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## FROM THE EDITOR

# Right to Try: Two Years In

BY JENNIE CREWS, MD, MMM, FACP



May 30, 2020, marks the two-year anniversary of the passage of the federal Right to Try law. Like the experiences in states that have passed similar legislation, there was considerable debate over the benefits versus harms that a national Right to Try law would usher in. Proponents argued that existing processes for patients seeking non-U.S. Food and Drug Administration (FDA)-approved, potentially life-saving medication were arduous, and a more direct approach was needed to improve patient outcomes. Opponents worried that this law would threaten patient safety, clinical trial enrollment, and stakeholder legal and financial liability.

Since the passage of Right to Try, reality looks quite different. The law allows patients with a life-threatening illness who have exhausted approved options or are unable to participate in a clinical trial to receive an investigational drug (that has been through Phase 1 testing) from a manufacturer by providing written informed consent to their treating physician. However, there is no obligation on the part of the physician to pursue the request, the manufacturer to provide the drug, or the insurance company to pay for treatment or treatment-related complications. The law also offers liability protections for physicians and manufacturers.

Thus, Right to Try truly is a “right to try,” leaving patients with little assurance and potentially high risk. It is difficult to know for certain how many people have tried to access investigational drugs under this law because there are no mandated reporting requirements. News outlets cite two patients who have used Right to Try—one with glioblastoma and one with Lou Gehrig’s disease. It is unknown whether either benefited from the treatments they accessed.

Instead of using Right to Try, many physicians and manufacturers prefer using the FDA’s Expanded Access Program, which was established in 1987 and offers some advantages over Right to Try. Expanded Access has similar eligibility requirements but provides patients with broader options by allowing access to drugs in earlier phases of development. The program also provides third-party oversight and guidance to physicians on drug dosing and safety monitoring. The FDA reports that 99 percent of the applications it receives are approved, usually within a few days. About 20 percent of these requests come from oncologists, and in June 2019 the FDA launched Project Facilitate to streamline the Expanded Access Program by providing a single point of contact for oncology requests.

Thus far, it appears that Right to Try has not substantially benefited patients and is not favored by providers or manufacturers. So, who is benefiting from this law? Perhaps organizations seeking to monetize this legislation. A clinical research organization has emerged with plans to broker Right to Try access between manufacturers and medical organizations by providing patients with medication and collecting real-world data on outcomes. The Access Hope clinical research organization (CRO) was founded by an attorney with experience in biotech and Right to Try legislation. Its website cites benefits of this business model to patients, providers, and sponsors for whom “Right to Try creates heretofore unthinkable flexibility, legal immunity, and time and cost reductions while creating new data”<sup>1</sup> and “truly exclusive control over your data.”<sup>1</sup> The website also states that Access Hope also will be exploring “patient pay”<sup>1</sup> for services and medications.

Red flag? Perhaps the concerns originally raised by opponents to Right to Try are founded after all. 

### Reference

1. Access Hope CRO. For Sponsors/CROs. Available online at ahcro.com. Last accessed February 18, 2020.