Right-to-Try Is NOT the Answer for Patients

Right to Try Could Harm Patients:

- Removing FDA from the process of obtaining investigational drugs **increases the risk of patient harm**, creates confusion, and endangers existing and future clinical trails
- FDA could **no longer make necessary improvements** to dosing, routes of administration, and dosing schedule for patient safety
- Right to Try's definition of who qualifies for access is broad enough that it could **shift health policy precedent and undermine patient safety standards and the current drug approval process**
- This bill would facilitate state laws that would **bar patients who use this pathway from hospice, and sometimes insurance coverage altogether**

Right to Try Will NOT Increase Access:

- FDA already allows access to experimental therapies through expanded access programs
- FDA **approves 99.7% of all expanded access requests** for patients with immediately life-threatening illnesses
- It is almost always ***the company*** **that prevents access to experimental treatments**
- This legislation **does little to address the reasons why companies refuse access** to their experimental treatments

What do the experts say?

Dr. Scott Gottlieb, FDA Commissioner:

"I think there is a perception, …that there are certain companies and products that aren't necessarily being offered under the current construct and the Right to Try legislation might provide more of an incentive and an opportunity. …I don't necessarily see that same opportunity because I think the biggest obstacle to offering drugs through expanded access is the supply constraints."

Mr. Kenneth Moch, President and CEO of Cognition Therapeutics:

"…the argument that Right to Try legislation is going to make more people have access to experimental medicines does not exist in my mind as a drug developer nor in anybody I know, and I can't say it more bluntly than that."

Dr. Ellen Sigal, Chair of Friends of Cancer Research:

"Any legislation that goes forward cannot circumvent the FDA and must be carefully crafted to assure that we do not create a loophole for those seeking to profit off the sick by offering false hope…. we must not subject patients to false hope or unacceptable side effects."

What can you do to help patients with terminal illnesses?

- Oppose Right to Try!
- Support alternative proposals that will safely and genuinely increase access to investigational drugs:

-Streamline the IRB process
-Ask FDA to enhance transparency and predictability for all stakeholders
-Enhance the Reagan-Udall Foundation's Expanded Access Navigator
-Enact liability protections
-Require FDA to clarify how companies submit expanded access data to FDA for review
-Study the financial hurdles to expanded access

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