Zyprexa Medicaid Gravy Train Derailed

February 20, 2006. By Evelyn Pringle

When Zyprexa was approved to treat adults with schizophrenia in 1996, Eli Lilly and the FDA knew about the drug's lethal side effects. Data from a 1996 six-week clinical trial revealed 27 deaths, 15 of which were suicides, and a drop-out rate of 65%.

In his book, Mad In America, investigative journalist Robert Whitaker, reported that one in every 145 subjects who entered the clinical trials for Zyprexa, Risperdal, Seroquel, and Serdolect had died.

FDA data obtained by Bob Whitaker, under the Freedom of Information Act, the year Zyprexa was approved, reveals adverse effects that include: cardiac abnormalities and hypotension in 10% to 15% of the patients; acute weight gain in 50% of the patients; Parkinson-like motor impairment in 11.7%; and unbearable restlessness (akathisia) in 7.3% of the patients.

In another one-year clinical trial, the patient drop out rate rose to 83%.

Two years after Zyprexa was approved, a series titled "Doing Harm: Research on the Mentally Ill," by Bob Whitaker, was published on the front page of the Boston Globe, on Nov 15-18, 1998, and reported that in pre-marketing clinical trials, Zyprexa was linked to life-threatening adverse effects in 22% of the adult patients tested.

Since its approval, Zyprexa has been exposed as allegedly responsible for a high incidence of stroke, diabetes, endocrine, cardiac problems and movement disorders. And yet, the drug has been routinely prescribed to adults of all ages and to children, despite the fact that the FDA has not approved Zyprexa for pediatric use.

In the July 2002 issue of *Pharmacotherapy*, P Murali Doraiswamy, the chief of biological psychiatry at Duke University, published a review of adverse events reported to the FDA by Zyprexa patients, that found 289 cases of diabetes, 100 patients with ketosis (a serious complication of diabetes), and 22 cases of pancreatitis, a life-threatening condition. The review documented 23 deaths, including a 15-year-old adolescent who died of necrotizing pancreatitis.

In February 2004, the American Diabetes Association, the American Psychiatric Association, the American Association of Clinical Endocrinologists and the North American Association for the Study of Obesity issued a joint statement confirming the association between diabetes and Zyprexa.

That same month, independent researcher Dr David Healy, after studying the FDA's raw data on Zyprexa, told the

New York Times that Zyprexa was among "the deadliest drugs ever to gain FDA approval".

In October 2005, the *Journal of the American Medical Association* published a meta-analysis of 15 randomized trials of more than 5,000 elderly patients treated with atypical antipsychotics which found patients taking the drugs had a 54% increased chance of dying within 3 months, compared with patients taking a placebo.

While the FDA allowed Lilly to subject patients to the risks associated with the drug, a recent study published in the September 2005 issue of the *New England Journal of Medicine*, found that although Zyprexa was the most expensive and most prescribed antipsychotic, it was only slightly more effective than the cheaper 40-year-old generic drug, Perphenazine.

In addition, the study determined that patients on Zyprexa reported more side effects than those taking the generic or one of the other antipsychotic drugs.

Sales of Zyprexa dwindled in the last quarter of 2005, as news of the drug's lethal side effects made headlines. In June 2005, word got out that Lilly had agreed to pay $690 million to settle a lawsuit filed on behalf of about 8,000 Zyprexa patients who claimed they had not been warned that the drug allegedly increased their risk of getting diabetes.

Ellen Liversridge was one of the litigants in the class action lawsuit. Ellen's 30-year-old son, Rob, died due to the adverse effects of Zyprexa.

"Rob gained almost 100 pounds on Zyprexa," Ellen reports, "back before there was a warning on the label."

He felt "funny" one Sunday morning, she recalls, "but his symptoms weren't psychiatric and, to my sorrow," she says, "I didn't take him to the ER."

"By Tuesday, he had fallen into a coma," Ellen said.

Rob never came out of the coma. He died of profound hyperglycemia four days later on October 5, 2002.

Ellen was devastated. "He didn't deserve to be killed by a drug carrying a lethal bomb that we knew nothing about," she said. "He didn't deserve to become another Eli Lilly statistic."

"And we, his family," she added, "don't deserve to carry the pain that never goes away."

According to Ellen, "Lilly continues to deny any of these ill effects because they don't want their market share disturbed."

"After the settlement in June," she says, "they continued to deny the ill effects of Zyprexa, and only mentioned diabetes, not hyperglycemia or death."

Although Zyprexa costs a small fortune, a 12-month study by researchers at Yale, published in the November 26, 2003, *Journal of the American Medical Association*, followed 309 schizophrenic patients at VA hospitals nationwide and found no statistically significant advantages in patients treated with Zyprexa over the older generic Haldol, on measures of compliance, symptoms, overall quality of life, or reduced hospitalizations.

The only difference was the cost. In 2003, Zyprexa cost $3,000 to $9,000 more per patient than Haldol. In fiscal year 2003, the VA spent more than $106 million on Zyprexa.

However, public reports of the drug's adverse effects are finally taking their toll, especially in the US. In the third quarter of 2005, Zyprexa sales fell 10% to $504 million. The previous year, Zyprexa was the top-selling atypical with sales of $4.4 billion.

And for 2006, the decline in sales is likely to be even worse because Lilly now faces a major reduction in the company's most lucrative customer base: the Medicaid population, served by federal and state funded programs that provide prescription drug coverage to the poor, disabled and people in the custody of state hospitals and prison systems.

In every state, Zyprexa represents a big line-item expense to Medicaid at a time when most states are facing a budget crisis. US sales of all anti-psychotics doubled between 2001 and 2004, largely because of purchases by Medicaid.

On September 29, 2005, Bloomberg News reported that Medicaid programs may reduce the $5.5 billion it spends annually on schizophrenia drugs for the poor after a study found a cheaper generic about as effective as new pills, including Zyprexa.

"The 40-year-old drug perphenazine costs less than $1.50 a day," Bloomberg wrote, "while the newer medicines can cost 10 times as much."

When buying a three-month supply, the retail price for Zyprexa in September, 2005 at drugstore.com, was $1,500. By comparison, a 3 month supply of perphenazine, was only $135.

"It seems that doctors were prescribing only the new drugs," said Marian McDonough, an assistant professor at Oregon Health and Science University in Portland, to Bloomberg News. She helps state and private insurers decide which drugs to encourage doctors to use, and said the new study "may very much change" that.

The new study in the New England Journal of Medicine will be used for a program in Oregon that reviews drugs for Medicaid plans in 14 states, according to Bloomberg News.

Washington state plans to use Oregon's information to decide which pills doctors should consider first for low-income patients, according to Siri Childs, pharmacy policy chief for the state's Medicaid program.

The state of Georgia has removed Zyprexa from its preferred drug list and any Georgia doctor who wants to start a Medicaid patient on Zyprexa, must now submit a clinical rationale stating why it's the only drug appropriate for the patient, according to the November 28, 2005 *Indianapolis Business Journal*. Illinois, Tennessee, Pennsylvania and Louisiana also require doctors to obtain prior authorization before prescribing Zyprexa, according to the November 2005, *Indianapolis Business Journal*.

Georgia spokeswoman, Julie Kerlin told IBJ that removing Zyprexa from the list in 2004 has saved the state nearly $7 million which means Lilly lost $7 million in one state alone.

Zyprexa is the most expensive anti-psychotic covered by the South Carolina Medicaid program, according to James Assey, a pharmacist with the South Carolina Department of Health and Human Services. A month's supply of 20-milligram tablets costs South Carolina $700.52, IBJ reports.

As an alternative to removing the Zyprexa from the list completely, South Carolina decided to ask doctors to voluntarily consider cheaper drugs before prescribing Zyprexa.

As more states are forced to rein in the costs of Medicaid, the use of big-ticket drugs like Zyprexa will have to be eliminated.

Zyprexa Resources

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