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Lilly Considers \$1 Billion Fine to Settle Case

By [ALEX BERENSON](#)

[Eli Lilly](#) and federal prosecutors are discussing a settlement of a civil and criminal investigation into the company's marketing of the antipsychotic drug Zyprexa that could result in Lilly's paying more than \$1 billion to federal and state governments.

If a deal is reached, the fine would be the largest ever paid by a drug company for breaking the federal laws that govern how drug makers can promote their medicines.

Several people involved in the investigation confirmed the settlement discussions, which began last year and took on new urgency this month. The people insisted on anonymity because they have not been authorized to talk about the negotiations.

Zyprexa has serious side effects and is approved only to treat people with [schizophrenia](#) and severe [bipolar disorder](#). But documents from Eli Lilly show that from 2000 to 2003 the company encouraged doctors to prescribe Zyprexa to people with age-related [dementia](#), as well as people with mild bipolar disorder who had previously had a diagnosis of [depression](#).

Although doctors can prescribe drugs for any use once they are on the market, it is illegal for drug makers to promote their medicines for any uses not formally approved by the [Food and Drug Administration](#).

Lilly may also plead guilty to a misdemeanor criminal charge as part of the agreement, the people involved with the investigation said. But the company would be allowed to keep selling Zyprexa to [Medicare](#) and [Medicaid](#), the government programs that are the biggest customers of the drug.

Zyprexa is Lilly's most profitable product and among the world's best-selling medicines, with 2007 sales of \$4.8 billion, about half in the United States.

Lilly would neither confirm nor deny the settlement talks.

"We have been and are continuing to cooperate in state and federal investigations related to Zyprexa, including providing a broad range of documents and information," Lilly said in a statement Wednesday afternoon. "As part of that cooperation we regularly have discussions with the government. However, we have no intention of sharing those discussions with the news media and it would be speculative and irresponsible for anyone to do so."

Lilly also said that it had always followed state and federal laws when promoting Zyprexa.

The Lilly fine would be distributed among federal and state governments, which spend about \$1.5 billion on Zyprexa each year through Medicare and Medicaid.

The fine would be in addition to \$1.2 billion that Lilly has already paid to settle 30,000 lawsuits from people who claim that Zyprexa caused them to develop [diabetes](#) or other diseases. Zyprexa can cause severe weight gain in many patients and has been linked to diabetes by the American Diabetes Association.

[Prescriptions](#) for Zyprexa have skidded since 2003 over concerns about those side effects. But the drug continues to be widely used, especially among severely mentally ill patients. Many [psychiatrists](#) say that it works better than other medicines at calming patients who are [psychotic](#) and hallucinating. About four million Zyprexa prescriptions were written in the United States last year.

Federal prosecutors in Philadelphia are leading the settlement talks for the government, in consultation with the Justice Department in Washington. State attorneys general's offices are also involved. Lawyers at Pepper Hamilton, a firm based in Philadelphia, and Sidley Austin, a firm based in Chicago, are negotiating for Lilly.

Nina Gussack, a lawyer at Pepper Hamilton who is representing Lilly, said she could not comment on the case. Joseph Trautwein, an assistant United States attorney for the Eastern District of Pennsylvania, also declined to comment.

While a settlement has not been concluded and the negotiations could collapse, both sides want to reach an agreement, according to the people involved in the investigation.

Besides the escalating pressure of the federal criminal inquiry, Lilly faces a civil trial scheduled for March in Anchorage, in a lawsuit brought by the state of Alaska to recover money the state has spent on Zyprexa prescriptions. A loss in that lawsuit would damage Lilly's bargaining position in the Philadelphia talks.

While expensive for Lilly, the settlement would end a four-year federal investigation and remove a cloud over Zyprexa. While Zyprexa prescriptions are falling, its dollar volume of sales is rising because Lilly has raised Zyprexa's price about 40 percent since 2003.

Federal prosecutors have been investigating Lilly for its marketing of Zyprexa since 2004, and state attorneys general have been doing so since 2005. The people involved in the investigations said the inquiries gained momentum after December 2006, when The New York Times published articles describing Lilly's years-long efforts to play down Zyprexa's side effects and to promote the drug for conditions other than schizophrenia and severe bipolar disorder — a practice called off-label marketing.

Internal Lilly marketing documents and e-mail messages showed that Lilly wanted to persuade doctors to prescribe Zyprexa for patients with age-related dementia or relatively mild bipolar disorder.

In one document, an unidentified Lilly marketing executive wrote that primary care doctors “do treat dementia” but leave schizophrenia and bipolar disorder to psychiatrists. As a result, sales representatives should discuss dementia with primary care doctors, according to the document, which appears to be part of a larger marketing presentation but is not marked more specifically. Later, the same document says that some primary care doctors “might prescribe outside of label.”

In late 2000, Lilly began a marketing campaign called Viva Zyprexa and told sales representatives to suggest that doctors prescribe Zyprexa to older patients with symptoms of dementia.

The documents were under federal court seal when The Times published the articles, and Judge [Jack B.](#)

[Weinstein](#) of United States District Court in Brooklyn rebuked The Times for publishing them.

The settlement negotiations in Philadelphia began several months ago, according to the people involved in the investigation.

Last fall, the two sides were close to a deal in which Lilly would have paid less than \$1 billion to settle the case, which at the time consisted only of a civil complaint.

Then Justice Department lawyers in Washington pressed for a grand jury investigation to examine whether Lilly should be charged criminally for its promotional activities, according to the people involved in the negotiations. A few days ago, facing the possibility of both civil and criminal charges, Lilly opened new discussions with the prosecutors in Philadelphia.

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