FDA review spotlights heart risk of diabetes pill

July 9 2010, By MATTHEW PERRONE , AP Business Writer

(AP) -- A review by federal health scientists reinforces potential ties between the diabetes pill Avandia and heart attack and death, opening the door for government action, including a possible withdrawal of the once blockbuster drug.

The FDA posted an exhaustive 700-page review of the GlaxoSmithKline drug online Friday ahead of a meeting next week to review the safety of Avandia, which is used by hundreds of thousands of diabetics in the U.S.

The FDA holds a special two-day meeting starting Tuesday to help decide what course of action to take. A panel of outside expert physicians will vote on a range of recommendations including:

- adding additional warning labels to the drug

- allowing only certain doctors to prescribe the drug

- pulling the drug from the market

The FDA is not required to follow the advice of its outside panels, though it usually does.

Part of the reason the FDA is seeking outside advice is because of disagreements among its own scientists.

"There's not complete unanimity within the FDA about interpretation of

these data and that's one of the reasons we're going to the advisory committee," said Dr. Janet Woodcock, head of the FDA's drug center.

Avandia was Glaxo's third best-selling drug in 2006 with U.S. revenue of $2.2 billion, according to health care statistics firm IMS Health. But safety concerns swirling around the drug have pummeled sales since 2007, with sales falling 75 percent to $520 million last year.

In 2007 an analysis of dozens of studies first linked the drug to heart attacks. The FDA responded by adding a warning label to the drug later that year.

But new data on Avandia's risks and pressure from Capitol Hill have prompted the agency to re-examine the drug's safety.

Despite the drop off, Avandia is still used by hundreds of thousands of Americans with type 2 diabetes to control blood sugar levels. The drug works by increasing the body's sensitivity to insulin, a key protein needed for digestion that diabetics lack.

That sort of treatment has long been presumed to lessen the heart risks already associated with the disease.

But critics of Avandia, including a high-profile FDA scientist, argue there are safer alternatives to GlaxoSmithKline's drug.

Last month a leading medical journal published an analysis suggesting Avandia is more likely to cause strokes and heart-related death than a rival drug, Actos.

The paper's author Dr. David Graham, the FDA scientist who wants the pill banned, estimated as many as 100,000 heart-related adverse events may have been caused by Avandia during its time on the market.

Graham and several colleagues analyzed medical records of more than 225,000 elderly Medicare patients taking Actos or Avandia.

Actos is made by Japan-based Takeda Pharmaceuticals and has gobbled up 70 percent of the market for diabetes drugs in Avandia's class. Avandia currently holds just 11 percent of the U.S. market.

In morning trading, shares of U.K.-based GlaxoSmithKline slipped 65 cents to $34.26.