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Before the United States House
Energy and Commerce Subcommittee on Health

Examining Patient Access to Investigational Drugs

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Chairman Burgess, Ranking Member Green, and other Members of the Committee thank you for the opportunity to address you today:

My name is Naomi Lopez Bauman, and I am the director of healthcare policy at the Goldwater Institute. We began our work on Right to Try about five years ago. Doctors and patients approached the Institute because dying patients were not getting access to innovative treatments while the wealthy and well-connected could seek innovative treatment overseas, leaving most others behind with few options.[1]

Diego Morris, who was diagnosed with osteosarcoma at age 10, is one of the lucky few. His family relocated to England for an entire *year* so that he could obtain a leading treatment that, seven years later, has yet to receive U.S. approval.[2] Diego is now a healthy 17-year-old who is helping to ensure that other patients are not left behind.[3]

Something is desperately wrong when terminal patients who are out of options are required to stand in line for permission to seek an investigational treatment that their

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[1] Olsen, Darcy, The Right to Try: How the Federal Government Prevents Americans from Getting the Lifesaving Treatments They Need (New York: HarperCollins, 2015), pp. 61-82 and 87-93 and Statement of Dr. Ebrahim Delpassand before the United States Senate Committee on Homeland Security and Governmental Affairs, "Exploring a Right to Try for Terminally Ill Patients," September 22, 2016 at https://www.hsgac.senate.gov/hearings/exploring-a-right-to-try-for-terminally-ill-patients.

[2] Statement of Diego Morris before the United States Senate Committee on Homeland Security and Governmental Affairs, "Connecting Patients to New and Potential Life Saving Treatments," February 26, 2016 at https://www.hsgac.senate.gov/download/testimony-morris-2016-02-25.

[3] Olsen, pp. 80-82.

doctor is recommending and that a manufacturer is willing to make available. Right to Try is about the terminal patients who don't fit into a control group, who can't afford to travel or move to another country, and who simply want permission to seek the same treatments that other patients — sometimes in the same medical facility[4] — are already receiving.

This inequity occurs despite the fact that one of the bedrock principles of medical ethics is patient autonomy: when a life hangs in the balance, decisions about health care are ultimately for the patient to make.[5] That is the basis of state Right to Try laws.[6]

Right to Try is now law in 37 states and counting.[7] Under these state laws, if you have a terminal diagnosis and you have exhausted all other options, you may seek, under your doctor's care, investigational treatments that have passed phase 1 of FDA clinical trials

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[4] Flatten, Mark, "Dead on Arrival: Federal "Compassionate Use" Leaves Little Hope for Dying Patients," Goldwater Institute Investigative Report, February 24, 2016, p. 10 at https://goldwater-media.s3.amazonaws.com/cms_page_media/2016/2/24/Dead%20on%20Arrival%20downloadable%20PDF.pdf.

[5] See, e.g., Runzheimer, Jane and Larsen, Linda Johnson, Medical Ethics for Dummies, (Hoboken, NJ: Wiley, 2010).

[6] Right to Try model legislation at http://scienceblogs.com/insolence/files/2014/10/GoldwaterInstituteRighttoTryModel.pdf.

[7] In just four years, Right to Try has passed in 37 states, often near unanimously and with bipartisan support. The current Right to Try states are: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, 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, Washington and Wyoming.

and are continuing to undergo FDA evaluation.

Simply put, this law extends to *all* terminal patients who are dying and out of options the same Right to Try to save one's own life that is already enjoyed by the wealthy and well-connected and the lucky few in clinical trials.

At the worst time of his life, Marc Hayutin was facing terminal cancer and insurmountable odds when he became a patient of Dr. Ebrahim Delpassand, a nuclear medicine physician who was testing a promising treatment. Then, the FDA terminated the study that Marc was participating in because there was no longer a need for more patient data. Marc was left without the ability to complete his treatment.[8]

It is because of the Texas Right to Try law that Marc was eventually able to complete the treatments. Today, Marc credits Dr. Delpassand and the Texas Right to Try law for saving his life.

The federal Right to Try legislation under consideration today is not a call to ignore research or undermine science, or for doctors to abandon obligations to patients, or for drug companies to disregard complex ethical questions such as how to distribute limited supplies of drugs. And obviously, Right to Try is not a guarantee that investigational medications will work, or that patients and doctors will have perfect information to inform their decisions.

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[8] Letter from Marc I. Hayutin to Susan Cork, Therapy Patient Coordinator at Excel Diagnostics dated June 2, 2017 at https://s3.amazonaws.com/goldwater-website-links/RTT+testimonial+Marc+Hayutin.

As the FDA admits, no system will ensure against all risks.[9] But that isn't the question. The question is: Who should ultimately decide what level of risk is acceptable to a dying patient—federal officials or patients themselves, in consultation with their doctors?

Respectfully submitted,

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[9] U.S. Food and Drug Administration, "Guidance for Industry and Food and Drug Administration Staff: Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and *De Novo* Classifications," August 24, 2016, p. 11 at https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm517504.pdf.