FDA Discredits Avandia Safety Study

By Catherine Bertram - 7/14/2010

Dr. Thomas Marciniak, a reviewer for the U.S. Food and Drug Administration, has sharply critiqued GlaxoSmithKline's clinical trial of Avandia, GlaxoSmithKline's popular diabetes drug. The study flatly ignored 12 instances of heart problems among the participants. Studies have demonstrated that Avandia also increases the risk of fractures, swelling, heart attacks, strokes, and death. One patient in the study suffered a brain bleed, but the records of this complication were reportedly deleted. Another patient spent nine weeks in the hospital for a stroke, but that patient's records apparently did not reflect the catastrophic event.

GlaxoSmithKline's spokesperson was reported as responding by defending the study, “The Record study was conducted according to good clinical practices and the data are reliable.”

The FDA's safety panel is meeting this week to decide whether Avandia, which had sales of $3.2 billion in 2006, should be pulled from the market or whether the warnings need to be strengthened regarding the complications associated with this medication.