



## **Right-To-Try drug proposal is a solution for a non-existent problem**

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This fall the House of Representatives is likely to take up legislation passed by the Senate that gives terminally ill patients the right to try unproven, experimental drugs that are not yet on the market. Thirty-seven states have already passed similar legislation.

All this may sound like terrific news for very sick patients with few or no treatment options left, but the issue deserves a much deeper look thanks to its potential impact on people's pocketbooks and health.

"The public has no idea this is not a good thing," says Alison Bateman-House, a medical ethicist at New York University's Langone Medical Center. "They know nothing about the bill except that the right-to-try sounds like a good thing."

For example, she said, few people in those 37 states know they may lose hospice coverage, or they may be denied coverage for home health care if they use an experimental treatment. In Colorado, Connecticut, Oklahoma and West Virginia, patients may lose their health insurance. Their coverage may be denied for six months after treatment ends.

So why is there a drive for a national law? According to Bateman-House and others who oppose the law, the underlying goal is to remove FDA involvement from a process that's currently in place regarding experimental drugs.

Under the current process for obtaining such drugs, patients must first find a doctor who will agree to try the therapy and contact the drug company for permission to use the experimental treatment. Once the doctor and patient have that permission, they fill out paperwork and send it to the FDA. If the FDA says yes, a patient can try the drug.

But there are other hurdles. An Institutional Review Board, also called an IRB, at the hospital or other institution where the treatment will take place, must also approve the treatment. Finally, the patient must give consent and have money to pay for it.

The right-to-try bill pending in Congress eliminates the FDA from the process. The Goldwater Institute, a libertarian think tank based in Phoenix, has led the drive for legislation, and other like-minded think tanks that aren't keen on government regulations have also weighed in. If someone is desperate, "I don't think a person or agency has a right to tell that terminally ill person, 'I'm sorry I don't think I'm going to let you try this,'" Phoenix physician Jeffrey Singer, also a fellow at the Cato Institute, another libertarian think tank, told MedPage Today.

But the FDA isn't the gatekeeper here, Bateman-House said. "The idea the FDA is the stumbling block is completely wrong." It's the drug companies, which decide if they'll let someone try one of their drugs that's still being developed and is not for sale to the public. "We don't know how many times requests to drug companies are approved or denied," says Bateman-House. "If the drug company says 'no,' that's the end of it."

The FDA, however, approves about 99 percent of the drugs that people who are terminally ill ask for, and the process moves quickly. The FDA turns around emergency requests within 24 hours, and in non-emergency situations within three to four days.

Why is FDA involvement important? For one thing, it doesn't have a vested interest in the outcome of someone's treatment the way a doctor or drug company has. For another, it knows about other drugs in the same class as the experimental drug and can look for problems that have arisen with those drugs. For example, how does the drug affect the heart? The FDA can also call for safety adjustments in the administration of the drug - such as what's the best dosage - should the patient be on a heart monitor.

Many patient advocacy groups don't support the legislation pending in Congress. The American Society of Clinical Oncology says it supports access to investigational drugs outside of clinical trials when adequate protections are in place. It doesn't support right-to-try legislation because it ignores "key patient protections without actually improving patient access to investigational drugs outside of clinical trials."

The Pharmaceutical Research Manufacturers Association (PhRMA) has issued noncommittal statements about the bill. "As long as you have private sector investment driving drug development, the priority is get the drug approved and sold and not to start giving it away, says medical ethicist Arthur Caplan.

It seems right-to-try laws are a solution looking for a problem, but that solution can cause problems of its own for desperately ill patients.