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Written by **Walter E. Williams** on October 15, 2014

FDA: Officially Killing Americans

The Food and Drug Administration can make two types of errors. It can approve a drug that has dangerous unanticipated side effects, or it can reject or delay approval of a drug that is safe and effective. Let's look at these errors, because to err on the side of under- or over-caution is costly.

It's in an FDA official's self-interest to err on the side of over-caution. People who are injured by incorrectly approved drugs — and their families — will know that they are victims of FDA mistakes, or under-caution. Their suffering makes headlines. FDA officials face unfavorable publicity, perhaps congressional hearings and possible termination.

The story is very different when the FDA incorrectly delays or denies drug approval — errs on the side of over-caution. Here victims are people who are prevented access to drugs that could have helped them. Their suffering or death is seen as reflecting the state of medicine rather than the status of an FDA drug application. Their doctor simply tells them there's nothing more that can be done to help them. This kind of FDA victim is invisible.

Dr. Henry I. Miller is a medical researcher, a 15-year veteran of the FDA and now a research fellow at Stanford University's Hoover Institution. He has an article in the *New York Post* titled "Life-saving drugs and deadly delays" (9/28/2014). He says that the FDA has just granted expanded access to an experimental drug for the Ebola virus. Safety and efficacy testing of the drug TKM-Ebola has barely begun, and there have been no clinical trials. Miller says, "It's OK as far as it goes, but it's an exception to the FDA's reluctance to approve the use of life-saving products."

Miller asks, "Why expend the agency's time and energy on a drug that will be used rarely, if at all, in the United States?" He asks us to consider the case of Bexsero, a vaccine for meningitis B. Bexsero has been approved by the European Union, Australia and Canada but hasn't been approved by the FDA, even though outbreaks occur on U.S. college campuses, recently killing a Georgetown University student. FDA policy is responsible for the death of that student, but you won't hear anything about it.

As early as 1974, FDA Commissioner Alexander M. Schmidt said: "In all of FDA's history, I am unable to find a single instance where a congressional committee investigated the failure of FDA to approve a new drug. But the times when hearings have been held to criticize our approval of new drugs have been so frequent that we aren't able to count them. The message to FDA staff could not be clearer." In other words, no problem as long as the victims are invisible.

Citizens have taken some initiative. Miller points to a mother of a University of California, Santa Barbara student who sent her son to England to be immunized with Bexsero. The mother of a woman who died from meningitis B organized bus trips for dozens of people, mostly college-age kids, to

Windsor, Ontario, where she arranged for the group to be seen by a doctor and vaccinated.

Miller cites the case of pirfenidone, a drug that treats idiopathic pulmonary fibrosis, which kills tens of thousands of Americans each year. Pirfenidone has been marketed in Europe (since 2011), Japan (2008), Canada (2012) and China. The FDA has yet to approve pirfenidone for use in the U.S. Miller guesses that it will approve the drug by the end of this year. The FDA's four-year approval delay has led to the deaths of 150,000 Americans from idiopathic pulmonary fibrosis.

Miller's *New York Post* article points to the needless death and suffering from other FDA approval delays. I have two recommendations. If U.S. doctors know that a lifesaving drug has been approved in Europe, Japan and Canada, it is their ethical duty to inform their patients. Second, when the FDA calls a news conference to announce approval of a drug, somebody should ask the official how many Americans died from the drug's not being approved the previous year.

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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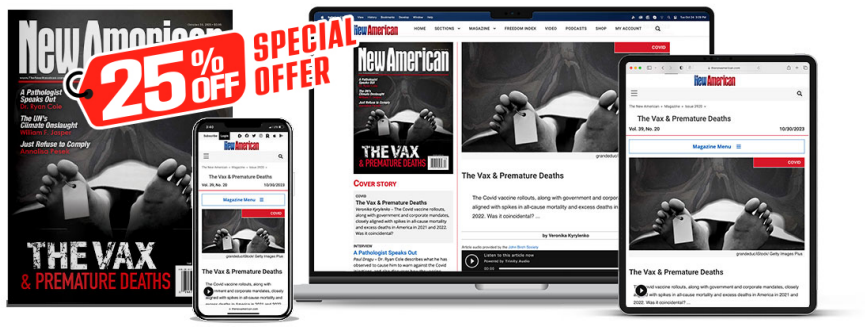

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