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## Pradaxa and Actos: Is Non-Preservation of Documents an Emerging Trend?

May 18, 2014, 08:00:00AM. By [Gordon Gibb](#)

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St. Louis, IL: When a US District Court judge fined Boehringer Ingelheim GmbH almost \$1 million at the end of last year for failure to preserve documents with regard to the blood thinner Pradaxa, the decision served as a precursor to a similar position taken by justices in the Actos portfolio. With the latter, Actos manufacturer Takeda Pharmaceuticals was cited for failure to preserve documents deemed important to legal proceedings. Such is the case, it seems, for [Pradaxa lawsuits](#) as well.



Pradaxa is a new-age blood thinner approved by the US Food and Drug Administration (FDA) in 2010 and hailed as a safe and effective alternative to a product that had been on the market for nearly 60 years, but a blood thinner that required more rigorous and regular monitoring.

Not so with Pradaxa, which was seen to effectively prevent blood clotting - an important attribute for those patients at risk for stroke. However, a problem with Pradaxa bleeding, characterized by uncontrollable bleed-out that could not be stopped, quickly put Pradaxa under a cloud.

That's because unlike the older Coumadin, through which bleeding could be reversed with the intervention of Vitamin K and plasma, there is no known or effective reversal protocol for Pradaxa. When Pradaxa bleeding occurs, from a

simple cut or bruise, there is no antidote. More than 500 Pradaxa deaths were attributed to the new-age blood thinner over a two-year period, according to various reports.

Plaintiffs in Pradaxa lawsuits - numbering about 1,700 according to a report in *Bloomberg News* (12/10/13) last December but now thought to be closer to 2,000 - allege that dabigatran Pradaxa manufacturer Boehringer knew about the potential bleeding profile of Pradaxa, but withheld that concern from doctors and patients.

When lawyers representing plaintiffs went through the discovery process, there were allegations that key documents were not properly preserved - allegations eerily similar to allegations and subsequent censure pertaining to the Actos portfolio. With the latter, Takeda noted documents that Takeda had directed be preserved regarding the development of Actos, a medication used to manage and control type 2 diabetes, were not preserved after all.

Boehringer, while maintaining there were plenty of documents available to support legal proceedings, was nonetheless called to the carpet over the same issue.

Last December, according to *Bloomberg*, US District Judge David Herndon in East St. Louis, Illinois, concluded that Boehringer executives acted "in bad faith" by failing to ensure that documents and files about the drug's development and marketing were preserved.

### Pradaxa manufacturer censured and fined

In a 51-page ruling released December 9, 2013, Judge Herndon accused Boehringer of making misrepresentations with regard to its efforts to preserve important documents deemed necessary to the Pradaxa file. For example, Herndon noted, company executives "failed to ensure the auto-delete feature of their employee cellphones, company owned and personal, was disengaged for the purpose of preserving text messages," Herndon said. This move "allowed countless records to be destroyed."

Dr. Shezad Malik, of the Dr. Shezad Malik Law Firm, noted in [comments](#) to LawyersandSettlements.com's Heidi Turner that "Boehringer Ingelheim either knew or should have known that there was no antidote for Pradaxa, but doctors and patients were not warned about that," Malik said.

The apparent and unexplained disappearance of documentation, in light of such serious Pradaxa side effects that can include Pradaxa heart attack and even Pradaxa death, is both curious and tragic. Patients with an opportunity to know about the risk factors for Pradaxa bleeding may have opted not to switch from Coumadin to the new drug - and might otherwise be alive today.

Similarly, many patients having switched to Actos to help manage their type 2 diabetes may not have made that decision had they known about the potential for Actos bladder cancer. There were also allegations of failure to preserve documents in the Actos bladder cancer arena as well.

One wonders if this will be a continuing trend in other cases, especially in light of electronic documents that can be purged and literally disappear with the push of a button, either performed out of malice or simple electronic "housekeeping." A paper trail, on the other hand, is a bit harder to make disappear.

The first bellwether Pradaxa lawsuits are to begin in August.

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