

## [Drug Injury Watch: FDA Drug Safety Concerns About Pradaxa And Serious Bleeding Side Effects Will Get Another Look By Means Of New 2014 Study](#)

### **A Primary Focus Is Gastrointestinal And Intracranial Hemorrhages In Patients Using Pradaxa For Atrial Fibrillation**

(Posted by Tom Lamb at [www.DrugInjuryWatch.com](http://www.DrugInjuryWatch.com) on January 15, 2014)

**SUMMARY:** On December 30, 2013 the FDA posted for public comment on a proposed protocol of a new study intended to be a one-time assessment of selected safety outcomes in adults with atrial fibrillation who are new users of Pradaxa (dabigatran) or Coumadin (warfarin).

Some background information about this Pradaxa FDA study of can be found in a January 3, 2014 *Forbes* article by Larry Husten, "FDA Plans New Safety Assessment Of Dabigatran (Pradaxa)".

We will be watching the FDA and the medical news reports for future developments concerning this latest FDA safety review regarding Pradaxa and serious bleeding side effects, some of which can result in death.

[\[Read this article in full at original source\]](#)

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

[The Pradaxa Gastrointestinal \(GI\) Bleeding Debate Continues: Is There An Increased Risk Or A Risk Reduction With Pradaxa Use?](#)

[Pradaxa Adverse Drug Events \(ADEs\) Result In Death More Often Than Other Anticoagulants / Blood Thinners ADE Reports](#)

[Pradaxa: February 2013 Update: Federal Court MDL Litigation Now Involves About 200 Lawsuits](#)

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

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

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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>