

First Avandia Lawsuits Filed, Many More Expected

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Avandia lawsuits against GlaxoSmithKline over the drugs alleged cardiac side effects are beginning to make their way through the courts, and many more are expected. One man is suing GlaxoSmithKline in federal court, claiming Avandia caused him to undergo heart bypass surgery. Attorneys allege the drug maker should have known that Avandia—prescribed to improve blood sugar in type 2 diabetes patients—is linked to a significant and increased risk of heart failure, heart attack, and stroke.

The lawsuit is among several filed nationwide targeting Avandia and Glaxo; it is believed there are thousands yet to be filed. Over six million Americans used the drug and concern about Avandia is nothing new. The connection between Avandia and increased heart failure risk has been known since 1999 when the drug was first approved. Avandia sales have plummeted since publication in *The New England Journal of Medicine* linking Avandia with increased risk of heart attack and failure, but Nancy Pekarek, spokeswoman for GlaxoSmithKline, said the company stands by Avandia, "We are certainly confident that when the courts or the juries look at the clinical data, the responsible way in which we communicated that information, and our openness in posting our clinical trial data online, they will see our position," she said. The lawsuit alleges that the company "had the knowledge, the means, and the duty to provide the medical community and the consuming public with more accurate descriptive information and more adequate warnings regarding the association between Avandia and heart failure..."

Pat Kelly, 59, said he took Avandia led to painful heart trouble and heart bypass surgery in 2007. Kelly had over 40 years in the auction business and frequently traveled nationwide for his work, but says he has no energy and no jobs. "To put it bluntly, I went from a hero to a zero. I simply don't have the energy that I did. I don't have the stamina I did," he said. "My God, how many other people has (the drug) touched?" Kelly wonders. Avandia breaks down the body's resistance to insulin but has long been known to cause fluid retention, a major risk factor for congestive heart failure.

The Food & Drug Administration (FDA) refuses to withdraw Avandia from the market, but has asked Glaxo to conduct a long-term study comparing Avandia with other type 2 diabetes drugs. The trial will likely commence in a year; however, full results are not expected until 2014. Patient advocates and FDA critics consider the recent black box warning—the strongest warning for a drug—for Avandia a feeble response to Avandia's safety issues, requesting it be pulled from the market. Meanwhile, the American Diabetes Association and the European Association for the Study of Diabetes released a revised consensus statement stating that emerging information suggests additional hazards associated Avandia and may result in increased risk of myocardial infarctions. The US Department of Veterans Affairs announced it was dropping Avandia from its drug formulary because, in some, Avandia did not afford the same margin of safety as other diabetes drugs. A Congressional Committee Report found Glaxo executives intimidated a diabetes expert into keeping quiet about Avandia's safety problems.