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Concerns Over Pradaxa's Increased Risk of Life-Threatening Bleeds

Pradaxa is a new blood-thinning medicine primarily used to reduce the risk of stroke and blood clots in patients with atrial fibrillation not caused by a heart valve problem. However, recently filed lawsuits claim that patients taking Pradaxa instead of established blood-thinning medicines have a higher risk of life-threatening bleeds. Further, these suits allege that the drug's manufacturer, Boehringer Ingelheim Pharmaceuticals, knew of the increased risk and failed to adequately warn patients and doctors.

Historically, atrial fibrillation has been treated with the prescription drug warfarin. Warfarin blocks the formation of tiny fibrin threads that help hold together the platelets that collect in a patient's blood to form a blood clot. Like all blood thinners, warfarin can cause unexpected bleeds. Warfarin also has two other noteworthy limitations: (1) it requires blood tests every 1 to 4 weeks to establish a patient's optimal level of anticoagulation, and (2) it interacts negatively with scores of other drugs. In spite of these apparent limitations, however, warfarin also has an important benefit; if an unexpected bleed occurs, it can be reversed by administration of vitamin K into the bloodstream.

Pradaxa gained FDA approval in October of 2010 and is the first new treatment alternative to warfarin in nearly 60 years. It quickly gained favor with patients over warfarin as it does not require monthly blood testing due to Pradaxa's "one size fits all" dosing of 150mg. In practice, this means that doctors are not monitoring a patient's blood level to see if they are getting too much of Pradaxa's active ingredient.

Marketing materials tout Pradaxa to be just as safe as warfarin, claiming that Pradaxa generally has similar, but lower overall total

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George is developing his practice in the areas of general civil, commercial and complex litigation including mass torts. Additionally, George has developed a niche in the area of oil spill claims resolution, representing clients in claims against the Gulf Coast Claims Facility as well as the National Pollution Funds Center.

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bleeds than warfarin. However, the clinical trial used to garner FDA approval demonstrated that with Pradaxa there is a higher rate of major GI bleeds as compared to warfarin, and a similar rate of major bleeds. Moreover, there is no reversal agent for Pradaxa like there is for warfarin; meaning that once a major bleed begins, doctors cannot stop the bleed until the drug is removed naturally by the patient's body.

As a result, lawsuits filed against the drug's manufacturer claim that patients who took Pradaxa for even a brief period of time were at increased risk for life-threatening bleeds since its levels in the blood are difficult or impossible to assess and bleeds cannot be stopped because there is no known reversal agent. Further, it is alleged that the manufacturer did not warn patients of the irreversible nature of Pradaxa in the "Warnings and Precautions" section of the drug's initial warning label, but instead chose to bury this critical fact in fine print in a section of the label which discusses "Overdosage" on the medicine.

In essence, the Pradaxa lawsuits claim that even if the warning labels were adequate, Pradaxa lacks any benefit sufficient to tolerate the extreme risk posed by the drug—that Pradaxa is dangerous and defective as formulated.

If you or someone you know has suffered a life-threatening bleed or death as a result of the ingestion of Pradaxa, please call our office for a free and confidential consultation.

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