
**PRO:**

The deadly Ebola outbreak spreading through Africa is so extreme, it is driving health officials to do something that they would instinctively resist in normal circumstances: Subject patients to unproven experimental drugs.

The drugs are risky. Some have not even been tested on humans. Even so, a World Health Organization ethics committee just declared such use ethical, and its reasoning is hard to dispute, at least for patients who would otherwise die. Some chance is better than none, even with unknown side effects.

Too bad American patients suffering from terminal illnesses have so much trouble getting the same chance.

The process for getting experimental drugs is so daunting that fewer than 1,000 people sought and got federal approval to take such drugs last year.

Food and Drug Administration rules require patients to clear a series of hurdles. First, they and their doctors must find a company to provide its drug. Many drug makers — worried that a patient's death will spur a lawsuit or harm their chances for final FDA approval — refuse.

Even then, patients still need a hospital review board to sign off, a contract between the hospital and the drug maker, and FDA approval. The FDA application process, according to its own estimates, can take up to 100 hours.

Now, the bureaucratic absurdity is generating a backlash.

Colorado, Louisiana and Missouri recently approved "right to try" laws, which seek to simplify the process. The Michigan Senate passed a bill last Wednesday; in Arizona, an initiative will appear on the November ballot.

These carefully crafted measures allow patients and their doctors to go directly to a pharmaceutical company to seek access to drugs, but only those that have cleared the first phase of clinical trials and remain in development. The laws protect drug makers from lawsuits. And, pointedly, they seek to cut out the FDA, which now has final say.

That's worth thinking about. The FDA's system for judging the safety and effectiveness of drugs prevents charlatans from peddling snake oil to desperate people. But in this case, the FDA's process is fatally flawed.
Although the agency says it often grants approval in 24 hours, the reality is that the system is too cumbersome for people with just weeks to live and little to lose. People such as Austin lawyer Andrea Sloan, who fought ovarian cancer for seven years.

After learning last July that she had exhausted all treatment options, Sloan sought a promising, unapproved drug. When she was turned down by one company, she flew with friends to Washington to lobby lawmakers.

With two top oncologists and a major cancer center, MD Anderson of the University of Texas, behind her, she found a drug maker to agree. Even so, it took until October to get the first dose.

By then, Sloan's health was failing. She died on New Year's Day. Her mother, Karen Sloan, wonders why exhausted cancer patients are forced to "run the obstacle course to the treatment that might save their lives."

The answer is that they shouldn't have to. The FDA should pre-empt the right-to-try movement by adopting its practices.

CON:

Suppose that you found out your son or daughter was dying of an untreatable brain tumor. Suppose you also found out that a pharmaceutical company was working on a drug to treat that disease but that it had only been tested in 10 adults.

While all the patients came through unharmed, only two showed a little improvement. If your doctor said that drug was your child’s only hope, but the Food and Drug Administration (FDA) might not let you get it, wouldn’t you want something done?

That is exactly what state "right to try” laws seek to do. The problem is that the FDA is not the main obstacle standing between desperately ill people and experimental drugs.

The FDA does take a look at requests from physicians to use experimental drugs and approves them 99% of the time. True, getting access to the agency can sometimes be slow if doctors aren’t sure how to do so. Things are even worse if families do not have access to savvy medical expertise to point them toward the latest drug research — something these laws don’t fix.

The FDA is not the main problem. Money is. Right-to-try laws do nothing to pay for unapproved drugs.

Families need money to travel to where the new drugs are. And small companies need money to cover their costs.

Nothing in right-to-try laws compels a company to make a new drug available even to a dying child.

Why wouldn’t they? Many companies that are working on the newest experimental drugs are tiny and have barely enough money to stay afloat. They often reason that it is better to use what supply of drug they have to get their product to market than to give it away and risk bankruptcy.

Right-to-try laws are basically "right to beg" laws. Begging is not what the dying and desperately ill should be asked to do. Legislators should stop enacting feel-good laws and show they care by finding the money to pay for experimental drugs and the travel and expenses involved in getting to them.