

# Avandia Researcher Calls for More Studies of Diabetes Drugs

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A prominent cardiologist told federal regulators yesterday that new diabetes drugs should be tested to insure that they don't cause heart problems. Dr. Stephen Nissen, the lead researcher on a study that found Avandia increased heart attack risks, told a Food & Drug Administration (FDA) panel considering new rules for the drugs that it is high-time the agency toughened requirements for new diabetes drugs.

Currently, the FDA only requires that the makers of new diabetes drugs to prove that they lower blood sugar levels before they are approved. But Dr. Nissen told the FDA panel that there are enough drugs on the market now that lower blood sugar very well.

"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.

In addition to more pre-approval studies, Dr. Nissen said drug makers should also be required to conduct large, long-term studies to monitor whether the drug increases the risk of cardiovascular disease after it has been approved.

Evaluating a diabetes drug by its ability to control blood sugar is known as a surrogate endpoint. In clinical trials, a surrogate endpoint is a measure of effect of a certain treatment that may correlate with a real endpoint but doesn't necessarily have a guaranteed relationship. For instance, it was widely assumed that lowering blood sugar would decrease the risk that a diabetic patient would develop heart disease.

But recent research has shown that is not always the case. Dr. Nissen's Avandia study, published last May, found that while Avandia lowered blood sugar, it might actually increase heart attack risks by as much as 43 percent. According to the Wall Street Journal, no drug that regulates sugar levels has shown beneficial cardiac effects in Type 2 diabetics, who make up more than 90% of all diabetes patients.

The FDA is reevaluating its reliance of surrogate endpoints in the wake of several drug safety scandals, including the one surrounding Avandia. The practice of allowing surrogate endpoints to approve new drugs was also questioned this year when Vytorin, a blockbuster cholesterol lowering medication, was found to be ineffective in preventing clogged arteries. Vytorin had been approved on the basis that it lowered bad cholesterol. It was thought that would correlate to a decrease in the amount of arterial plaque in patients taking the drug. But a study released in January showed that assumption to be wrong.