patients, the status quo is simply not working. As Matt Bellina has testified, the reality is that clinical trials are becoming more selective, and patients are often told they are too sick or have had the disease too long to participate. Despite modest improvements, under the FDA's existing attempt to address this issue—the expanded access program—only 1,268 applications were approved last year. As California Assembly Majority Leader Ian Calderon testified before my Committee in September: “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.”¹

This is why Frank and I were so grateful to hear of your continued commitment to fight on behalf of patients like Frank, Matt, Jordan, and countless others. We know we cannot provide patients with a magic pill, but what we can provide is hope, and that is what patients are so desperately seeking. S. 2912 had the bipartisan support of 44 Senators and I will be reintroducing the legislation shortly. This bill is, and will remain, a top priority for myself and Frank. We believe that with the President-Elect's and your leadership, we can begin to remove barriers to treatment and finally provide patients with the hope they deserve.

Thank you for your attention to this important matter.

Sincerely,



Ron Johnson
Chairman
Committee on Homeland Security
and Governmental Affairs



Frank Mongiello

cc: The Honorable Claire McCaskill
Ranking Member
Committee on Homeland Security
and Governmental Affairs

¹ U.S. Senate Committee on Homeland Security and Governmental Affairs, *Exploring a Right to Try for Terminally Ill Patients*, September 22, 2016. <http://www.hsgac.senate.gov/hearings/exploring-a-right-to-try-for-terminally-ill-patients>