Written by **Walter E. Williams** on February 9, 2011

FDA: A Killer Agency

Sam Kazman's "Drug Approvals and Deadly Delays" article in the *Journal of American Physicians and Surgeons* (Winter 2010), tells a story about how the U.S. Food and Drug Administration's policies have led to the deaths of tens of thousands of Americans. Let's look at how it happens.

During the FDA's drug approval process, it confronts the possibility of two errors. If the FDA approves a drug that turns out to have unanticipated, dangerous side effects, people will suffer. Similarly, if the FDA denies or delays the marketing of a perfectly safe and beneficial drug, people will also suffer. Both errors cause medical harm.

Kazman argues that from a political point of view, there's a huge difference between the errors. People who are injured by incorrectly approved drugs will know that they are victims of FDA mistakes. Their suffering makes headlines. FDA officials face unfavorable publicity and perhaps congressional hearings.

It's an entirely different story for victims of incorrect FDA drug delays or denials. These 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.

Beta-blockers reduce the risks of secondary heart attacks and were widely used in Europe during the mid-'70s. The FDA imposed a moratorium on beta-blocker approvals in the U.S. because of the drug's carcinogenicity in animals. Finally, in 1981, FDA approved the first such drug, boasting that it might save up to 17,000 lives per year. That meant as many as 100,000 people might have died from secondary heart attacks waiting for FDA approval.

In the early 1990s, it took the FDA more than three years to approve interleukin-2 as the first therapy for advanced kidney cancer. By the time the FDA approved the drug, it was available in nine European countries. The FDA was worried about the drug's toxicity that resulted in the death of 5 percent of those who took it during testing trials. This concern obscures the fact that metastatic kidney cancer has the effect of killing 100 percent of its victims.

Kazman says that if we estimate that interleukin-2 would have helped 10 percent of those who would otherwise die of kidney cancer, then the FDA's delay might have contributed to the premature deaths of 3,000 people. Kazman asks whether we've seen any photos or news stories of the 3,000 victims of the FDA's interleukin-2 delay or the 100,000 victims of the FDA's beta-blocker delay.

These are the invisible victims of FDA policy. In the 1974 words of FDA commissioner Alexander M. Schmidt: "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."

That message is to always err on the side of overcaution where FDA's victims are invisible and the agency is held blameless.

Kazman's day job is general counsel for the Washington, D.C.-based Competitive Enterprise Institute that's done surveys of physicians and their views of the FDA. On approval speed, 61 to 77 percent of physicians surveyed say the FDA approval process is too slow. Seventy-eight percent believe the FDA has hurt their ability to give patients the best care.

But so what? Physicians carry far less weight with the FDA than "public interest" advocates and politicians.

When the FDA announces its approval of a new drug or device, the question that needs to be asked is: If this drug will start saving lives tomorrow, how many people died yesterday waiting for the FDA to act?

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