

## [Safety "Cloud" Gets Removed From Spiriva By FDA In January 2010](#)

### **This COPD Medication Had Previously Been Possibly Linked To Stroke, Heart Attack, And Death**

(Posted by Tom Lamb at [www.DrugInjuryWatch.com](http://www.DrugInjuryWatch.com) on January 15, 2010; see <http://bit.ly/8aFaA3>)

On January 14, 2010 the FDA issued a news release, "[FDA Updates Earlier Guidance on Respiratory Treatment Spiriva HandiHaler -- Current data do not support increased risks for stroke, heart attack, or death](#)", which began as follows:

The U.S. Food and Drug Administration today announced that data from a recent review of the Spiriva HandiHaler, a long-acting respiratory treatment for chronic obstructive pulmonary disease (COPD), do not support an increased risk of stroke, heart attack, or death in patients using the medicine.

As you may recall, an FDA Early Communication issued in March 2008 had described data submitted by the manufacturer of Spiriva HandiHaler as suggesting a small increased risk of stroke in patients treated with tiotropium, the medicine's active ingredient. Later, in October 2008, an Updated Early Communication highlighted two additional publications suggesting an increased risk of stroke, heart attack, and death in patients using tiotropium.

Now, as explained in the FDA's "[Follow-Up to the October 2008 Updated Early Communication about an Ongoing Safety Review of Tiotropium \(marketed as Spiriva HandiHaler\)](#)", we get the apparent final word:

FDA has now completed its review and believes the available data do not support an association between the use of Spiriva HandiHaler and an increased risk for these serious adverse events.

As always, we encourage people to report any serious adverse events that may be related to Spiriva, or any other prescription medication, to the [FDA MedWatch program](#).

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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>