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FDA Fails to Withdraw Unproven Drugs

Written On October 27, 2009 By Bob Kraft

Did you know that the Food and Drug Administration has never pulled a drug off the market simply because the drug doesn't provide the benefits the manufacturer claimed it would? I have to admit I didn't know that either, until I read an Associated Press article about an upcoming report from the Government Accountability Office. That's just shocking. The most common situation is that the drug manufacturer never provides follow-up information to the FDA to prove the effectiveness of the drug. But even in situations where a later study showed the drug did not provide benefits, the FDA has allowed the drug to remain on the market. Here are excerpts from the article:

The Food and Drug Administration has allowed drugs for cancer and other diseases to stay on the market even when follow-up studies showed they didn't extend patients' lives, say congressional investigators.

A report due out Monday from the Government Accountability Office also shows that the FDA has never pulled a drug off the market due to a lack of required follow-up about its actual benefits — even when such information is more than a decade overdue.

When pressed about that policy, agency officials said they have no plans to get more aggressive.

The GAO says the FDA should do more to track whether drugs approved based on preliminary results actually have lived up to their promise.

"FDA has fallen far short of where it should be for patient safety," said Sen. Charles Grassley, R-Iowa, who requested the investigation.

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Of the 144 studies the FDA has required under the program since 1992, 64 percent have been completed and more than one-third are still pending, according to the GAO. Investigators said the FDA does not rigorously track whether companies are making progress on their required studies, although the agency is improving.

FDA officials say they have overhauled their tracking system since the GAO completed its report. And an outside analysis by contractor Booz Allen Hamilton concluded last month that most companies are meeting their study requirements on time.

But in the case of Shire Laboratories' low blood pressure treatment ProAmatine, the required study has gone incomplete for more than 13 years. The GAO found that ProAmatine has generated more than $257 million in sales, even though "the clinical benefit of the drug has never been established."

In other cases, the FDA has failed to act even when company studies show drugs did not improve patient outcomes.

The FDA approved AstraZeneca's lung cancer drug Iressa in 2003 based on early results showing it reduced the size of tumors. But later studies showed the drug did not significantly extend patient lives.

The FDA has left the drug on the market, despite hundreds of reports of a sometimes fatal pneumonia.

"The FDA has talked a lot about doing more enforcement, but this is an area where they're basically defending not enforcing the law," said Dr. Sidney Wolfe, of the consumer advocacy group Public Citizen.

Wolfe said the lax policy sends a message to companies that there is no penalty for failing to complete studies.

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