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FDA Advisory Panel on Avandia: Wrap Up

If you've been keeping up with our blog or Twitter feed this week, you have seen that we are keeping up with all the news and opinion from the FDA Advisory Panel Meeting on the diabetes drug Avandia. Now that the meetings are over what is the fallout and what does this mean for the future of the drug?

If you checked out some of the news we linked yesterday, you might have been confused. While the panel expressed concern about the safety of the drug after seeing reports and evidence of its elevated risks, they still, by majority vote, decided to leave the drug on the market. The only difference is that the drug will have the carry stricter restrictions and warnings. Now, only certain doctors may be able to prescribe Avandia and special education may be required by both doctor and patient before the drug is prescribed.

The FDA Advisory Panel also voted to continue with a Glaxo-sponsored clinical trial of Avandia. This trial will compare the cardiovascular risk of Avandia against its biggest competitor, Actos. It will take years to see the results from this trial.

QUOTES:
"I did not think the that the evidence was strong enough to suggest that the drug should be taken off the market, but the preponderance of studies all suggested that there is relative risk"
-Dr. Allison Goldfine, assistant director of clinical research at the Joslin Diabetes Center

"It would be very, very restrictive, essentially 95% of the use of this drug will go away if the [FDA] chooses that option."
- Dr. Steven Nissen, a cardiologist at Cleveland Clinic

"Per Sr Mgmt request, these data should not see the light of day to anyone outside of GSK,"
- GlaxoSmithKline internal e-mail discussing negative data about Avandia