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Diabetes Drug Tied to Heart Attack Risk

"Without being able to give a firm recommendation at this point... patients should talk to their doctors about this data," he said.

The findings prompted new calls to overhaul the drug safety system, which has come under intense criticism after a series of revelations about the dangers of widely used drugs, most notably the arthritis drug Vioxx.

"Here we have yet another example of a very commonly used drug taken by millions and millions of patients that has important safety concerns that the FDA has missed for years and years and years," said Jerome L. Avorn of Harvard Medical School. "How many of these do we really need to happen before we step back and do something?"

Congress is considering legislation that would give the FDA new powers to monitor drug safety. Avorn and others called for empowering the agency to require pharmaceutical companies to conduct follow-up research on drugs, especially those that are approved quickly.

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"Large long-term trials evaluating the risks and benefits of drugs like this need to be done as soon as possible. Here we have a case where we're eight years out and we're just now finding out about this," Psaty said.

Several members of Congress expressed concern about the new report, including Rep. Henry Waxman (D-Calif.), who announced plans to hold a hearing June 6 on the FDA's oversight of the drug.

Avandia was approved in 1999 for patients suffering from type 2 diabetes, which affects 20 million people and causes blood sugar to rise to dangerous levels, increasing the risk for a number of complications. The drug helps control blood sugar levels by increasing the effectiveness of insulin produced by the body.

Nissen said he became concerned about the drug's safety after noticing indications that people taking the drug might have an increased rate of heart attacks. Working with a colleague, Nissen analyzed 42 studies that have been conducted on the drug, pooling the data to examine the risks.

In a paper that will be published in the June 14 issue of the journal, Nissen and his colleague found a 43 percent increase in risk of heart attacks; the finding was considered statistically significant. They also found a 64 percent increased risk of death from any form of cardiovascular disease, including heart attacks and strokes. In that analysis, the conclusion fell just shy of being statistically significant.

Nevertheless, Nissen and others said the findings are worrisome, because diabetics already are at increased risk because of their disease.

Nissen previously had found a similar risk for a related drug, called Pargluva, that the FDA was poised to approve. That drug was not approved.

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that there may be an increased risk for heart problems from the drug in a similar analysis the company submitted to the FDA in August. But when company officials analyzed a number of other large studies, including large ongoing studies monitored by independent safety experts, they found no such risk.

"We place great weight on long term observational studies," Krall said. "Those studies have not shown evidences of an increased risk."

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