

[Drug Injury Watch: December 2012 Pradaxa Label Change: Contraindication: Use By Mechanical Heart Valves Patients](#)

A Look At The Events And The Evidence Leading Up To This Latest FDA Action Concerning The Safety Of Pradaxa

(Posted by Tom Lamb at www.DrugInjuryWatch.com on December 26, 2012)

SUMMARY: The events leading up to this December 2012 Pradaxa label change are set forth in this December 20 *Medscape* news report, "FDA Contraindicates Dabigatran for Those With Mechanical Heart Valves":

The US FDA is following in the footsteps of the European Medicines Agency (EMA) in warning that the anticoagulant dabigatran (Pradaxa, Boehringer Ingelheim) should not be used to prevent stroke or major thromboembolic events in patients with mechanical (also known as mechanical prosthetic) heart valves.

We will continue to watch for further developments concerning Pradaxa here in the U.S. and elsewhere.

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Earlier Pradaxa articles by Tom Lamb on the Drug Injury Watch blog:

[December 2012 Pradaxa Update: Prescription / Sales Numbers And Drug Company Safety Study Results](#)

[Pradaxa Safety Debate Continues During November 2012 With Many Different Conclusions And Positions](#)

[Fall 2012: Two Recent Medical Reports Regarding Safety Of Pradaxa, Boehringer Ingelheim's Anticoagulation Drug](#)

[Increasing Number Of Pradaxa Lawsuits Against Boehringer Are Consolidated In Federal Court MDL](#)

[Pradaxa Side Effects Update Mid-2012: Deaths, Hemorrhages, Acute Renal Failure, and Stroke Events Submitted To FDA MedWatch](#)

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.

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