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Dear Healthcare Professional:

I want to take this opportunity to respond to the recent media reports, and particularly an article in the New York Times (December 17), about Lilly and our product, Zyprexa® (olanzapine). This article, based on selective documents leaked by a consultant to plaintiffs' lawyers, fails to provide relevant facts that I believe are critical for physicians and their patients to know.

From the day Zyprexa was first marketed, its FDA approved label has identified potentially clinically significant weight gain and diabetes-related adverse events observed in clinical trials.

We have conducted more than 23 years of research on Zyprexa. Over the last ten years that Zyprexa has been on the market, we, our competitors and independent government research agencies such as the National Institute of Mental Health and the VA have conducted numerous studies on both the safety and efficacy of atypical antipsychotics including Zyprexa. These studies have not found that treatment with Zyprexa causes diabetes.

Weight gain has been observed with Zyprexa, as well as other antipsychotic medications. Weight gain in certain patients may increase the risk of diabetes. We know that diabetes is a multi-factorial disease, and weight gain is one of many well-established risk factors. The available scientific evidence, however, does not show that treatment with Zyprexa causes diabetes.

We have consistently shared our data with the FDA, as have other manufacturers of atypicals, and the FDA has continued to affirm the benefits that antipsychotic medications can provide to patients when accompanied by appropriate labeling regarding risks and benefits.

Documents referenced in the New York Times article are a tiny fraction of the more than 11 million documents that have been supplied to plaintiffs' attorneys in litigation that has been going on for more than three years. They have been taken out of context and they do not begin to tell the whole story about the litigation, much less the nearly quarter century of research and study that has gone into the development, testing and ultimately the marketing of Zyprexa.

Although we would very much like to provide the full context of these documents at this time to you and to the media, we cannot do so because the litigation is ongoing. We are not going to try our case in the press.

Most importantly, we are committed to being completely transparent regarding our clinical trial studies and have built an on-line clinical trial registry to disclose the results of our clinical studies for marketed products including Zyprexa. Moreover, clinical trial results are posted regardless of whether they are favorable to a Lilly product.

We will continue to disclose the results of our clinical trials that discuss the benefits and risks of our products so you can make the best possible decisions for those you treat.

On behalf of my Lilly colleagues world-wide, we thank you for all you do to ease the suffering of those with mental illness.

Sincerely,

Steven Paul, MD
Executive Vice President of Science and Technology
Eli Lilly and Company

Important Safety Information for ZYPREXA® (olanzapine)

Increased Mortality in Elderly Patients with Dementia-Related Psychosis
Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (eg, heart failure, sudden death) or infectious (eg, pneumonia) in nature. ZYPREXA is not approved for the treatment of elderly patients with dementia-related psychosis.

Cerebrovascular adverse events (CVAE), including stroke, in elderly patients with dementia—Cerebrovascular adverse events (eg, stroke, transient ischemic attack), including fatalities, were reported in trials of ZYPREXA in elderly patients with dementia-related psychosis. In placebo-controlled trials, there was a significantly higher incidence of CVAE in patients treated with ZYPREXA compared to patients treated with placebo. ZYPREXA is not approved for the treatment of elderly patients with dementia-related psychosis.

Hyperglycemia and diabetes mellitus—Hyperglycemia, in some cases associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics including ZYPREXA. All patients taking atypicals should be monitored for symptoms of hyperglycemia. Persons with diabetes who are started on atypicals should be monitored regularly for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Patients who develop symptoms of hyperglycemia during treatment should undergo fasting blood glucose testing.

Neuroleptic malignant syndrome (NMS)—As with all antipsychotic medications, a rare and potentially fatal condition known as NMS has been reported with olanzapine. If signs and symptoms appear, immediate discontinuation is recommended.

Tardive dyskinesia (TD)—As with all antipsychotic medications, prescribing should be consistent with the need to minimize the risk of TD. If its signs and symptoms appear, discontinuation should be considered.

Orthostatic hypotension—In premarketing schizophrenia trials, some patients taking ZYPREXA may have experienced orthostatic hypotension associated with dizziness, tachycardia, and, in some cases, syncope (15/2500, 0.6%).

Seizures—Occurred infrequently in premarketing clinical trials (22/2500, 0.9%). ZYPREXA should be used cautiously in patients with a history of seizures or with conditions that lower the seizure threshold.

Effect on prolactin—Modest elevations of prolactin were seen with ZYPREXA in acute-phase schizophrenia trials (incidence 34% vs 13% with placebo), although mean changes from baseline to endpoint were not statistically significantly different between olanzapine and placebo. Some patients may have persisting modest prolactin elevations.

Transient, asymptomatic elevations of hepatic transaminase—In placebo-controlled schizophrenia trials, clinically significant ALT (SGPT) elevations (≥3 times the upper limit of the normal range) were observed in 2% (6/243) of patients exposed to ZYPREXA compared to none (0/115) of the placebo patients. None of these patients developed jaundice. Rare postmarketing reports of hepatitis have been received. Very rare cases of cholestatic or mixed liver injury have also been reported in the postmarketing period. Periodic assessment of transaminases is recommended in patients with significant hepatic disease.

Special populations, elderly—Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Olanzapine should be used with caution in patients at risk for aspiration pneumonia. In 5 studies in elderly patients with dementia-related psychosis, adverse events reported more commonly with olanzapine than with placebo were falls, somnolence, peripheral edema, abnormal gait, urinary incontinence, lethargy, increased weight, asthenia, pyrexia, pneumonia, dry mouth, and visual hallucinations. Olanzapine should be used with caution in elderly patients with dementia. Olanzapine is not approved for treatment of patients with dementia-related psychosis.

Drug interactions—Coadministration of diazepam or ethanol with ZYPREXA may potentiate orthostatic hypotension. Lower doses of ZYPREXA should be considered in patients receiving concomitant therapy with fluvoxamine.

Medication dispensing and prescribing errors have occurred between ZYPREXA® (olanzapine) and Zyrtec® (cetirizine HCl). These errors could result in unnecessary adverse events or potential relapse in patients suffering from schizophrenia or bipolar disorder. To reduce the potential for dispensing errors, please write ZYPREXA clearly.

The most common treatment-emergent adverse events associated with ZYPREXA (vs placebo) in 6-week acute-phase schizophrenia trials were somnolence (26% vs 15%), dizziness (11% vs 4%), weight gain (6% vs 1%), personality disorder (COSTART term for nonaggressive objectionable behavior; 8% vs 4%), constipation (9% vs 3%), akathisia (5% vs 1%), and postural hypotension (5% vs 2%).

The most common treatment-emergent adverse events associated with ZYPREXA (vs placebo) in 3- and 4-week bipolar mania trials were somnolence (35% vs 13%), dry mouth (22% vs 7%), dizziness (18% vs 6%), asthenia (15% vs 6%), constipation (11% vs 5%), dyspepsia (11% vs 5%), increased appetite (6% vs 3%), and tremor (6% vs 3%).

For complete safety profile, see full Prescribing Information.

ZYPREXA is a registered trademark of Eli Lilly and Company.
Zyrtec is a registered trademark of UCB, SA.