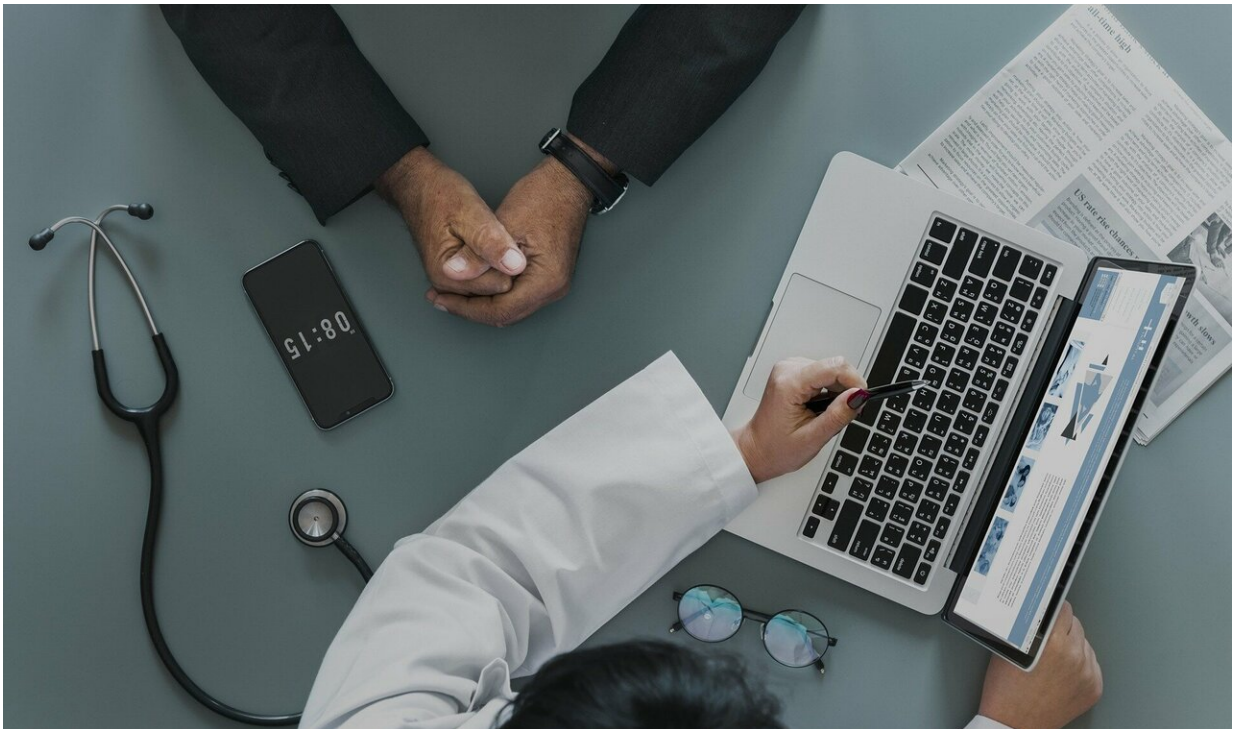


# How oncologists can ethically navigate the 'Right-To-Try' drug law

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The 2018 federal Right to Try Act allows patients with a life-threatening illness to be treated with drugs that have not yet been approved by the Food and Drug Administration (FDA). Many in the oncology community say Right to Try strips away important regulatory protections and view the move as a risky step bound to create ethical dilemmas for

physicians whose goal is to guide patients toward safe and appropriate treatment decisions.

Oncology is one field at the forefront of requests for unapproved drugs. An interdisciplinary team of bioethicists, oncologists, and lawyers from Penn Medicine and other institutions, along with the director of Penn's Abramson Cancer Center, Robert H. Vonderheide, MD, DPhil, penned a commentary published online this week in the *Journal of Clinical Oncology* to offer recommendations to help oncologists navigate this new "Right to Try" world, while maintaining their ethical obligations to patients.

"On its face, Right to Try sounds great. Who could argue with a law that promises patients with no other options early access to the fast-growing list of investigational cancer drugs that may help them? The problem is that we didn't need Right to Try to do that, but patients do need the protections that Right to Try gets rid of, including FDA's input on pre-approval use and careful safety reporting requirements," said first author Holly Fernandez Lynch, JD, MBE, an assistant professor of Medical Ethics in the department of Medical Ethics and Health Policy in the Perelman School of Medicine at the University of Pennsylvania. "In contrast, the Expanded Access pathway, which has been available for several decades, is designed to permit pre-approval access to drugs for desperate patients, while also preserving FDA's expert oversight."

For example, although FDA authorizes more than 99 percent of Expanded Access requests, it requires changes to the dose, safety monitoring, and/or informed consent in 11 percent of these cases. This suggests that seeking FDA's input helps provide optimal care for patients. The Right to Try law eliminates the requirement to seek FDA's input. It also weakens protections for informed consent and strips patients of their ability to hold drug manufacturers liable for damages and prevents them from holding physicians accountable outside of gross

misconduct.

Since the law was passed in May 2018, only two patients—one with [brain cancer](#) and another with [amyotrophic lateral sclerosis](#)—have been documented as securing access to investigational drugs under the provision, which the authors describe as a "relief." Importantly, under both Expanded Access and Right to Try, patients may use investigational drugs only if the manufacturer agrees to provide them.

Although the Expanded Access pathway is preferable to Right to Try, the authors said, oncologists should expect activity around the Right to Try law to ramp up. White House officials tout the law frequently and new business models are being developed to encourage its use. The appetite for investigational cancer drugs has only gotten stronger and shows no sign of slowing down, as cancer drug development moves at a rapid pace. More than 700 cancer molecules were in the [drug](#) pipeline in 2017—60 percent more than a decade ago. That increase may fuel the belief that more options are coming, and that dying patients could benefit from them if only they could access them immediately.

The authors also acknowledge "that not every oncologist will feel comfortable with adopting a blanket policy of refusing Right to Try requests, especially if a manufacturer will make a product available only through this pathway."

The authors offer a number of recommendations for how oncologists willing to use Right to Try can "satisfy their ethical and legal obligations ... and fulfill their envisioned role under the law to safeguard seriously ill, often vulnerable patients." Most importantly, physicians should make sure to have a full understanding of the law and its limits, including freedom to refuse Right to Try requests that are not in a patient's best medical interest. The authors also recommend doctors:

- Help patients to pursue appropriate clinical and research alternatives before moving to either Expanded Access or Right to Try.
- Consider FDA's Project Facilitate—a concierge program with a single point of contact for all oncology Expanded Access requests through which FDA staff guide oncologists through the process.
- Never rubber stamp Right to Try requests without full consideration of patient interests.
- Consider requests only from patients with whom there is an adequate relationship to understand the relevant medical context.
- Understand that Right to Try may be inappropriate for a patient even when relevant statutory eligibility criteria are satisfied; physicians can say no.
- Seek expertise from FDA and others with regard to the risks and benefits of unapproved products, regardless of whether such consultation is legally required.
- Facilitate patient understanding with regard to the risks, benefits, and uncertainties of unapproved products and the legal and financial consequences of using the Right to Try pathway.
- Collect and report information about patients' outcomes, even if not strictly legally required.
- Counter misinformation, and do not overpromise regarding the potential benefits of unapproved products.
- Engage in shared decision making with patients, considering whether the pursuit of unapproved interventions is likely to advance patient goals.

**More information:** Holly Fernandez Lynch et al. Right to Try Requests and Oncologists' Gatekeeping Obligations, *Journal of Clinical Oncology* (2019). [DOI: 10.1200/JCO.19.01741](https://doi.org/10.1200/JCO.19.01741)

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