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Lilly Said to Be Near $1.4 Billion U.S. Settlement

By GARDINER HARRIS and ALEX BERENSON

Eli Lilly, the drug company, is expected to agree as soon as Thursday to pay $1.4 billion to settle criminal and civil charges that it illegally marketed its blockbuster antipsychotic drug Zyprexa for unauthorized use in patients particularly vulnerable to its risky side effects.

Details of the agreement were provided by people involved in the negotiations.

Among the charges, Lilly has been accused of a scheme stretching for years to persuade doctors to prescribe Zyprexa to two categories of patients — children and the elderly — for whom the drug was not federally approved and in whom its use was especially risky.

In one marketing effort, the company urged geriatricians to use Zyprexa to sedate unruly nursing home patients so as to reduce "nursing time and effort," according to court documents. Like other antipsychotic drugs, Zyprexa increases the risks of sudden death, heart failure and life-threatening infections like pneumonia in elderly patients with dementia-related psychosis.

The company also pressed doctors to treat disruptive children with Zyprexa, court documents show, even though the medicine's tendency to cause severe weight gain and metabolic disorders is particularly pronounced in children. Over the last decade, Zyprexa's use in children has soared.

The case is being prosecuted by the United States attorney's office for the Eastern District of Pennsylvania. Patricia Hartman, a spokeswoman for the office, declined to comment.

Angela Sekson, a Lilly spokeswoman, said she could not comment on the status of the Zyprexa negotiations. Last fall, the company, anticipating a settlement, had set aside $1.4 billion for that purpose.

The amount of the settlement is a record sum for so-called corporate whistle-blower cases, which are federal lawsuits prompted by tips from company employees or former employees. In this case, the whistle-blowers have not been publicly identified.

Lilly executives have for years insisted that the company's Zyprexa marketing efforts were legal and appropriate. When asked whether she could repeat those assurances, Ms. Sekson said, "It would be inappropriate for me to comment further right now."

It could not be confirmed on Wednesday whether the company would acknowledge wrongdoing as part of the settlement. Without a settlement, Lilly risks being barred from participating in the federal Medicaid and Medicare programs — a huge part of its business — even though such bans are almost unheard of for big drug makers because their products are considered so essential.

In the United States, most of Zyprexa's sales are paid for by government programs because so many of those taking Zyprexa are indigent or disabled. Zyprexa had sales of $4.8 billion in 2007, making it the biggest seller by far for Lilly, whose revenue that year was $18.6 billion. Depending on dosage, the drug can cost as much as

$25 for a daily pill.

The settlement may have little impact on how doctors actually use Zyprexa, because physicians are free to prescribe drugs as they see fit. But drug makers are barred from promoting drugs for uses not specifically approved by the Food and Drug Administration.

Zyprexa has F.D.A. approval only for the treatment of schizophrenia and the mania and agitation associated with bipolar disorder.

Zyprexa has generated more than $39 billion in sales since its approval in 1996, making it one of the biggest-selling drugs in the world.

And despite mounting concern about Zyprexa's risks and the negative publicity surrounding the legal case, sales were $3.5 billion for the first nine months of 2008, 2 percent higher than in the first nine months of 2007. Prescriptions for the drug actually declined, but Lilly raised prices on the drug enough to increase its revenues.

Zyprexa was initially received as a significant advance over an earlier generation of antipsychotic drugs. But a series of landmark studies in recent years have cast doubt on that long-held view and suggested that Zyprexa is no better than older drugs that sell for far less.

A government study published in September, for instance, found that Zyprexa was no more effective in children than an older medicine but caused more serious side effects. The children receiving Zyprexa gained so much weight during the study that a safety monitoring panel ordered that they be taken off the drug.

In December 2006 articles in The New York Times detailed hundreds of internal Lilly documents and e-mail messages among top company managers that showed how the company sought for years to play down Zyprexa's tendency to cause weight gain and metabolic disorders, including diabetes, while promoting unapproved uses.

One 2000 e-mail message, for instance, described how a group of diabetes doctors that Lilly had retained to consider potential links between Zyprexa and diabetes had warned the company that "unless we come clean on this, it could get much more serious than we might anticipate."

After those articles were published, Lilly threatened to seek criminal contempt charges against Dr. David Egilman, a Massachusetts physician and associate clinical professor at Brown University, who made the documents available to The Times. In September 2007, Dr. Egilman agreed to pay Lilly $100,000 in return for the company's agreement to drop the threat of criminal sanctions.

On Wednesday, Dr. Egilman said he felt vindicated by the imminent settlement. "I'm glad Lilly is acknowledging their wrongdoing," he said. "Patients and doctors now know more about the side effects of the drugs they take."

The government's case will remain sealed until at least Thursday, when a judge is expected to approve the settlement. People involved in the negotiations say that prosecutors pressed for a resolution in the waning days of the Bush administration to avoid having to get another set of approvals from new bosses at the Justice Department in Washington.

While the settlement is intended to resolve all pending government claims, it is unclear whether all states, which are parties to the case through the federal-state Medicaid program, have agreed to the terms.

Some of the claims and evidence in the government's case are similar to those made in a pending California state whistle-blower lawsuit in which Jaydeen Vicente, a former Lilly sales representative, described years of what she said were illegal Zyprexa marketing efforts.

Ms. Vicente and other Lilly sales representatives distributed a Lilly study contending that elderly patients who were prescribed the drug "required fewer skilled nursing staff hours than patients prescribed other competing medications" and reduced "caregiver distress," the lawsuit states. Zyprexa often induces sleep in patients.

"In truth, this was Lilly's thinly veiled marketing of Zyprexa as an effective chemical restraint for demanding, vulnerable and needy patients," the lawsuit states.

In October, Lilly agreed to pay $62 million to 32 states and the District of Columbia to settle consumer protection claims related to Zyprexa. It has also paid the state of Alaska $15 million to settle a separate suit and agreed to pay $1.2 billion to 31,000 Zyprexa plaintiffs. Some private Zyprexa claims remain unresolved.