

# US states move to expand experimental drug use (Update)

May 17 2014, by Kristen Wyatt

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Colorado Gov. John Hickenlooper speaks at a news conference at the Capitol in Denver in this Wednesday, May 22, 2013 file photo. Hickenlooper Saturday afternoon May 17, 2014 will sign Colorado's "Right To Try" bill, which was passed unanimously in the state Legislature. The "Right To Try" law allows terminally ill patients to obtain experimental drugs without getting federal approval. The bill doesn't require drug companies to provide any drug outside federal parameters, and there's no indication pharmaceutical companies will do

so. (AP Photo/Ed Andrieski, File)

Nick Auden didn't live to see the legislation, but the case of the Colorado melanoma patient who died while seeking access to an experimental drug helped inspire a first-of-its kind law.

The "Right To Try" law allows terminally ill patients to obtain experimental drugs without getting federal approval. It's a proposal being advanced in several U.S. states by patient advocates who are frustrated by the yearslong federal approval process for experimental drugs in the pipeline.

"There are experimental drugs out there that can and do save lives, and access needs to be expanded," said Auden's widow, Amy Auden. Nick Auden died in November at age 41 after unsuccessfully lobbying two drug companies to use an experimental treatment outside of clinical trials. Auden had acknowledged there was no guarantee the drug would work.

Gov. John Hickenlooper on Saturday signed Colorado's "Right To Try" bill, which was passed unanimously in the state Legislature.

Similar bills await governors' signatures in Louisiana and Missouri, and Arizona voters will decide in November whether to set up a similar program in that state.

Supporters call it a ray of hope for dying patients trying to navigate the bureaucracy of existing "compassionate use" guidelines for obtaining drugs outside clinical trials. The process requires federal approval.

But skeptics call "Right To Try" a feel-good campaign that won't help

dying patients.

The law doesn't require drug companies to provide any drug outside federal parameters, and there's no indication pharmaceutical companies will do so.

A 2003 lawsuit to force the U.S. Food and Drug Administration to expand the availability of investigational drugs failed. A federal judge disagreed that terminally ill people have a right to access to investigational medicine, and the U.S. Supreme Court declined to consider an appeal.

State-level approaches are an effort to circumvent the federal system, but critics say they won't work.

"The FDA regulates drug development, and this doesn't do anything to change that," said Dr. David Gorski, a surgical oncologist and editor of the blog Science Based Medicine.

Gorski said a drug company "wouldn't do anything to endanger a drug they're potentially spending hundreds of millions of dollars to bring to market" through elaborate FDA trials.

Supporters insist the states should push the envelope on clinical trials to speed up the work of federal drug regulators.

"It's so basic, the right to fight for your own life," said Darcy Olsen, president of the Goldwater Institute, a conservative think tank that promotes "Right To Try" legislation in state legislatures.

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Citation: US states move to expand experimental drug use (Update) (2014, May 17) retrieved 6

May 2024 from <https://medicalxpress.com/news/2014-05-states-experimental-drugs.html>

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