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The Problem with State "Right to Try" Legislation

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Eleven states to date (Colorado, Louisiana, Michigan, Missouri, Arizona, Wyoming, Arkansas, South Dakota, Utah, Indiana and Virginia) have instituted "Right to Try" laws. Many other states are considering similar legislation. Although these laws are not directed at clinical research, they can affect study enrollment and public perceptions of clinical research.

Right-to-Try laws address the legitimate concern that the current process for making investigational therapies available to the public is too slow for those with terminal illnesses. The current system places a priority on proving safety and efficacy prior to public access. Advocates of Right-to-Try laws argue that, for people who might die waiting for a new therapy, the risk/benefit equation is too conservative. Right-to-Try laws attempt to give terminally ill patients, who have "nothing to lose," the opportunity to try an unproven and possibly dangerous treatment that might save or prolong their life. We can debate individual autonomy, risk tolerance, etc., but who could be against giving dying patients a chance to live with a proverbial "Hail Mary pass"?

In 1988, a similar issue arose with HIV/AIDS drugs and resulted in FDA's Expanded Access program, which gives the public access to investigational products outside clinical trials. However, critics complain that the FDA process is too labor-intensive and slow, with no guarantee that the FDA will approve the request. And, even if the FDA grants early access under this program, there are no regulatory or market incentives for the manufacturers to release their products. Early access programs can work against the interest of the manufacturers, since experimental products can be very expensive to produce, a very limited supply might be needed for clinical trials, the patients might be needed for clinical trials, and negative results might cast a shadow on a promising treatment. These are not just the selfish concerns of greedy and heartless corporations; they are the legitimate concerns of well-meaning companies (and other organizations) trying their best to develop new medical treatments for many sick people.

In 2014, the Goldwater Institute, a public policy advocacy and research organization, put forth model Right-to-Try legislation, resulting in the rapid passage of Right-to-Try laws in eleven states so far, with 20 or so more slated for approval this year. However, despite the rhetoric, none of these laws actually improve access and, in a bitter irony, add further obstacles of their own.

To improve access, Right-to-Try laws would have to address five obstacles commonly cited for blocking access to investigational products:

- Physicians have to do an inordinate amount of paperwork to obtain FDA approval.
- FDA approval is not guaranteed.
- IRB approval with a convened Board must be obtained in a timely manner.
- The manufacturers are generally unwilling to provide access, for a variety of reasons.
- The cost and/or time requirements for the entire process are prohibitive to patients, especially given their poor health and prognosis.

Unfortunately, the state laws do not address these obstacles. With respect to the first obstacle, nothing in the state laws streamlines FDA (or any other) paperwork, which remains solely under the authority of the FDA, as discussed below. With respect to the second and third obstacles, federal, not state, law governs. With respect to the fourth

obstacle, Right-to-Try laws explicitly state that the manufacturer is not required to provide the product and is allowed to charge for it. With respect to the last obstacle, Right-to-Try laws only add complexity to the process.

In fact, the author is familiar with hundreds of instances of early access attempts, in none of which a state Right-to-Try law would have made a difference. In the current system, the FDA, manufacturer, physician and patient must all cooperate to obtain early access. Under the supremacy clause of the U.S. constitution, State Right-to-Try laws do nothing to change that and, in fact, add *additional* obstacles. Consider these examples:

- Colorado, Michigan and Virginia require additional items in the consent form in addition to FDA's requirements.
- Louisiana, Arizona and Virginia require two physicians to diagnose the terminal illness, instead of just one.
- Colorado excludes hospitalized patients.
- Missouri disallows Schedule 1 controlled substances, which the FDA allows.
- Colorado allows insurance companies to withhold or limit coverage during the course of treatment under their right-to-try.

Unfortunately, in general, the public does not understand these "details" or how these laws would actually operate in practice.

Physician Immunity

Physicians may not want to recommend an investigational therapy (especially without approval under FDA's Expanded Access program) because a malpractice claim might lead to the revocation of their state medical license. All of the state Right-to-Try laws (as well as the Goldwater template) address this issue: Physicians who make a good faith recommendation of an investigational product under their state's Right-To-Try law have some protections for their medical license.

About half of the states extend this protection to the physician's Medicare certification. About half of the states offer some protections to the manufacturer against lawsuits for good faith provision of the product. About half of the states expressly provide similar protection for the institution providing or administering the product. Colorado, Missouri and Michigan are the only states that expressly provide this protection in all four areas.

To receive these protections, physicians must follow the state Right-to-Try law. However, two open questions remain:

- Do these protections apply if a physician follows the FDA's regulations for Expanded Access, but not his or her state's Right-To-Try law?
- Does following a state's Right-to-Try law have any impact on federal Medicare certification?

Federal Developments

The FDA has taken notice of popular support for state Right-to-Try laws and plans to simplify and accelerate its process for Expanded Access, as stated in its draft guidance, published in February 2015 and entitled "Individual Patient Expanded Access Applications: Form FDA 3926." Accelerating the FDA process does not fix the other obstacles and time traps, nor does the FDA's new proposed form eliminate the newly imposed state obstacles that vary from state to state with such legislation.

The Goldwater Institute says, "These [Right-to-Try] laws allow patients and doctors to go directly to a company without asking FDA for permission." ("The Push for 'Right to Try' Drugs for the Seriously Ill," Ed Silverman, Wall St. Journal, March 27, 2015). In fact, patients have always had the freedom to contact manufacturers, but FDA permission is still required to actually obtain the treatment. Kellie McLaughlin, a spokesperson for Janssen Biotech, states that manufacturers must go through the FDA as they "have an obligation to follow federal laws" ("Patients Seek 'Right to Try' New Drugs," New York Times January 10, 2015). State laws do not relieve anyone of the obligation to follow Federal statutes and regulations.

The Goldwater Institute states that, although Right-to-Try has not been formally addressed by the Supreme Court, it is consistent with its previous rulings on a person's right to self-preservation and non-interference with rescue. In fact, these arguments have already been heard in federal courts in the case *Abigail Alliance vs. von Eschenbach.* The Court of Appeals for the District of Columbia determined that these rights did not extend to the provision of investigational products without FDA involvement. The Supreme Court declined to review the case. Thus, while the Goldwater Institute is correct in saying that the Supreme Court has not heard the case, the Supreme Court did let the appellate court ruling stand. Consistency with Supreme Court's previous rulings on a person's right to self-preservation and non-interference with rescue is just a topic for conjecture.

Impact on Clinical Research

When a patient expresses interest in Expanded Access, clinical research professionals are likely to get involved. They should be able to answer questions about and comply with their state's Right-to-Try laws or proposed legislation. Prospective study participants have asked study coordinators questions along the lines of, "Why would I want to be a guinea pig in your trial when I can just get the drug under Right-to-Try?"

In 2007, the American Society of Clinical Oncologists (ASCO) addressed this issue by writing to the federal appellate court regarding the *Abigail Alliance vs. von Eschenbach* case (discussed later) as follows:

> [Although] "ASCO is sympathetic to patients who wish to access such experimental drugs when they have exhausted their treatment options or in situations in which they are ineligible for participation in clinical trials evaluating the sought-after drug,…ASCO and its colleagues at the NCCS and AAMC feel strongly that a constitutional right to access experimental therapies that have completed phase I trials *would pose substantial risk, not only to individual patients, but also to the clinical trials system as a whole* [emphasis added]."

Some state laws specifically consider clinical trial access:

- Colorado, Missouri, Arizona and Virginia laws require consideration of clinical trial participation (with some limitations).
- Missouri law states that the options must include all relevant clinical trials conducted in that state.
- Colorado and Virginia laws state that the patient must be unable to participate in a clinical trial for the terminal illness within 100 miles of their home address and/or not been accepted to the [sic] clinical trial within one week of completion of the clinical trial application process.
- Virginia law states that there has to be no reasonable opportunity for participation in a clinical trial.

In a related concept, Arizona law, for example, states that, although access to a clinical trial is not required as a condition of receipt of the investigational product, the manufacturer can require the submission of data back to that manufacturer as a condition of receipt under "Right To Try."

Conclusion

Regardless of their merits, state Right-to-Try laws are still laws, so read your state's "Right to Try" law, whether passed or in progress, and prepare to discuss it with potential study participants. If you have the opportunity, share your perspectives with your government representatives.

If, as it appears, state Right-to-Try laws actually complicate the process for obtaining treatment, legislators in states with problematic Right-to-Try laws eventually will have to explain to outraged voters how and why they created new obstacles for dying patients — real people with very sad stories. To paraphrase Friedrich Nietzsche, "Be careful when you fight monsters that you do not become a monster yourself."

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