

[When Considering A Possible Avandia Recall, Liver Injury Side Effects Should Be A Factor](#)

Heart Risk Is Current Focus Due To GlaxoSmithKline Past Conduct; But Public Citizen Has Pointed The Liver Failure Case Reports Linked To Avandia, Also

(Posted by Tom Lamb at www.DrugInjuryWatch.com on February 23, 2010; see <http://bit.ly/aWJMR6>)

As some of you may recall, [in October 2008 Public Citizen petitioned the FDA to ban the sale of the diabetes drug Avandia \(rosiglitazone\) in the U.S.](#) because its risks, which include heart attack and heart failure in addition to liver toxicity, far outweigh its benefits and because much safer alternatives exist for treating Type 2 diabetes.

To our knowledge, there is still no word from the FDA about how long the agency will need to make a determination on the Avandia recall requested by Public Citizen.

More recently, in late July 2009, a new medical journal article about Avandia and liver failure was published in *Pharmacoepidemiology and Drug Safety*. This article, "[Case series of liver failure associated with rosiglitazone and pioglitazone.](#)" -- by James S. Floyd, MD, Elizabeth Barbehenn, PhD, Peter Lurie, MD, MPH, and Sidney M. Wolfe, MD, of Public Citizen's Health Research Group -- seemingly adds further support to the contention that Avandia can cause liver failure and should be recalled by the FDA.

Soon thereafter a July 22, 2009 press release, "[Rigorous Study Adds to Case That FDA Should Ban the Diabetes Drug](#)", was issued by Public Citizen in connection with this new Avandia medical journal article.

Those few items, above, suggest that the serious liver injury risk associated with Avandia could (and should) be a factor in the FDA's determination about whether to order an Avandia recall, or not.

As far as when any Avandia recall determination will be made by the FDA, currently it seems this issue will have to wait until a joint public meeting of the Endocrinologic and Metabolic Drugs and Drug Safety and Risk Management Advisory Committees in July 2010. At that FDA meeting, the Advisory Committee will provide an updated assessment of the risks and benefits of Avandia.

Returning to the present, during this past week almost all (if not all) of the Avandia safety debate has had to do with the cardiac risks linked to Avandia, namely heart attacks and heart failure.

First, there was a February 19, 2010 *New York Times (NYT)* article, "[Research Ties Diabetes Drug to Heart Woes](#)", by Gardiner Harris, which was based on "internal FDA reports" and a [January 2010 Senate Committee on Finance staff report about Avandia](#) which concludes: "The totality of evidence suggests that [GlaxoSmithKline] was aware of the possible cardiac risks associated with Avandia years before such evidence became public."

Immediately afterward, in two separate press releases, GlaxoSmithKline (GSK) [disputed the reports set forth in the February 19 NYT article](#) and [took issue with the conclusions of the Senate Committee's Avandia report](#). Essentially, the party line for GSK is that "the scientific evidence simply does not establish that Avandia increases ischemic cardiovascular risk or causes myocardial ischemic events."

And then there is renowned cardiologist Steven Nissen, of the Cleveland Clinic, who has been vocal critic of Avandia due to safety reasons. To learn more about Dr. Nissen's position on Avandia, we refer you to these two items:

- 1) A February 23, 2010 *New York Times (NYT)* story, "[A Face-Off on the Safety of a Drug for Diabetes](#)", by Gardiner Harris, again; and,

2) This recent medical journal article from *European Heart Journal*, "[The rise and fall of rosiglitazone](#)", by Steven E. Nissen -- Advance Access published February 12, 2010 (includes a 1999-2009 timeline).

[Our law firm is continuing to investigate Avandia injury and death cases](#) involving liver failure as well as heart attack or heart failure.

Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
<http://www.DrugInjuryWatch.com>