'Right to try' laws make safety and efficacy secondary to speedy access

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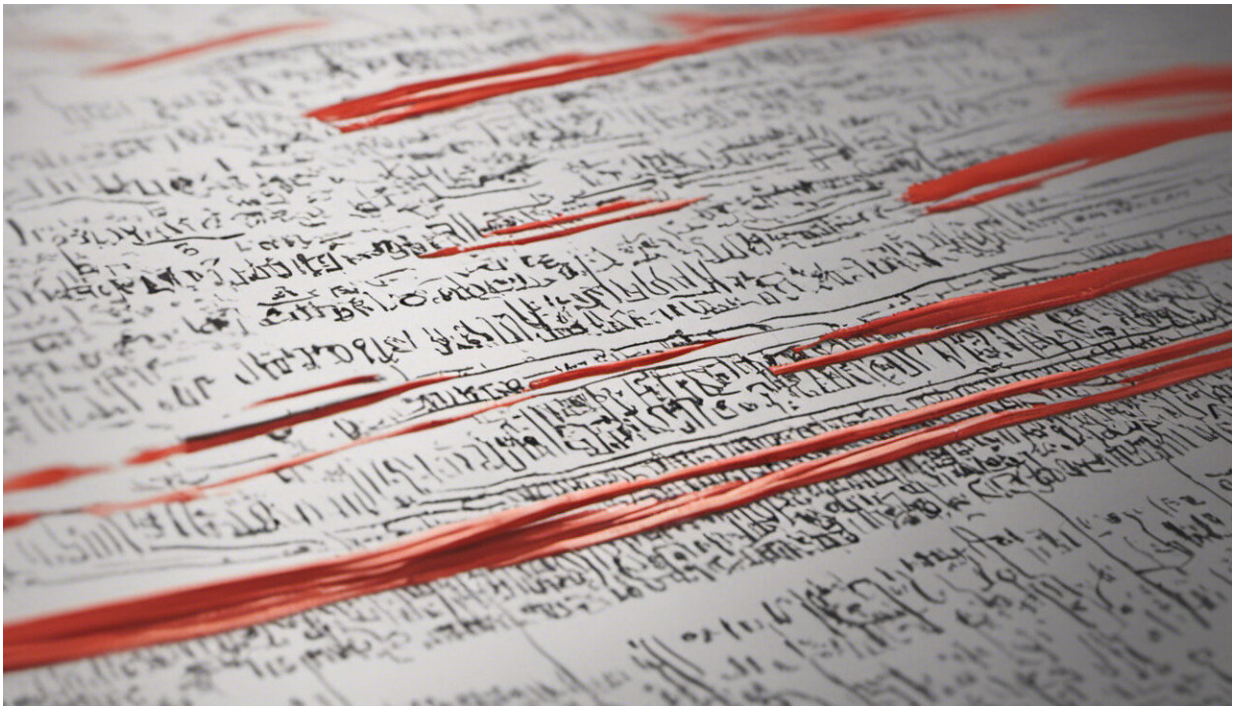

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State "right to try" laws can give terminally ill patients early access to experimental drugs and medical devices, but they arguably make safety and efficacy secondary to speedy access, according to a new report by science policy experts at Rice University's Baker Institute for Public Policy.

"The Impact of Right to Try Laws on Medical Access in the United States" was co-authored by Kirstin Matthews, fellow in science and technology policy at the Baker Institute's Center for Health and Biosciences, and Michelle Rubin, a graduate student in biomedical science at Baylor College of Medicine.

"Right to try" laws are intended to provide access to investigational drugs for terminally ill patients. "The goal of the laws is to remove the Food and Drug Administration (FDA) and ethical oversight required in the expanded access application process," the authors wrote. "However, these are important oversight mechanisms that can prevent harm and promote informed decision-making."

The report reviews the background and purpose of the FDA, the clinical trials process and the history of the FDA's expanded or early access policy, through which patients can be granted access to experimental drugs that are in phase 2 or 3 trials if there are no alternative therapies and the patients are ineligible or unable to participate in a clinical trial. It also reviews the "right to try" movement and the collection of laws it has produced. The authors discuss how "right to try" laws impact the FDA and patients' rights in the United States and recommend ways to promote faster access to safe treatments.

A major movement of patient advocates has worked since 2014 to hasten access to experimental interventions in the U.S., the authors said. As a result, a number of state legislatures, including in Texas, have passed "right to try" laws, which are designed to give terminally ill patients access to early investigational drugs before full FDA approval and before the drugs are available under the FDA's expanded access policy.

The public's perception of "right to try" laws is mixed, the authors said. The chance to access investigational drugs can naturally raise the hopes

of patients and families. "However, many policy scholars, physicians and scientists believe this can be a false hope and criticize the laws for, at times, causing more stress in a terminally ill patient's life," the authors wrote. "Critics also observe that ... state 'right to try' laws focus more on protecting the physician than ensuring drug or device access to terminally ill patients. 'Right to try' laws can perpetuate the idea that an experimental drug is worth the risk and potential danger, despite the fact that 85 percent of experimental drugs fail during clinical trials."

Instead of focusing on removing regulation, patients and advocates should work with the FDA to improve access issues to make the program more effective, the authors said. The FDA has already started the process of revising its application process to make it less cumbersome.

"'Right to try' laws are written with good intentions but do not provide patients with a new mechanism to access investigational drugs," the authors concluded. "Instead, the laws can be harmful to both patients and public good by delaying the testing process. Patient advocates should work with the FDA and pharmaceutical companies to improve the current federal system. This includes incentivizing the companies to provide the drug at little to no cost through federal subsidies or tax breaks for the company during production."

More information: "The Impact of Right to Try Laws on Medical Access in the United States" bakerinstitute.org/media/files … b-PolicyReport66.pdf

Provided by Rice University