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Will New Black Box Warning About Heart Attacks Lead GlaxoSmithKline To Withdraw Avandia From Market? powered by BlogBurst

POSTED: Friday, November 09, 2007

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

The following blog post is from an independent writer and is not connected with Reuters News. The opinions and views expressed herein are those of the author and are not endorsed by Reuters.com.

One Wonders Whether GSK Might Do A "Soft" Recall Of Its Embattled Diabetes Drug, As Was Done By BMS With Serzone And Tequin In Recent Years (Posted by Tom Lamb at [DrugInjuryWatch.com](#))

Avandia (rosiglitazone) is a prescription drug from GlaxoSmithKline (GSK) approved by the FDA in 1999 to treat Type 2 diabetes. As many people are aware now, while Avandia might have helped diabetic patients in some regards, it seems that this benefit comes at an increased risk of developing serious heart-related side effects including heart attacks and strokes.

The [Avandia safety story started for most of us in May 2007](#), as follows:

On May 21, 2007 the Los Angeles Times published an Associated Press (AP) article entitled "Diabetes drug linked to heart attack risk" which broke the story about a new analysis of Avandia data that was published online earlier this same day by the New England Journal of Medicine (NEJM). The new Avandia article, "Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death", by Steven E. Nissen, M.D., and Kathy Wolski, M.P.H., will appear in the June 14, 2007 print edition of the NEJM.

More recently, on November 6, 2007 Health Canada issued a MedEffect email alert about Avandia -- as well as the related Avandamet and Avandaryl -- to inform us that GlaxoSmithKline is informing Canadian doctors and patients about new restrictions on the use of its rosiglitazone products (Avandia, Avandamet and Avandaryl) due to "cardiac safety concerns".

More detail was provided in the [November 2007 Public Communication document about Avandia](#) posted by Health Canada:

- Rosiglitazone (Avandia®) is no longer approved for use alone to treat type 2 diabetes, except when metformin* use is contraindicated or not tolerated.
- Rosiglitazone is no longer approved for use with a sulfonylurea drug** (such

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- as glyburide), except when metformin is contraindicated or not tolerated.
- Rosiglitazone should not be used if you have heart failure, or have experienced heart failure in the past.
 - Patients who are taking rosiglitazone, especially those with underlying heart disease, or those who are at high risk of heart attack or heart failure, should talk to their doctor about the benefits and risks of continuing rosiglitazone therapy.

There was also a [November 2007 "Dear Doctor" letter about Avandia posted on the Health Canada web site.](#)

Two weeks before this news from Health Canada, in the U.S. the FDA had announced that it wanted Glaxo to add a "black box" warning about the increased heart attack associated with Avandia, according to an [October 24, 2007 article in *The Wall Street Journal*, "Tougher Avandia Warning Is Urged"](#):

Agency officials are pushing for a "black box" warning, [according to people with knowledge of the matter]. The new label is still being discussed with the company and its final form isn't yet clear. In high-profile safety matters, the agency tends to have strong leverage....

An FDA spokeswoman said the agency "is still involved in internal discussions on this matter" and that when there is a final decision it will become public. A GlaxoSmithKline spokeswoman said the company is "working diligently with the FDA to finalize the label, but it would be inappropriate for us to discuss the ongoing conversations with the agency."...

If it goes into effect, the new warning would focus on Avandia's potential for increased ischemic risk: a risk of events in which blood is choked off from the heart. An FDA analysis that crunched together multiple Avandia studies found that the drug appeared to be linked to a 38% higher risk of ischemic events....

When Avandia gets its new "black box" warning about increased heart attack risks, Avandia sales may be even further diminished going forward. In turn, GlaxoSmithKline could follow the lead of Bristol-Myers Squibb (BMS) when that drug company experienced increasing scrutiny about the safety of its antibiotic Tequin in 2006. Rather than do a Tequin safety recall, Bristol-Myers announced that it would stop marketing Tequin in the U.S. for "business" reasons -- which was very similar to what they did with their besieged anti-depressant drug Serzone back in 2004.

This new Big Pharma practice of withdrawing an alleged unsafe prescription drug for said-to-be business reasons (rather than safety reasons) could be called a "soft" recall.

We'll wait to see what Glaxo decides to do about its embattled diabetes drug as more is learned about Avandia side effects going forward.

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