

## Actos-Related Bladder Cancer: June 2011 Review Of Regulatory Actions And Safety Warnings

### **FDA And Health Canada Warn About Increased Risk, While France And Germany Suspend Actos Sales**

(Posted by Tom Lamb at [www.DrugInjuryWatch.com](http://www.DrugInjuryWatch.com) on June 17, 2011; see <http://bit.ly/jTfM3a>)

We will start this Actos - bladder cancer safety review with the most recent announcement, from Health Canada earlier today, June 17, 2011:

#### **[Health Canada reviewing diabetes drug pioglitazone \(Actos\) and potential risk of bladder cancer](#)**

In light of studies suggesting an increased risk of bladder cancer with the diabetes drug pioglitazone, as well as actions taken by other regulatory agencies, Health Canada is informing healthcare professionals and Canadians that it is undertaking a review of the drug's status....

A couple of days before, on June 15, 2011, the FDA informed us about an Actos label change concerning this diabetes drug's association with bladder cancer:

#### **[FDA Drug Safety Communication: Update to ongoing safety review of Actos \(pioglitazone\) and increased risk of bladder cancer](#)**

The U.S. Food and Drug Administration (FDA) is informing the public that use of the diabetes medication Actos (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer. Information about this risk will be added to the Warnings and Precautions section of the label for pioglitazone-containing medicines. The patient Medication Guide for these medicines will also be revised to include information on the risk of bladder cancer....

About a week earlier, on June 9, 2011, the European Medicines Agency (EMA) issued this press release:

#### **[Update on ongoing European review of pioglitazone-containing medicines](#)**

##### **Suspension of use of these medicines in France while Europe-wide review continues**

The European Medicines Agency (EMA) has been informed by the French Medicines Agency (Afssaps) of its decision to suspend the use of pioglitazone-containing medicines in France (Actos, Competact), while awaiting the outcome of the ongoing European review on the benefits and risks of these antidiabetic medicines.

This decision by the French authority follows receipt of results of a retrospective cohort study carried out in France which became available today. These results appear to suggest an increased risk of bladder cancer with pioglitazone....

##### **Notes**

... The French targeted epidemiological study is a retrospective cohort study conducted by the French health insurance (Caisse National d'Assurance Maladie) following antidiabetic patients taking antidiabetic medicines between 2006 and 2009.

As reported June 10, 2011 by *Reuters*, "[Germany joins France in suspending top Takeda drug](#)".

A May 18, 2011 article published online by *heartwire.org*, "[Review of data suggests risk of bladder cancer with pioglitazone](#)" (free registration required), let us know about a recent medical journal article concerning this Actos - bladder cancer "link" and reminded us that the FDA had a study of this Actos drug safety issue ongoing since September 2010:

An analysis assessing the safety profile of pioglitazone (Actos, Takeda Pharmaceuticals), one of two drugs approved by the US Food and Drug Administration (FDA) in the thiazolidinedione (TZD) class, shows a consistent association between use of the diabetes medication and the risk of bladder cancer.

Using data from the FDA Adverse Event Reporting System (AERS), Dr Carlo Piccinni (University of Bologna, Italy) and colleagues report that 93 cases of cancer were recorded between 2004 and 2009 in patients treated with antidiabetic drugs. Of these cases, 31 patients were treated with pioglitazone, a reporting rate "indicative of a definitive risk for pioglitazone," according to the researchers....

As reported by *heartwire* in September 2010, the FDA is currently reviewing the safety of pioglitazone, citing preliminary epidemiological evidence that suggests that the diabetes medication may be linked to a higher risk of bladder cancer. The review is based on an ongoing 10-year observational cohort study as well as a nested, case-control study of the long-term risk of bladder cancer in roughly 193 000 patients with diabetes who are members of the Kaiser Permanente Northern California health plan. A preliminary analysis of these data showed an increasing risk of bladder cancer with pioglitazone exposure, a risk that reached statistical significance after 24 months.

The analysis mentioned in that *heartwire* article is "[Assessing the association of pioglitazone use and bladder cancer through adverse event reporting](#)" which was published (early) online by *Diabetes Care 2011* back in April 2011 and is found in the June 2011 print edition of this medical journal.

As for the September 2010 FDA review, see "[FDA Drug Safety Communication: Ongoing Safety Review of Actos \(pioglitazone\) and Potential Increased Risk of Bladder Cancer After Two Years Exposure](#)".

We will continue to monitor the popular diabetes drug Actos for drug recalls and safety warnings worldwide as regards its association with bladder cancer.

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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>