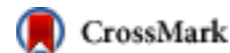


## False hope with the Right to Try Act

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Summary

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On Wednesday, May 30, US President Donald Trump signed the Right to Try Act, a law designed to remove the US Food and Drug Administration (FDA) from decisions on allowing patients to seek early access to experimental and unapproved drugs that have passed phase 1 trials. Advocates argue that streamlining the process will allow more people access, and perhaps allow lives to be extended or saved. Trump said that the new law could save “hundreds of thousands” of lives.

Critics—including the American Cancer Society and the American Society of Clinical Oncology, among many others—contend that right-to-try laws add little benefit over the existing FDA “[expanded access/compassionate use](#)” programme (active since the 1970s) that allows applicants to be granted access to experimental drugs and approves applications at a rate greater than 99%. The law also lowers the bar from terminal illness to “a life-threatening illness or condition”. Diabetes and heart disease are both life-threatening, but do they justify access to unproven, perhaps harmful or even deadly, experimental drugs? Scott Gottlieb, Trump's FDA commissioner, [criticised](#) that change, and it is unclear how the FDA will interpret the new law. Republican Senator Ron Johnson, author of the law, [has said bluntly](#) that it is intended to weaken the FDA.

Pharmaceutical companies decide who gets access to experimental drugs, and it is not clear the new law would make them any more inclined to accede. The new law offers little benefit in marshalling new drugs through the FDA's approval process. Patients given access to the drugs will be outside randomised controlled trials (RCT). Their data will not advance approval, and any adverse effects they might suffer could potentially damage a drug's approval chances. Patients might also intentionally try to circumvent the RCT system entirely, due to fears of receiving a placebo. The Right to Try Act removes a barely existent barrier. It is a political gesture, aimed at diminishing the power of the FDA over drug regulation, and intended to force critics to appear to stand between the dying and hope. The changes it offers will do little to help, and might do an unknowable amount of harm.

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