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Zyprexa And Diabetes: Is This A Tale Of Company Greed Coupled With FDA Failure?

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POSTED: Monday, March 24, 2008

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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Alaska v. Eli Lilly Trial: Focus Is On What Was Known About This Alleged Side Effect, And When They Knew It

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

News reports about the case *Alaska v. Eli Lilly & Co.*, 3AN-06-05630 CI, Alaska Superior Court (Anchorage), have been limited but interesting thus far.

The most prolific news coverage to date has come from Lisa Demer, reporting for the *Anchorage Daily News*. Her March 22, 2008 article, "[Defense opens in Zyprexa trial](#)", informed us about some interesting comments made by the trial judge during a court session that involved only the lawyers for the parties -- such that jurors did not get this earful:

Without lawsuits like the one the State of Alaska brought against Lilly, claims that drugs cause health problems "might well go unaddressed," Anchorage Superior Court Judge Mark Rindner said from the bench this week....

Rindner was reacting to an assertion by Lilly lawyer George Lehner that drug regulation is a matter for the federal Food and Drug Administration, not any state. Alaska's Unfair Trade Practices and Consumer Protection Act shouldn't apply to drugs, Lehner told the judge.

Rindner disagreed. Evidence presented by the state over the past two weeks established that the FDA "isn't capable of policing this matter," he said.

As background, Zyprexa is Lilly's top-selling prescription drug, with worldwide sales of \$4.8 billion in 2007. Zyprexa was approved in September 1996 for the treatment of schizophrenia. Starting soon thereafter, doctors began to report to the FDA and to Lilly that some patients using Zyprexa seemed to experience severe weight gain and high blood sugar which seemed to lead to diabetes in some instances.

The State of Alaska has sued Lilly to recover medical costs paid by the State when

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treating Medicaid patients who have developed diabetes after taking Zyprexa. The jury trial of that lawsuit, which started earlier this month, is being heard in an Alaska state court located in Anchorage.

A March 8 article, "[Lilly Waited Too Long to Warn About Schizophrenia Drug, Doctor Testifies](#)", by Alex Berenson, of *The New York Times*, provided this account of some early expert testimony in support the state's contention that this Lilly downplayed the serious side effect risks associated with Zyprexa in order to make more money:

Eli Lilly, the drug maker, could and should have warned physicians as early as 1998 about the link between Zyprexa, its best-selling schizophrenia medicine, and diabetes, an expert witness told jurors Friday in a lawsuit that claims that Zyprexa has caused many mentally ill people to develop diabetes.

Instead, Lilly hid Zyprexa's risks from doctors to protect the drug's sales, according to the witness, Dr. John Gueriguian. Lilly waited until 2007 to add strong warnings to Zyprexa's label to reflect the drug's tendency to cause severe weight gain and blood sugar changes.

Lilly put "profit over concern of the consumer," Dr. Gueriguian said Friday near the end of four hours of testimony....

By the fall of 1998, the combination of adverse-event reports, clinical trial data that showed hyperglycemia and weight gain, and problems in animal studies should have been enough for Lilly to warn doctors about Zyprexa's links to diabetes, Dr. Gueriguian said. Instead, the company did nothing.

Documents from 1999 and 2000 also showed that Lilly was accumulating evidence of Zyprexa's risks but not sharing it with doctors, he testified.

With this and other similar testimony being heard by Judge Rindner, it is understandable why he is doubtful about [the proposition that the FDA is on-the-job and, therefore, federal preemption is warranted](#).

In closing, if you are interested in learning more about this Alaska v. Eli Lilly trial, you need to visit the *Anchorage Daily News* online pages with Zyprexa articles by Lisa Demer, such as her March 14, 2008 report, "[Japan made Zyprexa labels reflect risk to diabetics](#)". On these pages there are links to resources that will give you insight to past and present developments, both, that are significant to this ongoing Zyprexa trial in Alaska.

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