PRE-APPROVAL
Access Programs

September 25-27th, 2017 ● Philadelphia, PA

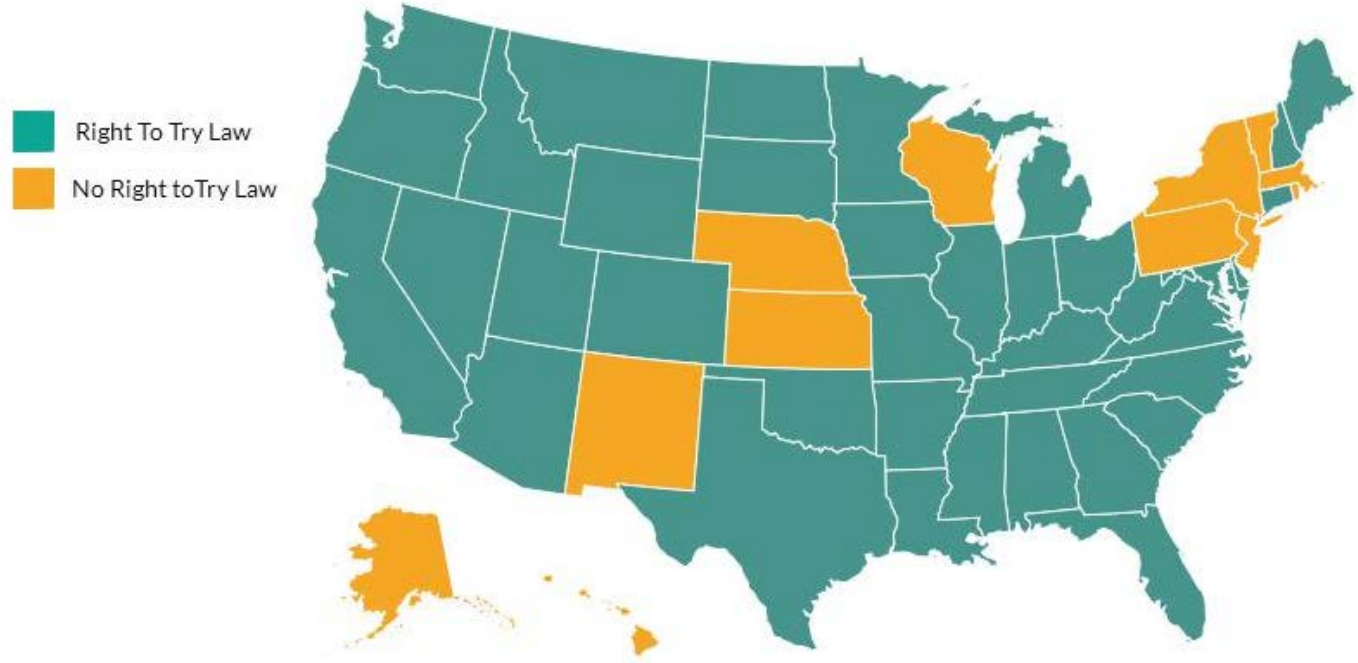
Right To Try At-A-Glance

What is Right To Try?

Since early 2014, more than 30 states have introduced so-called "Right to Try" bills in the hopes of allowing terminally ill patients to access experimental—and potentially life-saving—treatments more easily. These bills are modeled off a federal policy known as "Compassionate Use," but contain several key changes meant to reduce regulations and red tape around the FDA's expanded access program.

States with Right to Try Laws

Alabama
Arizona
Arkansas
California
Colorado
Connecticut
Florida
Georgia
Idaho
Iowa
Illinois
Indiana
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
Washington
West Virginia
Wyoming



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Trickett Wendler Right To Try (RTT) Act

First introduced in May 2016, the Trickett Wendler Right To Try (RTT) Act was re-introduced January 2017 by Sen Ron Johnson (R-Wis), chairman of the Senate Homeland Security and Governmental Affairs Committee. Intended to ensure terminally ill patients, their doctors, and pharmaceutical manufacturers are allowed to administer investigational treatments where no alternative treatment exists, it gives patients and doctors the freedom to try investigational treatments that have passed Phase 1 of the FDA's approval process, if they have exhausted all other treatment options.

Proponents argue that current government regulations wrongfully restrict access to potentially life-saving treatments and that patients have the right to determine what risks they are willing to undertake to save their own lives.

The Opposition Opinion

However, the Right to Try Movement is not without controversy. In fact, a **2016 study** conducted by NYU School of Medicine Working Group on Compassionate Use and Pre-Approval Access (CUPA) found that:

- There are no substantiated cases of patients receiving experimental products because of a right by try law as companies are still under no legal obligation to grant access to experimental drugs
- When companies are willing to grant requests, the FDA actually approves 99+% of "compassionate use" requests
- The average turn around time for the FDA's expanded access program is 1 day or less for emergency requests; 4 days for non-emergency requests and the FDA form can be completed in under one hour.
- The FDA very rarely penalizes a drug company if its product causes an adverse event during pre-approval use -only .2% over the past 4 decades

Interested in Learning More?

Hear both sides of the Right To Try debate and more at the **Pre-Approval Access Programs** this **September 25-27th** in **Philadelphia!**

HIGHLIGHTED SESSION
PANEL DISCUSSION: Explore How the New Trump Administration Affects the Future of Pre-approval
Tuesday September 26th, 2017

Download Our Agenda

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