Written by **Walter E. Williams** on June 11, 2014

Who Owns You?

Darcy Olsen, president of the Arizona-based Goldwater Institute, and Richard Garr, president of Neuralstem, a biotech company, wrote "Right to Try experimental drugs" in *USA Today* (5/28/2014). They pointed out that "this year, more than 5,000 Americans will lose their battle with ALS, commonly known as Lou Gehrig's disease." Up until recently, there was no medicine on the market that significantly improved the lives of ALS patients. But now there is one in clinical trials that holds considerable promise, but it has not been granted Food and Drug Administration approval. The average amount of time it takes to get a drug through the FDA approval process is 10 years. That's time that terminal patients don't have.

Legislators in Colorado, Louisiana and Missouri recently approved "Right to Try" legislation, and Arizona voters will vote on the measure this November. "Right to Try" is an initiative designed by the Goldwater Institute. It would give terminal patients access to investigational drugs that have completed basic safety testing. Under a doctor's supervision, people would be given the chance to try promising experimental drugs before they're given final FDA approval.

There's no denying that there's risk in taking a drug or medical procedure that hasn't completed clinical trials. The question is: Who has the right to decide how much risk a person will take — he or some faceless Washington bureaucrat? In my opinion, the answer depends upon the answer to the question: Who owns you? If one owns himself, then it is he who decides how much risk he takes. If government owns you, then you don't have the right to unilaterally decide how much risk you'll take.

The FDA's mission is to ensure the safety and effectiveness of pharmaceuticals. In doing so, FDA officials can make two types of errors. They can approve a drug that has unanticipated dangerous side effects, or they can disapprove or delay a drug that is both safe and effective. FDA officials have unequal incentives to avoid these two types of errors. If the FDA official errs on the side of under-caution — approving a dangerous drug — the victims are visible, and he is held directly accountable. If he errs on the side of over-caution — holding up approval of a safe and effective drug — who's to know? The cost and the victims are invisible. Politicians and bureaucrats prefer invisible victims.

Here are a couple of notable examples. Clozapine was approved and used in 1972 in Europe. Clozapine's ability to treat schizophrenics who did not respond to other medicines became well-known by 1979. Yet the drug was not approved in the United States until 1989 because companies believed that the FDA would reject it on the grounds that 1 percent of patients who took the drug contracted a blood disease. As an article in The New England Journal of Medicine stated, "what is remarkable is that clozapine has a beneficial effect in a substantial proportion (30 to 50 percent) of patients who have an

inadequate response to other … drugs." Nearly 250,000 people with schizophrenia suffered needlessly, when relief was at hand.

According to Robert M. Goldberg, writing for the journal Regulation, "Mevacor is a cholesterol-lowering drug that has been linked to reduction in death due to heart attacks. It was available in Europe in 1989 but did not become available in the United States until 1992. Studies confirm what doctors saw to be the case: taking the drug reduces death due to heart disease by about 55 percent. During that three-year period as many as a thousand people a year died from heart disease because of the FDA delay."

There is self-correction when a drug that has unanticipated dangerous side effects has been marketed. The drug is removed. But there's no self-correction when a safe, effective lifesaving drug is not approved or is delayed. Those 5,000 ALS patients who will die of their disease this year are invisible, and FDA officials are unaccountable. "Right to Try" legislation is a step in the right direction to remedy that.

Walter E. Williams is a professor of economics at George Mason University. To find out more about Walter E. Williams and read features by other Creators Syndicate writers and cartoonists, visit the Creators Syndicate Web page at www.creators.com.

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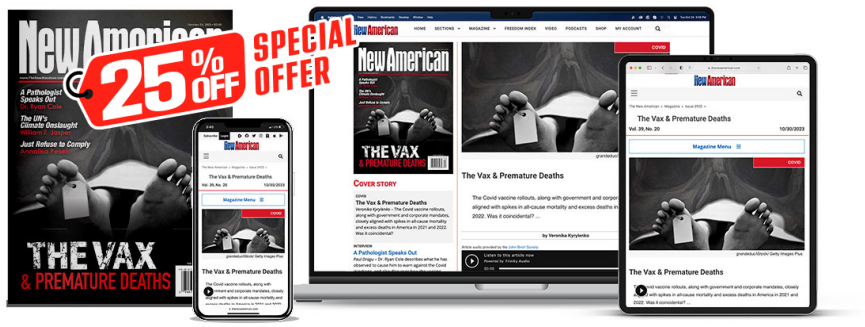

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