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## State AGs

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### Madigan turns up heat on disputed Zyprexa lawsuit

by Rob Luke

SPRINGFIELD -- Illinois attorney general Lisa Madigan has ratcheted up the pressure on pharmaceutical giant Eli Lilly over a controversial drug-marketing lawsuit that has drawn fire from reform advocates.



Lawyers at the consumer protection division of the Illinois attorney general's office last week demanded that company officials hand over documents concerning the marketing of Zyprexa, Lilly's blockbuster mental health drug.

Their counterparts in the Vermont AG's office have joined the action.

A five-state legal action against Eli Lilly alleges the company tried to cover up negative side-effects of Zyprexa and that it tried to market the drug for disorders other than its scheduled treatment for schizophrenia and bipolar disorder. Such "off-label" prescription is a violation of federal law.

But a prominent expert on medical law says the charges against Eli Lilly of "off-label" marketing, among others, are largely a creation of "unethical lawyering combined with shoddy journalism."

Henry I. Miller, a physician and fellow at Stanford University's Hoover Institution, said the case against Eli Lilly and its drug over the past few months has been distorted in the media because of "one-sided leaks" from lawyers. He singled out attorney James B. Gottstein and the New York Times as the worst offenders.

"Access only to documents that argue one side of the case has not deterred the Times from repeated, vicious attacks on Lilly and Zyprexa," Miller said. He said the Times made allegations against Lilly in articles and editorials based on material that was "obviously incomplete and out of context."

Coincidentally, the new orders from Vermont and Illinois point to an escalation of the legal action against Lilly and may be part of a multi-pronged strategy to force the drug-maker into a settlement.

"We can ask for documents; we can ask for answers to questions; and we can ask for people to come in and testify under oath," said Deborah Hagan, head of consumer protection in Madigan's office.

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Federal prosecutors in Philadelphia also have stepped up their investigations into Lilly's Zyprexa marketing. Attorneys-general in California and Florida also have taken action against the company to recover Medicaid payments the states made for Zyprexa prescriptions.

But Miller, a former FDA official, argues that the states' main charge against Lilly's marketing of Zyprexa - the off-label accusation - doesn't necessarily hold water.

"The F.D.A. - which carefully monitors and takes a dim view of such violations of federal regulations - has never issued a warning to [Eli Lilly] about this," Miller said.

Miller also said Zyprexa was "widely prescribed and highly regarded by psychiatrists" and is used by 20 million patients worldwide. The drug had sales of over \$4 billion in 2006 and \$30 billion since 1996.

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