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## **Vermont spent millions on suspect drug Zyprexa**

By Daniel Barlow Vermont Press Bureau

MONTPELIER – As the lawsuits against Eli Lilly over its top-selling anti-schizophrenia drug Zyprexa began piling up in 2006, Vermont's state-run insurance program spent nearly \$4 million on the drug, according to documents.

That amount may seem like a drop in the bucket when compared to Zyprexa's 2007 sales of \$4.8 billion in the United States, but the payments through Vermont's Medicaid program came at a time when 10 states and upwards of 30,000 people were suing the company over the drug.

Launched in 1996, Zyprexa has become the top-selling medication for drug-maker Eli Lilly. But those sales are dropping as lawsuits and leaked corporate documents reveal a decade-long effort to downplay the side effects, including weight gain and an increased chance of diabetes, in the company's promotion of the drug.

Just this week the state of Alaska, population 670,000, settled its lawsuit against Eli Lilly for \$15 million over what it claimed were increased Medicaid costs due to health problems associated with taking Zyprexa. That was the first state to settle with the company in the lawsuits.

Vermont is not one of the states now suing Eli Lilly. But on Thursday, the Vermont Association for Mental Health, a Montpelier-based advocacy organization, urged the state to pursue that legal option. Executive Director Ken Liberto said this case was a "sad commentary" on the influence of the pharmaceutical industry.

"No one doubts that psychotropic medications can be an important part of treatment, but as this case will show, improper marketing, concealment of important health information and huge financial payments have polluted the environment," Liberto said.

While it may not be suing Eli Lilly, Vermont is investigating how the company marketed its drug to doctors and others here, according to Julie Brill, Vermont's assistant attorney general. She said the state

subpoenaed marketing materials and internal company documents detailing its marketing plan in January 2007.

Brill said that inquiry is still on-going and she was mum on further details. She said she did not know when more information on their investigation could be made available to the public.

"We do have an ongoing consumer protection investigation," she said.

The \$3.96 million spent on Zyprexa by Vermont in 2006 appears to be an unusually high number – and impacted because that financial year was the start of the new federal Medicare Part D program that subsidized the cost of prescription drugs, according to Ann Rugg, the deputy director of the Office of Vermont Health Access, which oversees the publicly-funded insurance programs.

The spending has since dropped, although it is still in the millions. In 2007, \$1.5 million was paid by the state and during the first three quarters of the current financial year, the state is on track to pay about \$1 million.

Michael Hartman, the commissioner of the Vermont Department of Mental Health, said Thursday that all medications have potential side effects, but the situation with Zyprexa is especially troubling due to the allegation that the company went out of its way to downplay its health consequences.

He faulted the Food and Drug Administration for its lax authority over the testing of new drugs, saying the federal organization needs to rely more on independent tests as opposed to the ones submitted by the drug-makers.

"A patient needs to understand and have all the information about the medication to make an informed decision," he said.

Hartman said Zyprexa was likely marketed in Vermont in the same way that the drug was marketed in other states. He said there is an "awful lot of trust or acceptance that the information provided" to mental health professionals in the field is accurate.

"If we can find that there is reason to believe that this wasn't done properly ... show a purposeful pattern of deceiving people, that is a door that could be explored," Hartman said when asked if Vermont should join other states in the Zyprexa lawsuits. More than 23 million

people have taken Zyprexa since it hit the market as a medication to soothe hallucinations and delusions. But company documents leaked to the New York Times show that the company encouraged doctors to prescribe the drug "off-label," meaning for uses not approved by the FDA.

Federal law prohibits such off-label marketing, although doctors are allowed to prescribe drugs more freely.

Tens of thousands of lawsuits have also been filed over the side effects of the drug, which include massive weight gain and blood sugar boosts – all known risk factors for diabetes. So far, the company has paid out \$1.2 billion to settle many of the lawsuits.

So far, Eli Lilly has maintained its innocence. The company did not return a phone call for comment Thursday, but an executive told the New York Times this week that "a settlement helps us get back to what we want to focus on as a company ..."

Zyprexa has been an effective medication for some patients, but its use has dropped in recent years once reports of the side effects surfaced, according to Jonathan Wecker, a Montpelier psychiatrist.

"I don't remember any talk of these side effects when the drug first came out," he said. "And clearly, the association we've seen since to diabetes has caused this drug to drop off a bit."

The ironic twist to the surge and fall of Zyprexa is that a government-funded study has shown that the older antipsychotic medications can be just as effective as the newer, more expensive medications, according to Adrienne Fugh-Berman, an associate professor in the Department of Physiology and Biophysics at Georgetown University School of Medicine.

"The pharmaceutical companies have really gone out of their way to cast doubt on this government-funded trial in order to decrease its credibility in physicians' minds," said Fugh-Berman, who is also the director of PharmedOut, an independent, physician-led organization that provides information on pharmaceutical drugs.

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