Minnesota’s Right to Try law

Physicians may be better off following the FDA’s compassionate use process than turning to the state’s new law to help the terminally ill access investigational therapies.

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Patients with life-threatening illnesses who do not respond to current therapies often seek out alternative treatment options. Such patients may become frustrated when they learn that new therapies that are under investigation and available to patients participating in clinical trials are not available for general use. The Food and Drug Administration (FDA) does grant exceptions that allow patients who are not part of a clinical trial access to such therapies through a “compassionate use” process. However, gaining an exception has been criticized as being excessively arduous and time-consuming.

In response to the perceived shortcomings of the FDA process, 25 states, including Minnesota, have recently enacted so-called “Right to Try” legislation. These laws are an attempt to circumvent the need for the FDA compassionate use process by granting permission at the state level to use investigational therapies in a non-investigational context. Because of possible legal and other problems, physicians and patients seeking access to investigational therapies would be well-advised to continue doing so by following the FDA process rather than assume they are protected under the new state law.

Minnesota’s Right to Try law

Minnesota enacted Right to Try legislation in the spring of 2015. The law went into effect in August. Similar to those enacted in most of the 25 other states with Right to Try laws, Minnesota’s new law is largely based on model legislation proposed in 2014 by the Goldwater Foundation, a libertarian organization based in Arizona.

Minnesota’s law allows eligible patients to access investigational drugs, biologics and devices that have successfully passed a phase 1 investigational trial, are the subject of an FDA clinical trial and are not yet available to the public.

Eligible individuals include those whom a physician has deemed to have an illness that, “to a reasonable degree of medical probability, is not considered reversible and even with the administration of current FDA-approved and available treatments and the administration of life-sustaining procedures will soon result in death.”

In order to access an investigational treatment, three conditions must be met. First, the patient’s physician must document that both he or she and the patient have considered, but not necessarily tried, all currently available FDA-approved and available treatments and the administration of life-sustaining procedures will soon result in death.

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The law does not ensure access to the therapy. Nor does it require a pharmaceutical company or device manufacturer to make the prescribed or recommended treatment available. Additionally, nothing in the law prevents a company from charging the patient for the cost of manufacturing the treatment. The law does not require a health insurer, state health program, state employee coverage plan, or state or local health program for inmates to cover the cost of the treatment. Thus, while the law may ostensibly give eligible patients the “right” to have an investigational treatment, it does not help them obtain or pay for it.

At the same time, the law does provide certain protections for prescribing/recommending physicians. It protects a physician from disciplinary or other action against his or her medical license for having simply prescribed, recommended or provided a treatment. It also ensures that a provider or health care entity cannot be sued under Right to Try for damages that a patient may incur from using an investigational therapy, “so long as the health care provider or entity is complying with the requirements of this section [of the law].”

The FDA and federal law

Minnesota’s Right to Try law provides only theoretical access to investigational therapies outside a clinical trial. Although no
state Right to Try law has been challenged in court, it is likely that a court would find that the FDA has exclusive author-
ty to permit or deny compassionate use of unapproved, investigational therapies. As such, the FDA’s regulatory framework likely preempts Right to Try laws such as Minnesota’s.

Congress provided the FDA with the authority to grant access to investigational drugs and devices to individual patients or groups of patients upon a physician’s request. In order to grant such access, federal law requires the FDA to establish, with respect to each request for an investiga-
tional drug, that

1) The patient or patients have a serious or life-threatening disease or condition for which there is no comparable or satisfac-
tory alternative therapy;

2) The potential benefit to the patient justifies the potential risks of the treat-
ment and those potential risks are not un-
reasonable in the context of the condition to be treated; and

3) Providing the investigational drug for the requested use will not interfere with the initiation, conduct or completion of clinical investigations that could sup-
port marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.

In order to have the information nec-
ecessary to make such findings, the FDA requires the requesting physician to sub-
mit an application for expanded access or compassionate use that certifies, among other things, the rationale for the intended use of the drug, a description of the pa-
tient’s disease or condition, the “method of administration of the drug, the dose and the duration of the therapy,” and informa-
tion regarding the manufacture and phar-
macology of the drug. Alternatively, the sponsor of the clinical trial may provide information regarding the therapy to the FDA, amend its investigational new drug (IND) application to include a protocol for individual use or allow a requesting physician to refer the FDA to the spon-
or’s IND for relevant information. In
the case of an emergency, where treatment

must begin before the paperwork can be submitted (eg, “within a very limited number of hours or days”), this request may be made by telephone, with the under-
standing that the requesting physician must agree to submit a written application within 15 days of the FDA’s authorization of use of the investigational drug, and report the emergency use to the relevant Institutional Review Board within five days. The physician must also, under most circumstances, obtain informed consent for the use of the drug that takes into account its investigational nature.

A sponsor may charge for making its investiga-
tional drug available; however, it may only recover its “direct costs,” or costs per unit for manufacturing and shipping the drug.

What physicians need to know
Complying with FDA requirements for compassion use or expanded access can be time-consuming. The FDA estimates that it takes approximately eight hours for a physician to complete the application for a patient to be considered for expanded access to an IND. The vast majority of those applications are approved. Of the 1,069 emergency INDs that the FDA received between October 2013 and Oc-
tober 2014, 1,066 were approved. Of the 696 single-patient IND requests received during the same time period, 692 were ap-
proved.

In response to criticism about its ex-
panded access process, the FDA released draft guidance in February 2015 that, if approved, would streamline the process. It would establish use of a new simpli-
fied application form (Form FDA 3926), which the FDA estimates will take only 45 minutes to complete. However, until the guidance is approved, physicians should continue to submit Form FDA 1571.

Minnesota physicians and their patients may be better served by continuing to adhere to the FDA’s requirements, rather than by attempting to take advantage of the state’s Right to Try law. First, federal law would likely trump a state Right to Try law, should the latter ever be challenged in court. Generally, if both the federal and

state governments have enacted legisla-
tion on a particular subject, federal law will trump state law unless the federal legislation expressly permits conflicting or additional state regulation, or unless fed-
eral law contains no express preemption provision, does not provide a complete regulation of the subject in question, and does not conflict with relevant state law.

Congress expressly permits states to regu-
late drugs, to the extent state law does not conflict with federal law on the subject. However, given that Minnesota’s Right to Try law appears to conflict with federal law by pointedly diminishing the required safety provisions, it is quite possible that, if the state law is challenged, a court would hold that federal law preempts sections of Minnesota’s law.

Second, it seems doubtful that anyone citing only the authority of state law and not also federal law would be able to suc-
cessfully convince a commercial drug manufacturer to provide a patient with an investigational drug. PhRMA, the phar-
maceutical research and manufacturing association, has stated:

“While these [Right to Try] bills may be well-intentioned, they seek to bypass FDA oversight and the clinical trial pro-
cess, which is not in the best interest of patients and public health, and is unlikely to achieve our shared goal of bringing in-
novative, safe and effective medicines to patients as quickly as possible. Because of the FDA’s critical role in ensuring the safety and effectiveness of prescription drugs, and the agency’s ultimate oversight of clinical trials and new drug approvals, state-by-state ‘right-to-try’ legislation is unlikely to help optimize the existing fed-
eral expanded access process.”

To date, it does not appear that any patient has successfully used a state Right to Try law to access an investigational therapy.

Next step
One might wonder about the purpose of the Right to Try laws. Although they ostensibly offer an option for providing terminally ill patients with access to inv-
estigational therapies not yet approved
by the FDA, they cannot be used to force manufacturers to provide patients with unapproved therapies, nor can patients use these laws to force physicians to prescribe such therapies. If the point of the Right to Try laws is to spur the FDA to make compassionate use more user-friendly, they may be achieving that goal. In the meantime, patients likely will be best served if physicians continue to follow federal compassionate use regulations and urge the FDA to finalize its draft guidance streamlining the compassionate use process. MM

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REFERENCES


3. MN Code § 151.375, subd. 2(c) (West 2015).

4. MN Code § 151.375, subds. 2(d) & 3.

5. MN Code § 151.375, subd. 3(2).

6. MN Code § 151.375, subd. 3(4).

7. MN Code § 151.375, subd. 3(3)

8. MN Code § 151.375, subd. 4.

9. MN Code § 151.375, subd. 5(b).

10. MN Code § 151.375, subd. 7.

11. MN Code § 151.375, subd. 6.

12. MN Code § 151.375, subd. 8.

13. 21 U.S.C. §368(b)(a), (b) & (c) (West 2015).

14. 21 C.F.R. §312.305(a) (West 2015).

15. 21 C.F.R. §§312.305(b) & 312.310b(1).

16. 21 C.F.R. §312.310b(1), (2) & (3).


19. 21 C.F.R. §312.310(d)

20. 21 CFR 56.104(c) (West 2015).


22. 21 C.F.R. §312.8(c) & (d).


27. U.S. Const. art. VI, cl. 2.

