The Wild West of Medical Cures

Texas is poised to become the latest state to allow terminal ill patients to try medications that are not FDA approved. Advocates say it’s worth the risk.

Andrea Sloan, a brilliant lawyer who left her job to help victims of domestic violence, died last year after spending more than seven years fighting ovarian cancer.

Her friends, including a powerful aide in the Texas state House, believe she might very well be alive today if she had been able to take a new, unapproved medication sooner.

But terminally ill patients in Texas might be getting a new lifeline.

The state House just tentatively (and unanimously) passed Right to Try legislation that would make it much easier for them to get potentially lifesaving drugs that are still going through the FDA’s lengthy approval process.

The House will vote for final passage on April 22, and it’s expected to pass with overwhelming support.

“It just seemed to be a complete no-brainer to me,” said Texas state Senator Paul Bettencourt, who sponsored the version of the bill that recently passed the state Senate.

He said the legislation came to his attention because of his chief of staff, VA Stephens. Sloan was one of Stephens’s good friends.

“Right to Try aims at eliminating that undue waiting time that is frankly there only as a bureaucratic nightmare,” said Michelle Wittenburg, another friend of Sloan’s and an ardent supporter of the legislation. “It’s the paper-shuffling time.”

If Governor Greg Abbott signs off on it—and advocates are optimistic that he will—then Texas will be the 15th state to pass Right to Try legislation, and the 10th state to do so in the 2015 legislative year.

“The real problem is that time is a predator in situations like this,” said Bettencourt.

It can take a new drug as long as 15 years to get through the three phases of the FDA approval process, according to Kurt Altman of the libertarian-leaning Goldwater Institute think tank, which has worked extensively on Right to Try issues.

A process called Compassionate Use lets terminally ill patients use drugs that haven’t gotten their final FDA approval, but getting that OK is still its own massive headache.

It typically takes doctors more than 100 hours to fill out all the paperwork necessary to exempt their patients. That’s a huge amount of time—particularly for terminally ill patients, like Sloan, who often can’t wait. Since a wave of states passed Right to Try legislation, the FDA has moved to make the Compassionate Use process simpler.

But Altman argues that their changes don’t do enough to expedite the process. And when it comes to the FDA, there’s a major trust deficit.

The bureaucracy says they have the capability of approving patients for Compassionate Use in emergency situations. But that didn’t work for Sloan and numerous other applicants; Altman said he’s never heard of a terminally ill patient getting approval in that time frame.

Despite exhausting all other treatment options, it took Sloan 24 days to get FDA approval for a promising but unapproved drug. (24 days was extraordinarily fast; it’s more likely to take months, if ever.)

Wittenburg said she saw her friend nearly every day during that process as Sloan’s condition quickly deteriorated.

By the time she finally got the drug, she was substantially frailer than when she had started trying to get it, and she’d lost a lot of weight. There were initial indicators that her condition was turning around, but she died of pneumonia complications soon after she started the new regimen.

Because of the cancer, her immune system wasn’t strong to fight off the illness.

“I can’t guarantee an outcome,” said Wittenburg. “I can certainly say that if she had started that drug when she was at a healthier point—a month, two months, three months earlier—would she have increased her odds of being alive right now, because we know the drug was working? You bet. Absolutely.”

Sloan, who had previously worked as a lobbyist in the Texas state legislature, left a job at a powerful law firm to work for a nonprofit providing pro bono legal services to indigent victims of domestic violence. About six months after making the move, she was diagnosed.

“Her friends are lawyers and PR professionals and lobbyists, and we would all help her for free,” said Wittenburg. “And she said, ‘What if one of my indigent women clients had ovarian cancer just like me and needed Compassionate Use? What would happen to them?’ The answer was, they would have no chance.”

That may be changing.

Right to Try legislation removes bureaucratic hurdles that keep patients from getting unapproved treatments, dramatically expediting that process. The legislation only applies to patients with terminal illnesses seeking drugs that have passed the first phase of FDA approval.

Over the last two years, a host of states have made this policy change. And while it’s stirred up a little criticism in the science blogosphere—Florida attorney Jann Bellamy [argues here](https://www.sciencebasedmedicine.org/the-illusions-of-right-to-try-laws/) that these laws could give patients false hope—on the whole it’s been noncontroversial.

One influential opponent, bioethicist Arthur Caplan, [wrote for NBC last May](http://www.nbcnews.com/health/health-news/bioethicist-right-try-law-more-cruel-compassionate-n108686) that Right to Try bills are “flat-out cruel” because they don’t do enough for patients. But supporters of the legislation—and friends and family of people like Sloan—say they’re delighted with every baby step.

Right to Try bills have produced some unlikely alliances around the country. In Illinois, conservative Republican state Senator Michael Connelly and liberal Democrat state Representative Greg Harris teamed up to push for Right to Try legislation. It’s one of the few issues that has ever brought them together. The Florida legislature is looking at a similar bill. Colorado became the first Right to Try state in May of 2014, and a host of others have joined its ranks since then. Which is understandable.

“The coolest thing you can do as a legislature is pass something that saves somebody’s life in the future,” Bettencourt said.