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

Medical Journal Article Reports Pradaxa-Induced Rectal Bleeding And Hemostatic Disorder In Two Elderly Patients

(Posted by Tom Lamb at www.DrugInjuryWatch.com on June 28, 2012; see http://bit.ly/OEWYhR)

On May 31, 2012 the Institute for Safe Medication Practices (ISMP) released its 2011 Annual Report Issue (**PDF**) which included new data for the second half of 2011 found in the FDA Adverse Event Reporting System (AERS), which consists of serious drug side effects information taken from FDA MedWatch reports.

From a June 6, 2012 article by Michael R. Cohen, the ISMP President, "Drugs most frequently reported for adverse reactions", we get a rather disturbing summary of the MedWatch reports that the FDA has received concerning the still relatively new anticoagulant drug Pradaxa (dabigatran), followed by an explanation of the significance:

> Pradaxa surpassed all other monitored drugs in several categories, including overall number of reports (3,781), deaths (542), hemorrhage (2,367), acute renal failure (291), and stroke (644). It was also suspect in 15 cases of liver failure....
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> The data above come from QuarterWatch™ an Institute for Safe Medication Practices surveillance program that monitors all serious and fatal adverse drug events (ADEs) reported to the Food and Drug Administration through MedWatch, its adverse event reporting system.
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> The goal is to identify signals that may represent important new drug safety issues. The term “signal” as we use it means evidence substantial enough to warrant mention but which usually requires further investigation to determine how frequent an ADE happens and to establish a causal relationship to a drug.

Accordingly, given the apparent strong signal as regards serious side effects associated with Pradaxa, we expect the FDA to monitor closely this emerging drug safety issue.

On the medical journal front, in the June 2012 edition of *The Annals of Pharmacotherapy*, there is an article presenting two case reports of Pradaxa-induced rectal bleeding. From the Abstract for "Bleeding and Hemostatic Disorders Induced by Dabigatran Etexilate in 2 Elderly Patients":

> **OBJECTIVE**: To report rectal bleeding associated with hemostatic disorders in 2 elderly patients treated with [Pradaxa (dabigatran etexilate)].
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> **CASE SUMMARY**: A 79-year-old woman (weight, 69 kg) was hospitalized in a gastroenterology unit for severe rectal bleeding. She had been treated for 2 months with [Pradaxa (dabigatran etexilate)] 110 mg twice daily for chronic atrial fibrillation.... An 84-year-old man (weight, 71 kg) was admitted for rectal bleeding with acute renal failure and dehydration that began while he was treated with [Pradaxa (dabigatran etexilate)] 110 mg twice daily for atrial fibrillation.... In both cases, an objective causality assessment revealed that those adverse reactions were probably related to [Pradaxa (dabigatran etexilate)].

For some background on the drug-safety debate about Pradaxa, see one or more of these earlier articles:

1. Drug Injury Watch: Safety Developments Regarding Pradaxa: Boehringer Starts Drug Registry; EMA Wants Label Change; Study Compares Pradaxa Use To Coumadin As Regards Side Effects

2. Drug Injury Watch: Pradaxa Noted For Possible Heart Attack Risk In Addition To Serious Gastrointestinal Bleeding And Other Hemorrhages
3. Drug Injury Watch: Pradaxa Hemorrhage Cases May Occur In Oldest Patients Due To Age-Related Decline In Renal Function
4. Drug Injury Watch: Pradaxa: 2012 Label Revisions In The U.S. And Canada, Where A "Dear Doctor" Letter Was Sent Out
5. Drug Injury Watch: Pradaxa Bleeding Events: Four Major Factors Which Contributed To These Serious Side Effects
6. Drug Injury Watch: Pradaxa: Excess Number Of Severe Bleeding Events In Certain Patient Populations And Settings
7. Drug Injury Watch: Safety Profile Of New Stroke Drug Pradaxa Has Been Tarnished By Various Adverse Event Reports
8. Drug Injury Watch: Pradaxa: FDA Investigating Possible Higher Than Expected Incident Rate Of Serious Bleeding Side Effects
9. Drug Injury Watch: New Heart Drug Pradaxa May Be Sending "Early" Drug Safety Signals

We will continue to watch for news reports and medical journal articles about the serious side effects associated with Pradaxa and present significant developments here for your consideration.

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