



LATEST NEWS BOMB KILLS LEBANESE GENERAL TIPPED FOR ARMY CHIEF



Were you there?

Share the news **you capture** with Reuters and the world.

[Submit your photos](#)

REPLAY

Our 5-Step Investing Method can help you make better decisions in today's market.

Attend a FREE 2-hour introductory seminar.

You are here: [Home](#) > [Investing](#) > [News](#) > Article

HOME

BUSINESS

INVESTING

News

Market News

Economic News

Mergers/Acquisitions

Hot Stocks

New Issues & IPO's

Regulatory News

Bonds News

Markets

Industries

Stocks

Stock Buzz

Funds

ETFs

Options

Commodities

Bonds

Currencies

Analyst Research

Portfolio

NEWS

Do More With Reuters

RSS

Mobile

Podcasts

Newsletters

My Headlines

You Witness News

Partner Services

CareerBuilder

Affiliate Network

Professional Products

Mixed Reactions To Avandia's Revised Warning In November 2007 About Risk Of Heart Attacks

powered by BlogBurst

POSTED: Thursday, December 06, 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.

Drug Safety Experts And FDA Officials Discuss Avandia And The New Black-Box Warning

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

On November 14, 2007 the FDA issued a news release entitled "[FDA Adds Boxed Warning for Heart-related Risks to Anti-Diabetes Drug Avandia](#)", which carried the sub-heading "Agency says drug to remain on market, while safety assessment continues". By this means, the FDA announced that GlaxoSmithKline Plc (GSK), the manufacturer of Avandia (rosiglitazone), would add new safety information about a potential increased risk for heart attacks to the "black-box" warning part of the current Avandia package insert, or label.

As pointed out in a November 15, 2007 *Bloomberg* article, "[Glaxo's Avandia Gets Less Stringent Warning in U.S.](#)", this action by the FDA was not as strong as that taken by drug regulators in Canada and the European Union a bit earlier:

Health Canada withdrew approval for Avandia as a stand-alone therapy last week and said it should be given mainly with the older drug metformin. European regulators said it should be used only in select groups of patients.

That same *Bloomberg* article, by reporters Andrea Gerlin and Michelle Fay Cortez, provided the FDA's substantiation for their course of action as well the reaction of drug safety expert Steven Nissen, M.D.:

Glaxo has agreed to the FDA's request to conduct a new trial of Avandia, and the agency will ask that the medicine be compared directly with Actos and perhaps other drugs, Janet Woodcock, acting director of the agency's Center for Drug Evaluation and Research, said on a conference call with reporters.

The trial will start next November and last four to five years. While the

[Support \(Customer Zone\)](#)

[Reuters Media](#)

[Financial Products](#)

[Find a financial adviser](#)

[About Reuters](#)

results won't be available until 2014, interim analyses of the data should provide the agency and doctors with some guidance on the drug's safety, she said.

"We are keeping Avandia on the market because we have concluded there isn't enough evidence to indicate that the risk of heart attack" or of reduced blood flow to the heart is higher with Avandia than with other pills to treat diabetes, Woodcock said....

The FDA's statement doesn't provide doctors clear guidance on the proper use of Avandia, said Steven Nissen, the head of cardiology at the Cleveland Clinic, and the leader of the study on heart-attack risks published in May.

"We still have the dilemma of a drug that appears to have substantial risks without an answer in the short-term," Nissen said in a telephone interview. "That creates concern for both physicians and patients."

Another reporter, Sue Hughes, obtained some additional comments from Dr. Nissen and from Sanjay Kaul, M.D. -- who has been critical of the [May 2007 Avandia data meta-analysis by Nissen and Wolski](#) which first put Avandia in the spotlight as regards its association with an increased risk of heart attacks / myocardial infarctions (MI) and ischemic strokes. In her November 14 article for for the online publication *Heartwire* about Avandia, "[Rosiglitazone to Stay on US Market With New Warnings About MI](#)", Ms. Hughes reports on her interviews with Dr. Nissen and Dr. Kaul:

- Dr. Steven Nissen said: "I would have preferred a warning with greater clarity. I strongly preferred the language chosen by the Canadian authorities. But having said that, a black box is the strongest warning the FDA can make, short of drug withdrawal, and I think the message is unmistakable. By putting a black-box warning on a drug you are telling people to be extremely careful, and I think that message will be heard."
- Dr. Sanjay Kaul said: "The FDA's decision accurately reflects the uncertainty surrounding the cardiovascular risk associated with rosiglitazone. Clearly, more data are needed to adjudicate this uncertainty. Only prospective clinical trials designed for the specific purpose of establishing the cardiovascular benefit or risk of rosiglitazone will resolve the controversy about its safety. I am pleased to learn that the FDA has requested that GSK conduct a new long-term study to evaluate the potential cardiovascular risk of rosiglitazone and that GSK has agreed to conduct the study. Reason and logic seem to have prevailed over publicity blitz and fear-mongering."

This mid-November coverage of this FDA action on Avandia and the reactions from these two leading drug safety experts was followed by a related news reports later in the month.

From a November 27, 2007 *Reuters* article, "[FDA staffer seeks higher standards after Avandia concerns](#)", we learned the following from Dr. Robert Misbin, a medical officer in the FDA unit that reviews diabetes drugs:

...although the FDA doesn't have the authority to require that a new drug be superior to existing treatments, the FDA "is not required to have proof that a new drug is unsafe to deny approval."

He added that the FDA should "set a high standard for drugs that offer no advantage over existing therapy."


Misbin's original advice to require Glaxo conduct a post-marketing safety study as a condition for Avandia's approval was not taken by his superiors.

A safety trial should be required -- before approval -- of all diabetes drugs, Misbin advises.

While the FDA evaluates safety data as part of its clinical trials for approving a drug, Misbin is calling for a separate trial designed specifically to detect major safety problems. And that trial should not exclude patients at risk for serious adverse events, he said.

No doubt the issue of how well the FDA has dealt with the emerging drug safety "signals" concerning Avandia will continue to be the subject of debate among doctors and patients (and politicians) in the months and years to come.

[Read more from this blogger at Drug Injury Watch](#) | [Let us know what you think of this feature](#)

Reuters.com: [Help and Contact Us](#) | [Advertise With Us](#) | [Mobile](#) | [Newsletters](#) | [RSS](#)  | [Interactive TV](#) | [Labs](#) | [Reuters in S](#)
Reuters Corporate: [Copyright](#) | [Disclaimer](#) | [Privacy](#) | [Professional Products](#) | [Professional Products Support](#) | [About Reuters](#) |

International Editions: [Africa](#) | [Arabic](#) | [Argentina](#) | [Brazil](#) | [Canada](#) | [Chinese Simplified](#) | [Chinese Traditional](#) | [France](#) | [Gerr](#)
[Russia](#) | [Spain](#) | [United Kingdom](#) | [United States](#)

Reuters is the world's largest international multimedia news agency, providing investing news, world news, business news, technology news, headline market, and mutual funds information available on Reuters.com, video, mobile, and interactive television platforms. Reuters journalists are subject to the disclosure of relevant interests.

NYSE and AMEX quotes delayed by at least 20 minutes. Nasdaq delayed by at least 15 minutes. For a complete list of exchanges and delays, please