FDA issues hold on much-debated Avandia study

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In this June 30, 2010 file photo, a pharmacist holds a bottle of Avandia pills at Maximart Pharmacy in Palo Alto, Calif. Federal health officials say new patients should not be enrolled in a study of GlaxoSmithKline's controversial diabetes pill Avandia, after experts last week said the drug increases heart risks. (AP Photo/Paul Sakuma, file)

(AP) -- Federal health officials are barring new patients from enrolling in a safety study of GlaxoSmithKline's controversial diabetes pill Avandia, a week after a panel of experts ruled that the drug increases heart risks.

The Food and Drug Administration said it issued a "partial clinical hold" on the study to update researchers on the latest concerns about Avandia, which has been under scrutiny since 2007.

Last week a panel of experts voted that the drug appears to increase heart risks, but they ultimately voted to leave the drug on the market because the evidence was not definitive.

The FDA is currently reviewing the panel's opinions and deciding what action to take.

GlaxoSmithKline said in a statement it would halt recruitment for the so-called TIDE trial and update the study's chief investigators on last week's meeting. Patients already in the study will be permitted to continue participating.

The London-based drugmaker agreed to conduct the trial in 2007, after safety questions about Avandia were first publicized.

The TIDE study is designed to give a definitive picture of whether Avandia's heart risks are greater than its chief competitor Actos.

Last week, the FDA's panel of outside advisers voted 20-10 that the trial should continue if Avandia stays on the market.

However, Avandia's critics have argued that the trial is unethical since current evidence already shows Avandia is riskier than Actos, which is made by Japan-based Takeda Pharmaceuticals.

"It's the ethically correct thing to do," said Dr. Steven Nissen, chairman of cardiovascular medicine at the Cleveland Clinic. "It was the only decision the FDA could have made."

Nissen first drew attention to Avandia's risks in a 2007 medical journal article estimating the drug increases heart attack risk by 43 percent. He noted that the FDA's advisory panel specifically voted last week that Avandia increased risk of heart attacks more than Actos.

"I still think there's a very good chance that the FDA will decide to remove Avandia from the market," Nissen said.

The TIDE study is supposed to enroll 16,000 patients, though safety concerns surrounding Avandia have slowed recruitment. Glaxo reported last week that just 1,100 patients have volunteered for the study.

The FDA first approved Avandia in 1999 and it quickly became the top-selling diabetes pill in the world. However, U.S. sales have plummeted from $2.2 billion in 2006 to $520 million last year as safety concerns swirled around the drug.

The drug works by increasing the body's sensitivity to insulin, a key protein needed for digestion that diabetics don't adequately produce.

The FDA added a black box warning to the drug in 2007. New studies on the drug's safety combined with pressure from safety advocates has prompted the agency to take another look at the drug.

The FDA is expected to make a decision on whether to keep the drug on the market in coming months.