Right to Try? Right to Die? Federal and State Laws in Fl for Providers Who Treat Terminally Ill Patients

Right to Try? Right to Die?

The past week has brought two significant changes to the rights of California healthcare providers who treat terminally ill patie On May 30, President Trump signed into law a new federal "right to try." Meanwhile, on May 24, a California judge invalidated California's physician-assisted suicide (more controversially known as the "right to die" law).

What do these changes mean for California healthcare providers?

New Federal Right to Try Act

The new federal Right to Try Act provides patients suffering from life-threatening diseases or conditions the right to use investigational drugs for which a Phase 1 clinical trial has been completed, but has not been approved or licensed for any use the Food and Drug Administration ("FDA"). It amends the Food, Drug, and Cosmetic Act to exempt investigational drugs provi to patients who have exhausted approved treatment options and are unable to participate in a clinical trial involving the drug. Patients have long complained about the delays involved in drug development, as new medications go through three phases clinical trials (Phase 1 human safety trials, followed by two additional trials evaluating effectiveness and side effects) that can years to complete. Advocates of right to try laws have sought to accelerate access to new drugs for terminally ill patients who running out of options. Arguably, the law does not represent a radical change in this and several other states, however, becau 2016, California had already joined the majority of other states in adopting a law enabling physicians to help terminally ill patie pursue investigational therapies, without fear of Medical Board or state civil or criminal liability. In addition, critics of the law question its underlying premise that the FDA's regulatory oversight is the cause of delays to investigational drug access for su patients, noting that in 2016, the FDA's overhaul of its "expanded access" or "compassionate use" program designed to strea access to unapproved drugs to such patients has been effective, as evidenced by the FDA's own reports that it authorizes ov 99% of expanded access requests it receives. Regardless, the new Right to Try law should give physicians, as well as drug manufacturers, some added comfort about FDA enforcement in these cases. Physicians working with unapproved drugs still n to be careful to consider clinical trial compliance before relying on the Right to Try Act's limited protection.

The End of Life Option Act

California's End of Life Option Act (ELOA), which decriminalized physician-assisted suicide for terminally ill patients in Califor two year ago, has been in the news lately. On May 15, 2018, a Riverside Superior Court judge declared the law unconstitutio On May 24, a three-judge Court of Appeal panel declined California Attorney General Xavier Becerra's petition to stay the dec immediately to keep the law in effect, but set a briefing schedule and plans to rule on the issue in the next several months. Enactment of the ELOA made California the fourth state in the country (after Oregon, Washington, and Vermont) to adopt suc law. Since that time, Colorado, Hawaii and the District of Columbia have adopted similar laws.

Under the law, physicians immune from civil or criminal liability if they follow the law's specific procedure in assisting patients are mentally competent and have six months or less to live. To get the prescription, a patient must submit two oral requests – days apart – to the physician, and one written request. The terminally ill person must be able to self-administer the drugs.

As the law was about to take effect, a group of doctors who objected to the law filed the case, Ahn v. Hestrin, together with a national advocacy group, the Academy of Medical Ethics. They argued that the law violated due process and equal protection guarantees of the U.S. and California Constitutions, and also argued that the California Legislature did not have the legal auth when it passed the law during a special session addressing healthcare funding issues. Riverside Superior Court Judge Danie Ottolia agreed with the plaintiffs on the latter issue, finding it to have been beyond the scope of the limited, emergency nature legislative session. He allowed Attorney General Becerra time to make an emergency appeal of the issue. The appellate cour

declined to “stay” the case, and instead set a roughly six-week schedule on an “Order to Show Cause” why it should not grant Attoney General’s petition. The appellate court hearing and decision are not expected until later this summer.

In the interim, Judge Ottolia’s decision has taken effect as of May 24, meaning that the law has been invalidated. Judge Ottoli also set a hearing for June 30, when he will consider the Attorney General’s request to vacate the judgment, which would also reinstate the law. So it remains to be seen whether the legislative procedural flaw will be fatal to the End of Life Options Act. If occurs, the State of California is likely to reinstate the law based on public support for the law and support from political leade but the process could take many months to be resolved, extending the uncertainty.

Physician-assisted suicide opens up the potential risk o civil liability suits

How should physicians who treat terminally ill patients and advise their families interpret these decisions? What risks are there physicians who have advised or continue to advise patients? Since the law is no longer in effect, physicians who continue to prescribe drugs are no longer guaranteed immunity from review going forward. Physicians have no need to worry about prescriptions made prior to May 24, when the legal protection applied, but until the law is either reinstated or a new law is pas there are new risks to be considered. The support of the Attorney General for the law may make it unlikely for a state criminal prosecution or a Medical Board review (since the Board itself is represented by the Attorney General). At the same time, local district attorneys in some counties in California may be open to reviewing and investigating cases brought to their attention by people who object to assisted suicide. Moreover, the change in the legal status of physician-assisted suicide opens up the po risk of civil liability suits from family members or others who object to physician assistance in suicide.

For California healthcare providers treating terminally ill patients, both changes present good opportunities to consider risk iss in weighing options with patients and their families. In both cases, the coming months should bring greater clarity to the limits challenges involved in experimental therapies and assisted suicide.

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