

Right to Try Legislation

Executive Summary, July 2015

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Overview

On May 17, 2014, Colorado's governor signed the Right to Try Act (Act), which became effective immediately. The next day, news outlets published articles lauding and criticizing Colorado's new law. Some stories reported that the law allowed terminally ill patients to obtain experimental drugs without getting federal approval.¹ Others attacked the law as an unethical one that was "not compassionate but, actually, flat-out cruel."² On the morning of Monday, May 19, 2014, University of Colorado Hospital Cancer Center staff arrived to a voice mailbox full of messages from patients wanting access to drugs they believed they had the "right to try," but patients' understanding of the law was flawed. While some media accounts likely gave patients the impression that the law required physicians to prescribe experimental drugs, this incomplete portrayal discounted the reality of the law.

Since Colorado passed the Act, similar laws have been added to the books of at least 20 states (Alabama, Arizona, Arkansas, Florida, Indiana, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, North Dakota, Oklahoma, South Dakota, Tennessee, Texas, Utah, Virginia, and Wyoming) as of July 1, 2015. Similar legislation has been introduced in 18 other states (Alaska, California, Connecticut, Delaware, Georgia, Hawaii, Illinois, Kansas, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, West Virginia, and Wisconsin). This Executive Summary focuses specifically on Colorado's law, which was modeled after an initiative from the Goldwater Institute, a think tank that is spearheading the push to reform patient rights.

Before state Right to Try laws were passed, a patient who sought access to an Investigational New Drug (IND) or device had to work with her provider to comply with the U.S. Food and Drug Administration (FDA) regulations for expanded access, often

¹ The Associated Press, first published May 18, 2014, *available at* www.nbcnews.com/health/health-news/right-try-states-move-expand-access-experimental-drugs-n108316.

² Art Caplan, Bioethicist: 'Right to Try' Law More Cruel and Compassionate, *available at* www.nbcnews.com/health/health-news/bioethicist-right-try-law-more-cruel-compassionate-n108686.

referred to as “compassionate use.”³ The FDA regulation requires the patient and provider to submit paperwork to FDA that establishes:

- The patient has a serious disease or condition associated with morbidity that has a substantial impact on day-to day functioning or a disease or condition that is immediately life threatening;
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition;
- The patient cannot obtain the drug under another IND or protocol;
- The potential benefit justifies the potential risks, and those risks are not unreasonable; and
- The provision of the investigational drug in the expanded access case will not interfere with clinical investigation of the IND that could support the approval or development of the IND.

Even if FDA approved the compassionate use of an IND, the patient still would need access to the product. Because of research requirements, INDs are closely controlled by the manufacturer and not available in pharmacies like normal prescriptions. This meant that the drug manufacturer also had to agree to provide the IND to the patient.⁴

Colorado’s Law

Colorado’s legislature unanimously passed the Act in both chambers. The law declares that:

- FDA approval protects patients in the long run, but generally, the FDA approval process to obtain access to experimental or INDs takes too long for patients with terminal illness;

³ 21 C.F.R. § 312.300, *et. seq.*

⁴ See www.fda.gov/ForPatients/Other/ExpandedAccess/ucm20041768.htm#different-types.

- Patients who have a terminal illness have a fundamental right to attempt to preserve their lives; and
- Patients have the right to decide their course of care with their physician.

Despite this strongly worded legislative intent, the Act has many of the same requirements present in the FDA regulation. Colorado's law permits eligible patients to use investigational drugs, biological products, or devices that are pending FDA approval.

Eligible Patients

The law defines an eligible patient as an outpatient who has documentation from her physician (not a mid-level provider) that:

- (1) The patient has a terminal illness (like the FDA requirement);
- (2) The patient has considered all other treatment options currently approved by FDA (like the FDA requirement);
- (3) The patient has been unable to participate in a clinical trial for the terminal illness within 100 miles of the patient's home address *or* has not been accepted to the clinical trial within a week of completing the clinical trial application process (like the FDA requirement);
- (4) The patient has received a recommendation from her physician for an investigational drug, biological product, or device; and
- (5) The patient has given written informed consent for the use of the investigational drug, biological product, or device.

The law defines terminal illness as a disease that, without life-sustaining procedures, will *soon* result in death or a state of permanent unconsciousness from which recovery is unlikely.

Informed Consent

The written informed consent is beyond that typically thought of as an informed consent for a procedure. The written informed consent must:

- (1) Explain the currently approved products and treatments for the patient's disease or condition;
- (2) Attest to the fact that the patient concurs that conventionally recognized treatments are unlikely to prolong the patient's life;
- (3) Clearly identify the specific proposed investigational product that the patient is seeking to use;
- (4) Describe the potential best and worst outcomes with a realistic description of the most likely outcome, including death or worsening symptoms;
- (5) Make clear that the patient's health insurer and provider are not obligated to pay for any care or treatment resulting from the use of the investigational product;
- (6) Make clear that the patient's eligibility for hospice care may be withdrawn;
- (7) Make clear that the patient's eligibility for home health care may be denied; and
- (8) State that the patient understands that she is liable for all expenses consequent to the use of the investigational product (including the patient's estate).

Legal Protections for Providers and Manufacturers

Colorado's law provides some security to physicians who follow the Act's protocol. As long as recommendations to a patient regarding investigational treatment are consistent

with medical standards of care, professional licensing boards may not revoke, renew, suspend, or take any action with regard to a physician's license. Further, the Act does not create a private right of action: unless there was a failure to exercise reasonable care, a patient has no right to recover from the manufacturer, health care provider, or other involved entity for any harm done to the patient resulting from the investigational product, if the Act was complied with in good faith.

Role of Health Insurance and Drug Manufacturers

In addition to the physician and patient, the Act addresses health insurers and drug manufacturers. The Act explains that the patient's health insurance may, but is not required to, provide coverage for the cost of the investigational product. Additionally, the insurer may deny coverage for the patient's care from the time the patient starts using the investigational product through six months *after* the patient has stopped using the product. Likewise, the drug manufacturer may, but is not required to, provide the product to the patient, and in doing so may require the eligible patient to pay the costs associated with the product.

Conclusion

Colorado's Right to Try Act does not resolve some of the major challenges that face patients and providers—most importantly, access to the investigational products. Even if a provider and a patient determine the best course of care would be to use an investigational product, to invoke any of the state laws, the provider and the patient must be able to access the product. Because the state laws are viewed as a way to circumvent FDA, and FDA regulates access to investigational products, it remains to be seen whether manufacturers will be willing participants because of potential penalties and because of the importance of relationships between manufacturers and FDA. To date, there are no legal challenges regarding whether the FDA regulations on compassionate use preempt the state laws. But, that question may never need to be answered, because on February 4, 2015, in what some deem a response to the

grassroots Right to Try movement, FDA announced it planned to streamline the existing application process for compassionate use by creating a new three-page form for an individual seeking a compassionate use waiver. FDA explains that it plans to consider a completed form to comply with the compassionate use submission requirements. FDA hopes this form will remove any perceived administrative barriers related to complying with federal regulations.⁵

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⁵ Individual Patient Expanded Access Applications: Form FDA 3926; Draft Guidance for Industry; Availability; 21 C.F.R. 312. See <https://federalregister.gov/a/2015-02561>.

