RxLegal: A Rapid Review of Right-To-Try

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Abstract

Right-to-try legislation is intended to allow patients with life-threatening illnesses access to investigational medical treatments without formal Food and Drug Administration (FDA) involvement. Currently, right-to-try laws have been enacted in 40 states. Despite the increased passage of right-to-try legislation at the state level, individuals have detailed arguments both for and against these laws. Proponents state that right-to-try removes regulatory burdens and improves timely access to potentially lifesaving medications for terminally ill patients, reduces inequalities regarding access, and improves patient-provider communication and decision making. Opponents argue that right-to-try does not really guarantee access, reinforces preexisting health care inequalities, prioritizes rapid access over safety and the interests of the individual over the public, and produces concerns regarding informed consent. Despite these issues, right-to-try has recently gained traction on the federal level with both Congressional chambers passing separate bills.

Keywords

legal aspects, ethics, investigational drugs

Since 2014, there has been a surge in interest on both the state and federal levels in “right-to-try” legislation. This legislation is intended to allow patients with life-threatening illnesses access to investigational medical treatments without formal Food and Drug Administration (FDA) involvement.¹ Currently, right-to-try laws have been enacted in 40 states.² The main requirements of these state laws are fairly similar as they are based on a model law drafted by the Goldwater Institute (a libertarian public policy think tank).^{3,4} These requirements generally include that the patient has a terminal diagnosis with no other treatment options available; the investigational agent is recommended by the patient’s health care provider; the treatment has successfully completed phase 1 safety evaluations and is at least in early phase 2 testing; and the patient or his or her guardian has given informed consent.³

Even without passage of right-to-try legislation, patients are able to access investigational treatments through enrollment in an ongoing clinical trial or via the FDA expanded access program.^{1,5,6} However, some patients do not meet criteria for inclusion in a clinical trial or may reside too far away from a trial site to realistically participate. In addition, terminally ill patients may not want to risk enrolling in a clinical trial where there is a 50% chance of assignment to a control group instead of the desired investigational therapy.³ Accessing an investigational therapy through an expanded access program, which attempts to balance rapid investigational agent access without interfering with the conduct of ongoing clinical trials, requires approval by both the FDA

and an independent institutional review board (IRB). Historically, this program has been time-consuming and cumbersome for patients and providers; however, more recently, the FDA has made strides in reducing the complexity of forms and the time to approval, particularly with regard to emergency requests.

With the intensifying interest in right-to-try legislation, individuals have detailed arguments both for and against their enactment.^{3,7} Proponents of right-to-try state that these laws remove regulatory burdens and improve timely access to potentially lifesaving medications for terminally ill patients, reduce inequalities regarding access, and improve patient-provider communication and decision making as more potential therapeutic options are available for terminal patients. Opponents argue that right-to-try does not really guarantee access, but only confers a “right to ask” the pharmaceutical manufacturer. The manufacturer may still decide to deny access and many are inclined to do so for various reasons such as potential negative publicity if a patient develops adverse effects or dies as a result of the investigational agent. In addition, right-to-try may reinforce preexisting inequalities as many laws result in patients losing health care benefits (eg, patients who use an experimental treatment may

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lose their right to hospice care, home health care, or insurance) or being personally responsible for the financial cost of the experimental therapy, which may be quite costly. Critics of right-to-try are also concerned that these laws prioritize rapid access over safety since many agents that complete phase 1 trials eventually fail to receive FDA approval due to efficacy or safety concerns. The equitable balance of individual and public interests has also been an issue when discussing right-to-try legislation. Namely, should manufacturers and researchers redirect resources from clinical trial development programs that benefit large numbers of patients to ensure access for an individual patient and, if so, how should this be financed? Finally, there are concerns regarding informed consent and whether true informed consent can be given in this setting due to the limited information regarding benefits and risks.^{3,8}

Despite these discussions, right-to-try legislation was recently passed by Congress and signed into law by President Trump in late May 2018.⁹ The next step for the legislation will be full implementation by the FDA.¹⁰

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