

# Diabetes Drugs Need Tougher Testing for Heart Risk, FDA Panel Says

Jul 7, 2008

Last week, a Food & Drug Administration (FDA) advisory panel voted to back tougher testing requirements for diabetes drugs. In a 14-2 vote, which came late last Wednesday at the end of 2-day meeting, the outside experts recommended that diabetes drugs undergo more thorough safety reviews to ensure they don't raise the risk of heart problems. The panel also recommended that after approval, the makers of diabetes drugs conduct long-term studies to assess heart risks, even if initial clinical trials have not turned up such issues.

The FDA decided to take a look at diabetes drug testing after one popular medication - Avandia - was linked to an increased risk of heart attacks. Currently, the FDA requires the makers of diabetes drugs to prove they lower blood sugar levels. This outcome is known as a surrogate endpoint, because it was thought that lowering blood sugar would have a positive effect on cardiac risks and life span - the true goals of a diabetes drug. But the Avandia debacle has led many experts to call on the agency to require drug makers to meet other bench marks, including whether they reduce the risk of cardiovascular problems - the number one killer of diabetics.

Last Tuesday, Dr. Stephen Nissen, whose study published last May uncovered the Avandia safety issues, told the FDA advisory panel that it was time to toughen testing standards. "Merely lowering blood-glucose levels in diabetes is too simplistic," Dr. Nissen said. "We must reduce the complications of diabetes, including cardiovascular disease." Cardiovascular disease is the leading cause of death among diabetics.

The FDA panel did not recommend that diabetes drugs should show a benefit to patients' cardiovascular health, citing FDA evidence that no diabetes drug has shown such a benefit.

Drug makers are less than happy about this development. If the FDA adopts the panel's recommendations, additional clinical trials could add years and millions of dollars to the development of any new type 2 diabetes drug.

The FDA is not bound to follow recommendations from its advisory panels, but in most cases, it does so.