Senator Steve Huffman
5th District

Senator Kristina Roegner
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Senate Health Committee
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Senate Bill 170- Right to Try 2.0

Vice Chair Johnson, Ranking Member Liston, and fellow members of the Senate Health Committee, I am grateful to provide sponsor testimony today on Senate Bill 170.

Senate Bill 170 would allow patients to undergo investigational treatments if they are suffering from a life-threatening or severely debilitating illness and have exhausted all other options. The Right to Try for individualized treatments, also known as Right to Try 2.0, is the next step in expanding freedom and access to life-saving treatments. Patients with rare diseases will be able to receive treatments tailored to their own genetics, without having to wait months or even years for FDA approval.

In 2016, then Representatives Robert Sprague and Marlene Anielski passed House Bill 290—which was the original Right to Try bill here in the state of Ohio. HB 290 passed with unanimous support in both chambers. However, Right to Try 2.0 is needed due to the FDA's current regulatory scheme and how it's not designed to handle these kinds of individual treatments; instead, the drug approval process is designed for drugs that are manufactured for large populations. Since individualized treatments are designed for one individual rather than large populations, the treatments aren't available through the original right to try pathway since they generally do not go through the clinical trial process[1].

As foreign countries continue to adapt their laws and regulations to the rapid pace of medical innovation, the U.S. is falling further behind. Counties like Germany, Japan, Israel, and Italy are now leading many of the world's medical breakthroughs. SB 170 seeks to address these delays by providing pathways that keep innovation within our borders, while also ensuring vulnerable patients are able to seek access to cutting-edge treatments without prolonged delays that eventually lead to patients leaving the country.

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[1] https://righttotry.org/faqs/.

To qualify for Right to Try 2.0, a patient must be diagnosed with a life-threatening or severely debilitating illness, considered approved treatment options, has a recommendation from their physician, and gives written informed consent regarding the risks associated with taking the investigational treatment. Individualized Right to Try treatments must also comply with the same requirements and regulations required by federal law for the protection of human subjects in research. Also, facilities that hold a Federalwide Assurance (FWA) have been accepted and approved by the federal Department of Health and Human Services in meeting these standards. Only facilities that hold a Federalwide Assurance are eligible to provide an individualized treatment.

We would also like to mention that everything about this bill is voluntary. A physician is not required to recommend an investigational treatment; a manufacturer is not required to provide the treatment to the patient; and eligible facilities are not required to facilitate treatment. Both Right to Try and the proposed SB 170 work in tandem with long-established and effective guardrails that ensure physician guidance, patient safety, and informed consent.

According to the Goldwater Institute, the U.S. Constitution provides a floor of protection for these individual treatments, not a ceiling. States may provide additional and greater protections of individual rights, and all of them do. The Supreme Court has long recognized that states have great latitude in regulating health and safety, specifically medical standards, which are primarily and have been historically protected as a matter of local concern.

The Right to Try for Individualized Treatments is now law in fourteen states, passing with strong bipartisan support. Legislative support for this reform was either unanimous or near unanimous in each state that has passed it, demonstrating the bill's bi-partisan support. This legislation will essentially reduce government bureaucracy and will help save countless lives. The bipartisan support for the original Right to Try law and now Right to Try for Individualized Treatments exemplifies a united effort to put vulnerable patients first. It is our hope that more patients today will be able to access the right treatment at the right time.

Thank you for allowing us to testify before you today. We would be happy to answer any questions that you may have.