

# Know your patients.

- Michael is in his mid-30s, highly functional, has been your patient for years, and is in good general health
- He reports a decreased need for sleep
- You've ruled out substance abuse and possible organic causes
- He strongly resists your attempt to refer him for psychiatric treatment

## His wife has shared her concerns with you...

*"He has these sudden mood swings—I never know what to expect."*

*"He talks so quickly, bouncing from subject to subject."*

*"He's being so erratic. He's spending money we just don't have."*

## Goals of treatment may include:

- Stabilize mood
- Reduce agitation

irritability  
anxiety  
poor sleep  
elevated mood

ZY401985

# Know ZYPREXA.

**ZYPREXA**  
Olanzapine 

EXHIBIT F  
PAGE 1 OF 4

*Lilly*

## Other prescribing considerations

The most common treatment-emergent adverse event associated with ZYPREXA in placebo-controlled bipolar mania trials was somnolence\* (35% vs 13% for placebo). Also observed (ZYPREXA vs placebo) were:

- |                          |                               |
|--------------------------|-------------------------------|
| dry mouth* (22% vs 7%)   | dyspepsia (11% vs 5%)         |
| dizziness* (18% vs 6%)   | increased appetite (6% vs 3%) |
| asthenia* (15% vs 6%)    | tremor (6% vs 3%)             |
| constipation (11% vs 5%) |                               |

### Orthostatic hypotension

In premarketing schizophrenia trials, some patients taking ZYPREXA may have experienced orthostatic hypotension associated with dizziness,<sup>7</sup> tachycardia,<sup>8</sup> and, in some cases, syncope (15/2500, 0.6%).

### Transient, asymptomatic elevations of hepatic transaminase

In placebo-controlled schizophrenia studies, clinically significant ALT (SGPT) elevations ( $\geq 3$  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 experienced jaundice. Periodic assessment of transaminases is recommended in patients with significant hepatic disease.

As with all antipsychotic medications, the following considerations should be taken into account when prescribing ZYPREXA:

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

**Seizures**—occurred infrequently in premarketing clinical trials (22/2500, 0.9%). Confounding factors may have contributed to many of these occurrences. ZYPREXA should be used cautiously in patients with a history of seizures or with conditions that lower the seizure threshold. Such conditions may be more prevalent in patients age 65 years or older.

\* In bipolar mania trials, 4 adverse events occurred with statistically significantly higher incidence with ZYPREXA than with placebo—none of these resulted in discontinuation.

<sup>7</sup> In acute-phase schizophrenia trials (n=366), dizziness (11% vs 4%) and tachycardia (4% vs 1%) were reported; these events were not always associated with hypotension.

For additional safety profile and other important prescribing considerations, see the full Prescribing Information.

ZY4019 86



Lilly

Eli Lilly - Zyprexa Products Liability Litigation  
Zyprexa MDL Plaintiffs' Exhibit No.00229

006120

Confidential and Subject to Protective Order  
Page 2

EXHIBIT F  
PAGE 2 OF 4

## Favorable safety profile

- No black-box or boxed warnings
- No baseline ECG required
- No difference in clinically significant QT prolongation with ZYPREXA compared to placebo in patients with
- No higher discontinuation rate due to adverse events
- The most common treatment-emergent adverse events with ZYPREXA in placebo-controlled studies in patients with bipolar depression were somnolence (15% vs 12% for placebo)

ZYPREXA has been used by more than 6 million patients worldwide.

ZY4019 87

ZYPREXA  
Ziprasidone

EXHIBIT F  
PAGE 3 OF 4

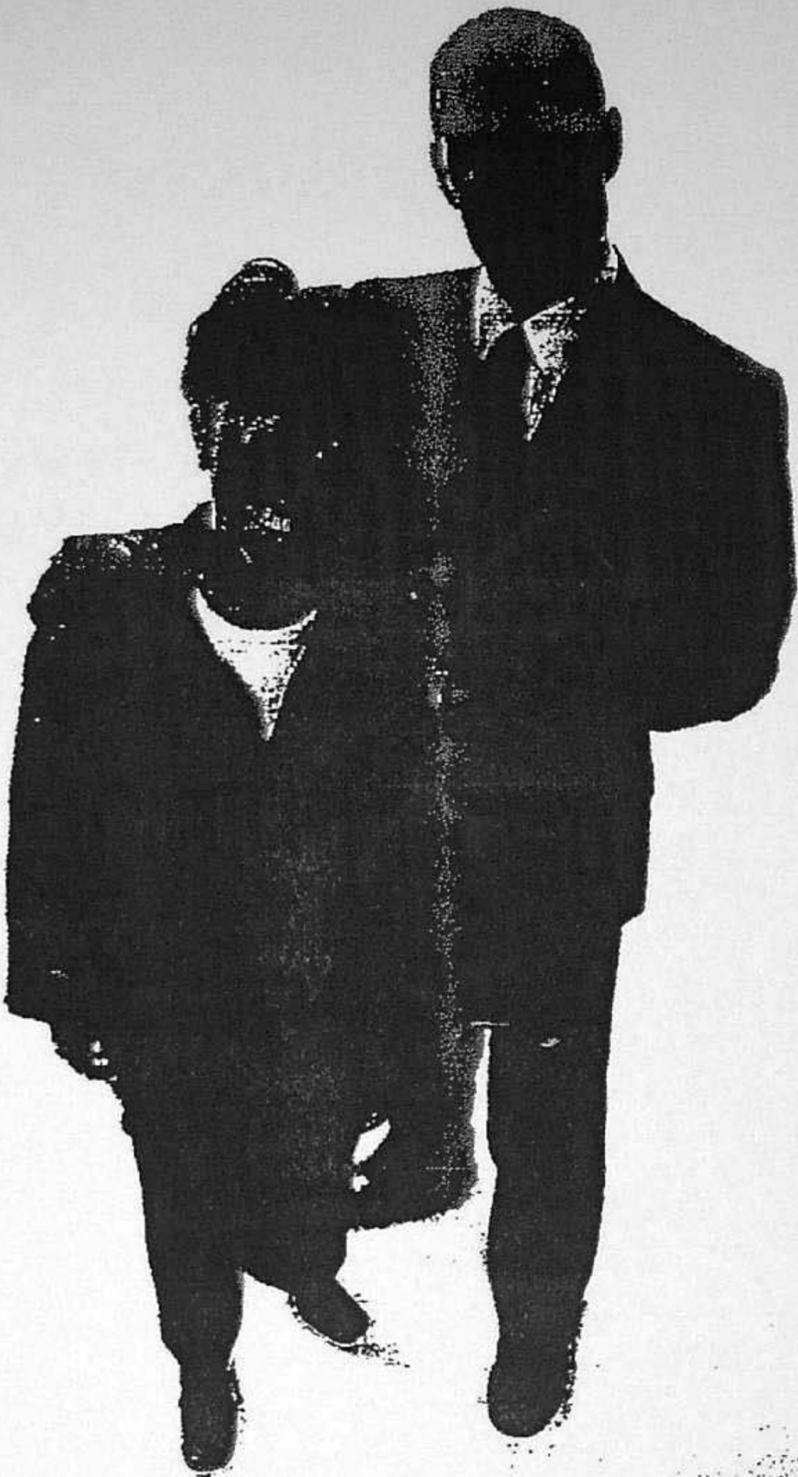
Lilly

Confidential and Subject to Protective Order  
Page 3

006121

Eli Lilly - Zyprexa Products Liability Litigation  
Zyprexa MDL Plaintiffs' Exhibit No.00229

Unsealed in Alaska v Lilly 3AN 06-5630 CIV



### *Favorable safety profile*

- **No black-box or bolded warnings**
- **No baseline ECG required**
  - No difference in clinically significant QTc prolongation with ZYPREXA compared to placebo in premarketing clinical trials
- **No routine blood monitoring required**
- **The most common treatment-emergent adverse event associated with ZYPREXA in placebo-controlled clinical trials for acute mania was somnolence (35% vs 13% for placebo)**

*ZYPREXA has been used by more than 6 million patients worldwide.*

ZY4019 88

See inside for additional safety information and full Prescribing Information.  
21153 PRINTED IN USA 10198737 50180 ©2001, ELI LILLY AND COMPANY. ALL RIGHTS RESERVED.  
ZXA is a registered trademark of Eli Lilly and Company.



www.ZYPREXA.com

*Lilly*

Eli Lilly - Zyprexa Products Liability Litigation  
Zyprexa MDL Plaintiffs' Exhibit No.00229

006122

EXHIBIT F  
PAGE 4 OF 4

Confidential and Subject to Protective Order  
Page 4