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Article

"I Think It's Been Met With a Shrug:" Oncologists' Views Toward and Experiences With Right-to-Try

Cambray Smith, BS,[1] Jeremiah Stout, BA,[2] Alex A. Adjei, MD, PhD,[3] Jan Buckner, MD,[3] Mark Wentworth, BS,[4] Jon Tilburt, MD,[5] Zubin Master, PhD[6,*]

[1]Biomedical Ethics Research Program, Mayo Clinic, Rochester, MN, USA and School of Medicine, University of North Carolina - Chapel Hill, Chapel Hill, NC, USA; [2]Biomedical Ethics Research Program and Alix School of Medicine, Mayo Clinic, Rochester, MN, USA; [3]Department of Oncology, Mayo Clinic, Rochester, MN, USA; [4]Office of Research Regulatory Support, Mayo Clinic, Rochester, MN, USA; [5]Biomedical Ethics Research Program and General Internal Medicine, Mayo Clinic, Rochester, MN, USA and [6]Biomedical Ethics Research Program and Center for Regenerative Medicine, Mayo Clinic, Rochester, MN, USA

*Correspondence to: Zubin Master, PhD, Biomedical Ethics, Biomedical Ethics Research Program and Center for Regenerative Medicine, Mayo Clinic, 200 First St, SW, Rochester, MN 55905, USA (e-mail: master.zubin@mayo.edu).

Abstract

Background: The federal Right-to-Try (RTT) Act created an alternate regulatory pathway for preapproval access to investigational drugs. A few studies have examined the experiences of physicians with the Food and Drug Administration's Expanded Access Programs, but to our knowledge, no study has yet to examine their attitudes and experiences toward RTT. **Methods:** This study explored the views of 21 oncologists at a major cancer center with 3 main sites across the United States using semi-structured interviews and qualitative analysis. Participants were selected to have experience with Expanded Access Programs. **Results:** Most oncologists had limited familiarity with RTT, and several reported confusion about the legislation, including whether patients have a right to investigational drugs and an obligation for companies to provide them. Although oncologists were interested in decreased regulatory burdens, 3 areas of concern were articulated: lack of safety and oversight, unclear structure and no provision for data collection, and potential heightening of patient expectations. Only 4 oncologists had experience discussing RTT, and none formally attempted to obtain the drug through this mechanism. Participants questioned the practicality of RTT legislation and suggested alternative ways to improve access. **Conclusions:** The study provides foundational empirical data underlying challenging ambiguities by experienced oncologists familiar with off-trial use of investigational therapeutics and reaffirms the role of physicians and regulatory bodies in mitigating the risks of investigational drugs. Our findings highlight the need for medical centers to inform oncologists about RTT and other preapproval pathways so that they are able to address questions from patients interested in nontrial investigational drugs.

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Congress passed the federal Right-to-Try (RTT) bill in May 2018 (1). RTT was designed to give patients with life-threatening illnesses easier access to unapproved drugs, and similar laws have been passed in 41 states (2,3). The federal RTT law removes oversight for unapproved therapeutics by the Food and Drug Administration (FDA) and institutional review boards (IRBs) (4–6). The law bypasses the FDA's Expanded Access Program (EAP; sometimes called "compassionate use" for individual requests) for preapproval access to drugs outside of clinical trials. The federal RTT Act has several differences in preapproval access compared with EAP in terms of patient eligibility, oversight, informed consent, monitoring and reporting, and liability protections (Table 1).

The academic community and several professional organizations have raised concerns about the federal RTT Act, especially the removal of safeguards presented in EAPs already in clinical practice for decades (7–14). Moreover, the RTT moniker itself implies patients have a right to access unapproved drugs (15,16). Despite these concerns, little is known about physicians' experience with and attitudes towards EAPs (17–19), and no study to our knowledge has examined their views on RTT. Oncologists submit over one-third of the total number of EAP requests to the FDA (20,21); thus, capturing their

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Table 1. Comparison of features between the Federal RTT Act and FDA's Expanded Access Program[a]

Provisions	Federal RTT Act[1]	FDA's Expanded Access Program
Patient eligibility	Immediately life-threatening disease or condition (21CFR312.300) (4) Exhausted options for using approved products, either on- or off-label Providing investigational drug will not interfere with initiation, conduct, or completion of clinical investigations. Patient is unable to participate in a clinical trial.	Immediately life-threatening disease or condition or serious disease or condition (21CFR312.300) (4) Exhausted options for using approved products, either on- or off-label Providing investigational drug will not interfere with initiation, conduct, or completion of clinical investigations. Patient is unable to participate in a clinical trial.
When can investigational drugs be provided to patients?	After phase I, and product must be under active development or production	Any stage of product development, including preclinical or phase I, II, or III
FDA review	Not required	Required
IRB review	Not required	Required
Physician Involvement	Certify patient eligibility	Certify patient eligibility
Informed consent requirements	Written informed consent required but elements of consent are unspecified	Specifies informed consent requirements for physicians to explain to patients (21CFR50) (5)
Payment	Patients pay only for direct costs, eg, manufacturing, shipping (21CFR312.8d)	Patients pay only for direct costs, eg, manufacturing, shipping (21CFR312.8d)
Patients' rights	Right to ask a company for a drug (This existed before the federal RTT Act) May reduce patient rights to seek legal redress for negligence (see below under liability)	Right to ask a company for a drug
Manufacturers' obligations	Companies not obligated to provide drug	Companies not obligated to provide drug, but many companies need to have a publicly available expanded access policy outlining conditions for granting/refusing products (21st Century Cures. Sec. 3032) (6)
Monitoring and reporting requirements	Manufacturer or sponsor submits an annual summary of use of drug, including doses supplied, number of patients treated, uses for which drug was made available, and known serious adverse events (but not efficacy or other outcome measures). FDA will post annual summary report on its website.	Physician must report serious and unexpected adverse events to FDA in an Investigational New Drug safety report. Physician must also report a written summary of treatment results, including patient response, all adverse events, and product disposition to FDA and pharmaceutical company Sponsors must submit investigational drug safety reports and annual reports (when protocol continues for 1 year or longer) to FDA
Liability protections	No liability for providing or not providing an investigational drug shall lie against a sponsor or manufacturer. No liability for providing or not providing an investigational drug shall lie against a prescriber, dispenser, or other individual unless conduct constitutes reckless or willful misconduct, gross negligence, or intentional tort under any applicable state law.	Not applicable

[a]FDA = Food and Drug Administration; IRB = institutional review board; RTT = federal Right-to-Try Act.

views could help inform practice guidelines for RTT implementation. We interviewed clinical oncologists to understand their familiarity, attitudes, and experiences with RTT and EAP at several sites that are part of a single academic medical center.

Methods

Recruitment

We initially identified 39 oncologists at Mayo Clinic who had varying experience with EAP from 2014 to 2019. We used snowball sampling to recruit additional participants (see Supplementary Methods for greater details, available online).

Interviews and Qualitative Analysis

We developed a semistructured interview guide by first identifying several a priori categories. The interview guide was subsequently modified after exploratory pilot interviews identified that oncologists had little or no knowledge about RTT. The subsequent interview guide included a definition of RTT (Supplementary Methods, available online). All participants gave oral informed consent before the interview. Telephone or in-person interviews were conducted and transcribed. This study was deemed exempt by the Mayo Clinic Institutional Review Board #19–005556.

A finalized codebook was used to analyze transcripts using modified grounded theory (22) with constant comparison analysis (23) to develop a common set of themes by 2 coders (C.S. and J.S.) in duplicate to achieve consensus.

Table 2. Areas of uncertainty, misperceptions, and confusion surrounding RTT[a]

Themes	Example quotes
Patients' rights to investigational drugs	Right to Try in my mind says that the patient has the right to try a drug despite it not being maybe rigorously studied. . .From what it sounds like is that a patient has a right to try. There's legislation in place. It offers another avenue or some support, advocacy on the patient's behalf to get a drug that they may not be able to get otherwise. (Participant 1)
	The Right to Try is more extensive [than EAP], in my opinion. Basically, a patient wants everything, correct? They can request anything they want. I don't know if I would support [that] they want any experimental medication. (Participant 3)
Role of drug companies	I understand there is some legislation, but I'm not sure whether that legislation trumps—whether or not the drug company's agreeable to allowing a patient to try it. (Participant 1)
	. . .The name sounds like the company would be forced to share the drug. Right to try sounds like that to me, the patient and the physician agrees that the company has to share the drug, which is not true. (Participant 16)
Differences between EAP and RTT	I think there's one little brain cell that's saying it's almost more of a—that there's some preliminary data or maybe small, low-level study data—those drugs are more fast—I don't know—maybe more fast-tracked through? (Participant 2)
	Then right-to-try comes along, and I'm like, 'Well, that's compassionate use. We've been doing this for a long time.' Why is it different now other than of course legislation, but now that gets a new name? It's like, 'Okay, is that different than what we've already been doing?' (Participant 10)
IRB involvement	Sure, what I understood it to be back when I spoke to these folks is that even if a drug or a therapy is not approved by the FDA, a patient is allowed to obtain it if they have been informed and consent to obtaining it if it is I guess something that both the patient and the physician agree is a good idea. I believe the local IRB also has to agree that it's a good idea. (Participant 13)
	I think there's still a requirement from the IRB protocol. (Participant 17)
Eligibility of drugs	Of course Expanded Access would be something where we know there has been record of patient probably benefiting. We know the side effects, and we know what kind of cancers may benefit. With the right-to-try, that becomes a little murky because I wouldn't be able to tell if this patient's population [would be] represented in that particular study of the drug of interest. (Participant 4)
	Well, I would think it would just mean if there's something that's potentially beneficial that patients can have a right-to-try it, I guess. I guess I don't know how that would play out in oncology because if something's truly unproven—I feel like in order to invoke that there would have to be some background data or reason to make you think that it's going to work. . .Because if you look at phase I studies which is basically that, the response rate is less than 10 percent, so I feel like, is that appropriate use of resources and cost? (Participant 19)
Unclear rationale for RTT legislation	I'm dubious about this new right-to-try law. I think it is showmanship, or I think it's PR, and so. . .to the extent that I understand it, which is poorly, I'm a little skeptical. (Participant 6)
	[In order to share additional thoughts], I'd have to know more about why there's 2 separate pathways rather than just eating away hurdles. (Participant 17)

[a]EAP = Expanded Access Program; IRB = institutional review board; RTT = federal Right-to-Try Act.

Results

Demographics

We interviewed 21 attending oncologists (7 women, 14 men) across the 3 main campuses of Mayo Clinic in Minnesota, Arizona, and Florida. Our participants had an average of 17 years (range = 7-34 years) of practice experience and represented several oncology subspecialties. Interviews averaged 37 minutes (range = 18-54 minutes). Our sample included 1 full-time clinician with the remaining participants having a combination of clinical, research, and administrative duties. All oncologists were involved in recruiting, referring, or enrolling patients in clinical trials, and many were clinical trial principal or co-investigators.

Limited Familiarity and Confusion With RTT

All participants had at least 1 experience navigating patients through EAP, although not all of them had yet administered the experimental agent to patients. A few participants with substantive experience completed as many as 5 or more single-patient EAP protocols, and several had participated in larger (intermediate or treatment group) EAP requests. Three oncologists with less experience were in the process of completing their first single-patient EAP protocol. In general, participants with more EAP experience reported having greater familiarity with the pathway.

Despite familiarity with EAP, about one-half reported being either unaware or mostly unfamiliar with RTT laws. Those mostly unfamiliar with RTT laws knew of their existence, but were unsure about, or had misperceptions of, the legal requirements. Many oncologists reported that RTT had not been relevant in their practice thus far: "That's part of the reason I'm not as familiar with it because obviously if the topic had come up, I would have made sure [I] stay current with it" (Participant 5). Among those who reported more familiarity with RTT, a few were able to describe the features of the federal law, including lack of FDA oversight or that drug manufacturers were not legally obligated to provide investigational products. Oncologists who knew about RTT reported learning about it from a variety of sources, including the federal legislation, academic meetings, the FDA website, their local IRB, academic journals, and the media.

Uncertainty, Confusion, and Misperceptions About RTT

Most participants reported being uncertain or confused about RTT or had misperceptions about the law or process compared with EAP (Table 2). Multiple participants assumed that RTT enshrines a right for patients to access investigational drugs

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and requires drug companies to provide them. For example, 1 oncologist reported "I think (RTT is) an effort to mandate that companies make their drugs available in a more open process. I just don't know more details than that" (Participant 8). Oncologists also reported a lack of clarity about the differences between EAP and RTT, especially regarding IRB involvement, which drugs are available to patients, the role of health insurers or drug costs, and the rationale of the RTT legislation. Some participants reported appreciating the chance to discuss the topic during the interview and for clarifying aspects about different preapproval pathways.

A Few Oncologists Had Direct Experience With RTT

Only 4 oncologists reported having experience discussing RTT with a patient. These conversations were initiated by patients either considering access through RTT or requesting more information about the law. Two physicians reported discussing RTT further with an IRB representative, and 1 discussed the process with a drug company representative. No physicians reported using RTT to request investigational drugs from a company.

Concerns About RTT

After gauging physicians' initial understanding and experiences, we provided information about the differences between the federal RTT and EAP pathways to assess views on RTT. On learning the differences between these 2 preapproval pathways, a few oncologists strongly objected to the use of RTT or voiced immediate concerns about the lack of oversight.

> Honestly, that is unbelievable to give an experimental therapy to a patient without having some sort of IRB oversight. . .I would never do it. I would never do it. (Participant 10)

> I'd be very uncomfortable doing anything under that sort of procedure. It's reassuring me as much as I complained about the IRB slowness. . .that there are [a] separate set of eyes looking at what I [am] proposing to do. I think patients benefit from that in the long run. I am not in favor of engaging down this road without some real oversight. (Participant 5)

Many oncologists who had experienced high administrative burdens with EAP expressed interest in a simpler pathway. However, they still voiced substantial concerns about the federal RTT legislation, worrying about the lack of adequate oversight and patient safety, lack of process structure and data collection about investigational drugs, or increasing patient expectations and confusion (Table 3). A few also wondered about the practical utility of the law. Specific concerns are summarized below.

Almost all oncologists described the risks inherent to working with unknown drugs and the threat this posed to patient safety (Table 3). Many reported feeling responsible for the safety of their patients and explained that it was sometimes difficult counseling patients about investigational drugs when little safety data were available. They also reported that even after securing access to an investigational drug, it can be challenging to manage the unpredictable side effects of pharmaceuticals with which they and their teams are unfamiliar.

In response to this concern, physicians stressed the importance of oversight bodies to protect patients and to help busy clinicians navigate clinical uncertainties. Several oncologists recognized and explained the ways in which regulatory and ethics oversight creates additional burdens. However, they expressed that those burdens are often justified by the necessity of such oversight to protect patients, specifically to help manage risks and navigate clinical uncertainties about unapproved products with limited safety profiles. Multiple oncologists expressed gratitude for the IRB's help in thinking through past ethical and safety issues. They also reported that the FDA was the least burdensome step with EAP requests, with a few physicians reporting their surprise at how quickly their recent requests were approved.

Some oncologists found the federal RTT law too ambiguous to consider utilizing (Table 3). While recognizing a need to make investigational drugs more easily accessible, most oncologists said they would only consider RTT once there was a clear, established process for doing so. Examples of the proposed process structure included guidelines on scientific, clinical, and ethics review, often at the institutional level, and broader reporting. Oncologists reported that the lack of structure around RTT made it potentially difficult to access and generate information needed to inform clinical decision making regarding investigational drugs (Table 3). They expressed concerns about accessing information, including unpublished data, necessary to counsel their patients about unproven options and wanted clear processes to ensure that they did not lose valuable data that could be used to help guide future uses of investigational drugs.

Physicians expressed worries that RTT legislation might lead patients to believe they have a right to access investigational drugs (Table 3). A few physicians predicted these expectations could increase their clinical burden, as time would have to be taken to clarify the law's provisions and the largely palliative use of many investigational drugs through compassionate use.

Oncologists with experience discussing RTT with patients reported that their patients did not appear to understand the law, especially the lack of legal obligation for pharmaceutical companies to provide the drug a patient wants. One physician reported spending nearly 2 hours in an informed consent discussion with a patient who wanted to use RTT to avoid being placed in the control arm of a clinical trial.

> (My patient said): 'Well, Trump put through right to try. We just want it as it is.' I said, 'Well, I know the company, and they're not participating in that.' They said, 'Well, it's a law; they have to give us the drug.' (Participant 9)

The oncologist explained to the patient why these are not circumstances in which RTT could be used because the patient was eligible for the clinical trial and thus needed to participate in the random assignment. This lengthy discussion illustrated the oncologist's strong concerns about the legislation and its impact on patient expectations under RTT.

Looking to the Future: Oncologists' Willingness to Use RTT Was Contingent on Many Factors

Some participants who expressed openness to or interest in RTT described several factors that would influence their willingness to pursue the pathway, including the degree of administrative support available, time sensitivity of the request, a physician's familiarity with the drug, the drug company's receptiveness, and potential costs to patients. Some also reported

Table 3. Concerns about RTT and the federal RTT law[a]

Themes	Example quotes
Lack of adequate oversight and patient safety	I think that [RTT] could lead potentially to some risk beyond what the patient might be willing to take if they had been informed or what might be in the best interest of the patient. . .Certainly, we don't know the risks when we put a patient on a phase I study, but there, at least we have some safety checks in place more so than you might have when you are going without IRB or FDA oversight and there's been no vetting. (Participant 13)
	I would say, as much as the regulatory work is for the Expanded Access Program, there is enough rigor in there. You have to fill out the IRB application. You had to put out your—the monitoring, for example, what's your monitoring plan. You had to have some solid rationale to do this, and then there were checks and balances. You had to then—once my patient was off study, I had to give follow-up. . .How did the patient do and what were the toxicities? I think that that is a robustly regulated way to do it. I am a little concerned about, 'Hey, there's a drug. It's out there. I can get access to it.' [With RTT], I'm a little afraid that if you weren't being careful by someone who wasn't detail-oriented and rigorous, certain things could fall through the cracks. What's the monitoring plan? How often should they be seen? How often should you do lab tests? (Participant 15)
	As much of a hassle as it is, oversight remains important. These are drugs where not all the side effects are known. Managing risk, managing reporting and things like that, I take a somewhat more conservative stance on that. Yes, it's a hassle, but there are reasons for it and until the drug has been through the development process and you know what it is, I don't like the idea of just, 'Sure, go ahead. Try it. See if it works.' (Participant 21)
Lack of process structure and data collection about investigational drugs	I think that the lack of the lesser amount of FDA involvement is sort of a double-edged sword, right? I suppose it makes it easier for patients to get, and less burdensome for their physicians to get it, especially in the community where they may not have as much regulatory help as we do on the academic side. The flipside is that without that FDA monitoring and outcomes collection, you're potentially missing out on a whole trove of data that we can learn from, right? (Participant 8)
	When I think about the headlines that come out when this black box wording and these things that we learn sometimes even after FDA approval. . .If the signals are there early when there is a major safety concern if right-to-try if we are not collecting this data and this information, we are not going to learn these important things if they're all happening in isolation and nobody's talking, nobody's reporting, and that's the whole darn purpose. (Participant 10)
	I don't see it for me in the near future, just because it's a complete black box. If somebody comes back and explained to us and there is way to do this, there is little less regulation involved, but like I said, I'm still going to be responsible, but maybe if we could get the same drug sooner with less people involved, then maybe we would try that. I just don't know yet. (Participant 16)
Increased patient expectations and confusion	Yeah, I think it sets up an expectation that we have a right, so I think that that's potentially damaging and actually gets in the way of the doctor-patient relationship and confuses good care. I'll also tell you the flipside of that is it's been a zero issue in my clinic. (Participant 6)
	It could be very disappointing for patients once they see that. It could also create some extra work for the oncologist because now a patient is coming in saying, 'I want this drug. I have the right to take this drug.' The oncologist has to argue why you should not take that drug, why it doesn't make sense to take that drug. I think maybe it should be rebranded to an oncologist right to consider, rather than a right-to-try. (Participant 12)
	I don't think [patients] do [understand], because they come in and go, 'I read about that. I want it. Why can't I? Don't I have a right-to-try?' Then you have to walk through that process. (Participant 18)

[a]FDA = Food and Drug Administration; IRB = institutional review board; RTT = federal Right-to-Try Act.

they would consider whether other regulatory pathways were available.

> Again, if there was a compassionate access program, I would go through that first with the clear parameters in place. If there wasn't a compassionate access program in place, and there was a solid rationale, and it's something that I could get access to by dealing with the company directly, and the patient was on board, and I had the right materials and resources to be able to take care of that patient safely, then I would do [RTT]. If I felt like I couldn't do it safely, then I wouldn't do it. (Participant 15)

Gatekeepers and Incentives Remain Unchanged by RTT

Oncologists recognized that pharmaceutical companies remained the ultimate decision makers and that access was dependent on the receptivity of companies to requests. Many reported that pharmaceutical companies were surprisingly receptive to requests and helpful throughout the EAP process. Others reported using pharmaceutical companies as a resource to help decide whether a drug was appropriate for their patient, describing them as another layer of oversight. Despite these experiences, oncologists speculated, and 1 physician directly confirmed, that some pharmaceutical companies would prefer to use EAP pathways than RTT.

> I mean, will a sponsor really do that? If I were a sponsor, I'd say, yeah, they have a right to try. By the way, we have an Expanded Access Program. Let's do that and make sure we can do this properly. That's what I would do it if I was a sponsor, and then the sponsor's just fulfilled their obligation. The doctor fulfilled their obligation. Nothing changed, and you're just back to where you started. (Participant 6)

Oncologists Recommended Education, Personnel, and Regulatory Streamlining to Improve Nontrial Access to Investigational Drugs

Oncologists acknowledged a prevailing need, at least in the cancer community, for a nimbler regulatory framework to make

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targeted drugs available to patients outside of clinical trials. However, when asked about the future of the legislation, many expressed skepticism that RTT was the answer.

> I think it's been met with a shrug. I work in one of the largest comprehensive cancer centers in the country. It's a 3-site comprehensive cancer center. . .We've never discussed this. (Participant 6)

> Creating a program where there is no regulation from my IRB or no regulation from FDA seems to me like a solution to a nonexistent problem. Maybe other people had problems. (Participant 16)

Instead, many oncologists suggested several practical measures that would improve patient access, including education on the process, regulations, and vocabulary of each program to reduce the burden of navigating a patchwork of programs and regulatory bodies. Many cited administrative personnel with expertise in these programs as a crucial resource for reducing the burdens and easing the clinical responsibilities of physicians. Some recommended that effort be placed into creating a simpler, more user-friendly structure for EAP rather than creating new programs with additional process ambiguity for oncologists and patients.

Discussion

Our results demonstrate that oncologists at 1 major academic medical center are not that familiar with the federal RTT pathway for nontrial preapproval access, and, when briefed, expressed concerns about its implementation (24). Oncologists identified practical burdens associated with EAP consistent with other studies, including the time and resources needed to secure the investigational product, and FDA and IRB reviews (17,19), and preferred streamlining them. Balancing oversight burdens with the safeguards within the EAP resonated more with participants than removing safeguards altogether as in RTT. Many of our participants ultimately had reservations regarding whether RTT promotes the best care for oncology patients.

Our data also demonstrate that RTT has had limited impact on the practice of oncology at 1 cancer center. Many participants were initially unfamiliar with the law, and few had discussed the pathway with patients. Despite limited utilization, confusion among many participants, including that patients had a right to drugs and companies had a legal obligation to provide them, shows the rhetorical power of the RTT name and its ability to mislead (15,16). This is a concerning addition to the existing environment of health misinformation that may negatively affect the therapeutic relationship (25,26). Because our sampling was purposefully conservative, including oncologists with EAP experience, the results from our cohort are likely to differ from oncologists without previous experience with EAP, whether in academic or community settings. Further investigation regarding physicians' views and experiences with these regulatory topics is needed.

As the responsibility of protecting patients potentially becomes less centralized under legislative shifts such as RTT, medical institutions may need to develop their own specific policies to integrate RTT into their clinical practice (27). For example, medical institutions may develop policies prohibiting the use of RTT or build in safeguards requiring scientific and clinical review by a specific committee within the institution, ethics review by the IRB, or provisions to collect and report data on patient outcomes from the investigational product. Given concerns about the lack of centralization and data sharing, this may not be widely desirable, but medical institutions may choose to create their own internal processes that ensure investigational drugs are considered with care. Although oncologists in our study generally valued the expertise of regulatory bodies and suggested they would benefit most from clearer and simpler processes, some of these oversight functions could be performed internally under the guidance of IRBs or expert panels. Ultimately, oncologists will have to determine how best to uphold their professional obligations to patients under institutional and national policies in the changing landscape RTT perpetuates (28). Studies investigating how institutions are choosing to respond to RTT are warranted.

It is worth noting that our qualitative analysis was limited to a single major cancer center with 3 sites across the United States and does not represent the views of oncologists generally or from different institutions. Although our data suggest possible reasons explaining the views of our participants, it is difficult to know with certainty the causes behind respondents' views. Despite its limited sampling, the themes identified are the first to document the range of considerations that would need to be addressed if RTT were to be implemented or, alternatively, how legislative harmonization might better address the perceived need behind RTT with the EAP framework—a move more consonant with the professional impulse to uphold access and protection.

Although RTT is intended to accomplish the goal of cutting regulatory red tape, our data suggest that additional work is needed to meaningfully affect safe access to promising experimental therapies. Access to experimental and off-label therapies holds broad relevance beyond oncology and extends even to our current pandemic crisis (29). Establishing the guardrails for such access in a politically polarized environment can be fraught. Hopefully, bringing nuanced empirical data to that conversation based on the concerns experts express on behalf of patients interested in investigational drugs can inform subsequent regulatory reform. Our findings illustrate the important role physicians play in navigating the implementation of ambiguous or redundant regulations as they balance risks and often unknown benefits of investigational drugs.

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Role of the authors: CS helped with the design of the study, and was involved in participant recruitment, conducting interviews, the collection, analysis and interpretation of data, and wrote the first draft of the manuscript and revised it for important intellectual content. JS was involved in the analysis and interpretation of data, helped write the first draft of the manuscript and revised it for important intellectual content. AAA was involved in the design of the study, participant recruitment, performed a high level analysis, and revised the manuscript for important intellectual content. JB was involved in the design of the study, participant recruitment, performed a high level analysis, and revised the manuscript for important intellectual content. MW was involved in the design of the study, participant recruitment, performed a high level analysis, and revised the manuscript for important intellectual content. JT was involved in the conception and design of the study, performed a high level analysis, and substantially revised the manuscript for important intellectual content. ZM was involved in conception and design of the study, participant recruitment, conducted a first set of interviews, participated in collection, analysis and interpretation of data, helped write the first draft of the manuscript and subsequently revised it for important intellectual content. ZM led the project and supervised CS and JS throughout the project as the main analytical team. All authors agreed to be accountable for their work.

Data Availability

The data underlying this article cannot be shared publicly due to protecting the privacy of individuals that participated in the study. Deidentified data will be shared on reasonable request to the corresponding author.

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