

“RIGHT TO DIE” AND “RIGHT TO TRY”

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RIGHT TO DIE

My last two columns^{1,2} have been devoted to the subject of Physician-Assisted-Dying (PAD), also known as Death with Dignity or the Right to Die, which has been legal in Oregon for 18 years, and for lesser time periods in Washington, Vermont, Montana, and New Mexico. Having already explained why I favor legislation to permit PAD under carefully defined circumstances, I had not intended to devote further columns to the same subject, but a major development prompts me to comment further, albeit briefly.

First, even a casual observer of American society will have noticed that seemingly hardened public opinion can change to a new perspective with remarkable speed if the public's attention can be directed away from the emotional aspects of an issue and towards a rational analysis of its impact on individuals. On matters of public policy, the American public generally favors individual rights, freedom of choice, and "fairness," and in our current socially progressive era, if these instincts are aroused effectively a tipping point can be reached on some seemingly intractable social controversies. Gay marriage, for example, an impossible dream throughout our nation's history, has not only become the law of the land seemingly overnight, but it has garnered the support of a majority of the public.

That experience is why I consider it worth noting that in October 2015 Governor Jerry Brown of California signed a PAD bill into law.* By bringing to bear on this issue the position of the nation's most populous and sociologically influential state, California cannot fail to have an impact on the public debate about this controversial subject.

California is "sociologically influential" because the state has regularly been in the vanguard on major public policy issues, such as when it sets standards for automobile emissions, safety, and gas mileage; when it supports and incentivizes the use of renewable energy; or when it responds to environmental imperatives and establishes

standards for air quality and rules for water conservation. And when California gets out ahead of other states or even the federal government, the rest of the country finds it hard to ignore and usually catches up. After all, California has almost 40 million people (1/8th of the U.S. total of 320 million), and its gross domestic product of over \$2 trillion is more than 13% of the U.S. economy. If it were a country, California's economy would be the 8th largest in the world. Markets cannot ignore such a behemoth.

Finally, as a well-timed coda to this story, in October 2015 Medicare announced that starting Jan. 1, 2016 it would reimburse physicians for Advance Care Planning, i.e. discussion of end-of-life issues.

With the addition of California, PAD is now legal in states with a combined population of 54 million people under rules that vary only slightly. It seems likely that California's action will mark a tipping point that presages similar legislation in other states. For states like New York that are already considering such legislation, swift passage seems more likely.

Despite dissenting voices, the public will demand approval of PAD. Now that physicians are reimbursed for Advance Care Planning, many, perhaps most, will have more detailed discussions with patients about all their options. We've come a long way since Dr. Jack Kevorkian was hounded, castigated, and eventually imprisoned for actions that most would now see in a different light. My last column² reported the results of a Franklin and Marshall College poll of registered voters in Pennsylvania, which found that 57% felt that "doctors should be allowed to help terminally ill patients end their lives," only 35% felt they should not, and 8% were undecided.

RIGHT TO TRY

"Right to Try" laws, enacted in 24 states thus far, allow people with fatal illnesses to access medications not approved

*The bill was passed during a special legislative session, so under California law it will take effect when that session ends, which may not occur for three or more months.

**"The powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people."

by the FDA, provided the drugs have passed through Phase I safety trials. Insofar as their defiance of the federal government depends upon the principles of federalism enshrined in the 10th Amendment,** they are actually...analogous to Right to Die laws. Thus, although the federal government’s constitutional authority generally pre-empts state laws (which is the basis for the FDA’s authority to regulate use of medicines), states retain authority to protect the rights and health of their citizens. From a political perspective, some of the recent decisions by the U.S. Supreme Court that preserve the traditional authorities of the states in health care and education actually cut both ways. When the U.S. attorney general’s office challenged Oregon’s “Right to Die” law under the Federal Controlled Substances Act, the Court rendered a 6-3 decision in 2006 that narrowly construed the federal law, and asserted that regulation of medicine is traditionally entrusted to the states. Thus, a conservative decision legalized a liberal initiative.

The impetus for Right to Try is the assertion by its proponents (principally the Arizona-based, libertarian Goldwater Institute, which has actually drafted many of the legislative bills) that the well-known “compassionate use” exemption process is cumbersome and unwieldy. Actually, the FDA approves the vast majority of such requests—over 99 percent of nearly 1,900 applications last year. Between 2010 and 2014, the agency turned down only 33 requests, while it approved 5,995; in compelling circumstances applications were often approved in several days.

Critics argue that compassionate use involves such a tedious process that it is less helpful than it seems because most patients don’t bother to apply. Their assertion is difficult to substantiate, though they have naturally found a few patients (usually with cancer) who experienced dramatic improvement after obtaining a drug overseas that is unapproved and still in clinical trials in the United States. They hold these examples up as proof that “lives are being lost” because of the FDA, and seem unaware that for most chemotherapeutic agents statistically significant effectiveness is

usually not a matter of cure, but rather an additional period of survival that—depending on the power of the study—may be as short as a few weeks or months. Nonetheless, three federal lawmakers, with the help of the Goldwater Institute, have introduced a national version of the legislation in the U.S. House of Representatives.

Space does not permit me to explore many other questions about this initiative, such as whether removing patients from the pool of subjects eligible for randomization could undermine the randomized Phase II and Phase III trials that are essential to developing new drugs. The concern has also been expressed that an early complication in an unrandomized Right to Try patient could discourage FDA approval of the drug, but this argument seems specious since compassionate use poses the same risk.

Furthermore, this process inevitably involves physicians, who may then face a conflict because their desire to assist an individual patient could undermine the traditional process by which the effectiveness and regimens for new therapies are established.

In a counterpoint to his positive action on Right to Die, one week later Governor Jerry Brown vetoed Right to Try legislation because there already is a compassionate use alternative, and the FDA is rapidly streamlining the process. It should also be noted that the law Brown vetoed, like that of all the other states does not require that a manufacturer make available an investigational drug. It thus does not even convey a true “Right” to Try, but more like a Right to Apply.

We will follow with interest (and possibly comment about) future developments in this field.

CORRECTION

In the last issue (Fall 2015) a collating error resulted in printing the wrong references for the article on Lipid Management.³ The correct references are published with the article in the online edition.⁴

REFERENCES

1. Bonchek LI. Physician assisted dying. *J Lanc Gen Hosp.* 2015; 10(2):33-36
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3. Davis TM, Andersen RL, Hussar EF, et al. Lipid Management; current challenges of reaching consensus. *J Lanc Gen Hosp.* 2015 (3); 10:81-84.
4. <http://jlgh.org/Past-Issues/Volume-10--Issue-3/Lipid-Management.aspx>