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# United States Senate

COMMITTEE ON  
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS  
WASHINGTON, DC 20510-6250

CHRISTOPHER R. HIXON, STAFF DIRECTOR  
MARGARET E. DAUM, MINORITY STAFF DIRECTOR

October 2, 2017

The Honorable Greg Walden  
Chairman  
Committee on Energy & Commerce  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Michael C. Burgess, M.D.  
Chairman  
Subcommittee on Health  
U.S. House of Representatives  
2336 Rayburn House Office Building  
Washington, DC 20515

The Honorable Frank Pallone, Jr.  
Ranking Member  
Committee on Energy & Commerce  
U.S. House of Representatives  
2322A Rayburn House Office Building  
Washington, DC 20515

The Honorable Gene Green  
Ranking Member  
Subcommittee on Health  
U.S. House of Representatives  
2470 Rayburn House Office Building  
Washington, DC 20515

Dear Congressmen Walden, Pallone, Burgess, and Green:

We write to provide additional information to consider as part of the Subcommittee on Health's hearing on October 3, 2017.<sup>1</sup> We understand this hearing will include discussion of S. 204, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017,<sup>2</sup> a bill that passed the Senate unanimously on August 3rd.

As the sponsors of S. 204, named after just a few of the amazing patients who have inspired our work on this issue, you can understand we are passionate about opening potential pathways to treatment for terminal patients when no other alternatives are available. We are proud of this measure's bipartisan support in the U.S. Senate, including 46 cosponsors. Over two-thirds of states have already adopted versions of this legislation, with over 97 percent of state legislators voting in favor.

When Chairman Lamar Alexander and Ranking Member Patty Murray of the Senate Committee on Health, Education, Labor & Pensions raised concerns about certain provisions in the bill, we were happy to work with them in a collaborative fashion to successfully address those issues. As such, the bill as passed by the Senate reflects sensible changes, including:

- (1) greater transparency surrounding reporting serious adverse events;

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<sup>1</sup> U.S. House Committee on Energy & Commerce, Subcommittee on Health, "Examining Patient Access to Investigational Drugs," Hearing, October 3, 2017.

<sup>2</sup> S. 204, 115th Cong. (2017). The bill is an update of a previous bill introduced in May 2016 which garnered 43 bipartisan cosponsors. S. 2912, 114th Cong. (2016).

- (2) a uniform federal definition of eligible patients;
- (3) a cap on the price charged for treatments;
- (4) further clarification that other provisions governing regulation of drugs still apply (e.g., good manufacturing practices, labeling requirements, etc.);
- (5) provisions maintaining the FDA's use of adverse outcomes; and
- (6) clarified liability provisions to protect good actors and exclude bad actors.

These changes were made in addition to the bill's existing provisions that explicitly maintain incentives for patients to participate in clinical trials and pursue other available treatments, require certification by a doctor that the patient has exhausted available options, and limit eligible treatments to those that have completed a Phase I clinical trial.

Last Congress, the Senate Committee on Homeland Security and Governmental Affairs, which has jurisdiction over the regulatory process, held two hearings on this issue. We heard testimony from terminally ill patients across the country—such as Matt Bellina of Bucks County, Pennsylvania and Jordan McLinn of Indianapolis, Indiana—for whom the FDA's status quo is not working. We also heard from a brave doctor in Texas who successfully treated patients under his state's Right to Try law despite risk of federal sanction.<sup>3</sup>

We have always been careful not to represent Right to Try as a promise for a cure—Congress cannot legislate a miracle. This pursuit has always been about protecting hope. Patients (along with their doctors) are informed, capable of making rational decisions, and have the right to do whatever they can to try to save their own lives.

Finally, we understand that there may be some discussion regarding who ought to be eligible to participate in Right to Try—whether the definition contained in the legislation is too broad. Our test has always been a simple one: will the legislation benefit Jordan McLinn, a seven year-old old boy with Duchenne Muscular Dystrophy, a terminal disease by anyone's standards, but not one that will likely take his life within six months, one year, or even two.

Every day that Congress fails to act is a day during which potentially thousands of patients lose hope. As Frank Mongiello, who suffers from amyotrophic laterals sclerosis, pled when we first introduced the Senate bill over 16 months ago, “We don't have the luxury of time.”<sup>4</sup> On behalf of Frank, Matt, Jordan, and Trickett's family, we must do whatever we can to ensure that Right to Try is passed by the House and signed into law as soon as possible. We are urging the House to take up and pass S. 204 without amendment.

Thank you for working with us on this legislation.

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<sup>3</sup> U. S. Senate Committee on Homeland Security and Governmental Affairs, “Exploring a Right to Try for Terminally Ill Patients,” Hearing, September 22, 2016 (statement of Dr. Ebrahim Delpassand), <https://www.hsgac.senate.gov/hearings/exploring-a-right-to-try-for-terminally-ill-patients>.

<sup>4</sup> U.S. Senate Committee on Homeland Security & Governmental Affairs, “ICYMI: Johnson Introduces the Trickett Wendler Right to Try Act,” May 11, 2016, <https://www.hsgac.senate.gov/media/majority-media/icymi-johnson-introduces-the-trickett-wendler-right-to-try-act>. The full details of the Committee's efforts related to Right to Try can be found here: <https://www.hsgac.senate.gov/media/majority-media/johnson-right-to-try-bill-passes-senate>.



Ron Johnson  
Chairman

Sincerely,



Joe Donnelly  
U.S. Senator

cc: The Honorable Joe Barton  
The Honorable Fred Upton  
The Honorable John Shimkus  
The Honorable Tim Murphy  
The Honorable Marsha Blackburn  
The Honorable Steve Scalise  
The Honorable Robert Latta  
The Honorable Cathy McMorris  
Rodgers  
The Honorable Gregg Harper  
The Honorable Leonard Lance  
The Honorable Brett Guthrie  
The Honorable Pete Olson  
The Honorable David McKinley  
The Honorable Adam Kinzinger  
The Honorable Morgan Griffith  
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The Honorable Tim Walberg  
The Honorable Mimi Walters  
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The Honorable Bobby Rush  
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The Honorable Peter Welch  
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The Honorable Paul Tonko  
The Honorable Yvette Clarke  
The Honorable David Loebsack  
The Honorable Kurt Schrader  
The Honorable Joseph Kennedy  
The Honorable Tony Cárdenas  
The Honorable Raul Ruiz  
The Honorable Scott Peters  
The Honorable Debbie Dingell