FDA panel: Diabetes drug should stay on market

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FILE - In this June 30, 2010 file photo, a pharmacist holds a bottle of Avandia pills at Maximart Pharmacy in Palo Alto, Calif. Federal health advisers discuss whether GlaxoSmithKline's diabetes pill Avandia should be pulled from the market. The one-time-blockbuster drug's sales have shrunk markedly since studies suggested potential ties to heart attacks. (AP Photo/Paul Sakuma, file)

(AP) -- A majority of federal health experts voted Wednesday to keep the controversial diabetes pill Avandia on the market despite evidence that it increases the risk of heart attack.

A panel of Food and Drug Administration advisers voted 20-12 against withdrawing GlaxoSmithKline's once-blockbuster drug. Panelists who voted to keep the drug on the market were split between several options, including adding new warning labels and restricting use of the drug.

The vote marks a win for British drugmaker Glaxo, which has been battered in the press and on Capitol Hill for its the handling of the drug.

The FDA is not required to follow the advice of its panelists, though it usually does. Officials said they would review the meeting transcript and make a decision on Avandia as soon as possible.

The vote also came despite an earlier ruling by the panel that Avandia appears to increase heart attack risk compared with other diabetes treatments. The panel voted 21-4 that Avandia is more likely to cause heart attack than its closest competitor Actos. Eight panelists said there was not enough information to make a decision.

Ultimately though, panelists said the dozens of contradictory studies of Avandia didn't show strong enough evidence to justify removing a drug used by hundreds of thousands of patients.

"I would be concerned about the precedent that would be set to have this quality of data sufficient to remove a drug," said John Teerlink of the University of San Francisco.

The agency convened the two-day panel meeting to help untangle reams of conflicting data over Avandia.

The FDA has been down this road before. Three years ago a similar FDA panel voted to keep Avandia on the market and the FDA responded by adding bolder warning labels to the drug.

"In terms of what has changed since 2007, I think the totality of evidence is much stronger," said panelist Clifford Rosen of the Maine Medical Research Institute. "It's still not absolute but it's stronger. Clearly there is a signal."

Despite the vote on Avandia's heart risks, panelists didn't reach a firm conclusion on whether Avandia is more likely to cause death than older drugs. Twenty panelists said it did not appear to cause death, while 12 said they didn't know. Only one panelist concluded the drug leads to death.

The panel's vote to keep Avandia on the market is

a vote of confidence in FDA leadership, who have been criticized by some members of Congress for not pulling the drug earlier.

Minutes before the final vote on Avandia, the FDA's director for new drugs emphasized the high bar needed to pull a previously approved drug from the market.

"The two that have been withdrawn for cardiovascular concerns - Vioxx and Zelnorm - showed three, four or five fold-increase," said John Jenkins "That's the background of where we stand in terms of increased risk of very rare events."

Since diabetics are already predisposed to heart risks it is extremely difficult to tell which heart attacks are drug-related and which are simply a result of the underlying disease.

The task of evaluating the possible side effects across dozens of studies has dragged on for years without definitive answers.

Panelists sat through about a dozen FDA presentations over the course of two days that often contradicting each other.

FDA reviewer David Graham told the panel Avandia's risks were real enough "to put you in a hospital or a cemetery."

Graham, who wants the pill banned, recently published an analysis estimating that as many as 100,000 heart-related problems may have been caused by Avandia among seniors on Medicare.

But higher ranking FDA officials played down the drug's risks, pointing out that clinical trials have not shown increased risk of heart attack or death with Avandia. Considered the gold standard of medical research, clinical trials randomly assign patients to receive one of two drugs and follow them to see how their health fares.

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