

COMPETITIVE INFORMATION

GENERAL ADA FINDINGS

Source—Dr. John Newcomer

- ADA findings are the first phase of market shift in atypicals that will disrupt Zyprexa's dominance.
- The ADA pronouncements will lead to guideline for treatment using atypicals, specifically recommending monitoring of the patient's weight gain, cholesterol, and potential for diabetes.
- Newcomer, as chair of the APA subcommittee on metabolic issues, will issue its own guidelines at the APA in NYC. The position will be somewhat the same as the ADA treatment guidelines
- These guidelines will give trial lawyers ammunition for class action suits against drug companies, and will likely make doctors more reticent about using Zyprexa.
- ADA-APA guidelines may allow Medicaid programs to remove Zyprexa because of doubt raised about its use.
- Also, new supplemental rebate program will allow each state to ask pharma companies for individual pricing and rebates.
- The market dominance of Zyprexa is due to marketing and not superior efficacy. All atypicals have the same MOA with different side effects.
- Zyprexa has the same efficacy as all others atypicals on the market. Most meta-analyses show the same D-2 receptor antagonist effect in all the drugs when the dose is corrected for.
 - *“Zyprexa is the most sedating, with the most H-1 receptor anti-histaminic effect, for sure, but all the drugs work the same.”*
 - *“You achieve 70% D-2 receptor antagonism, you got yourself an atypical antipsychotic. You can raise all dosages of all these atypicals to get the same response. Only the side effects differ.”*
 - *“Only one study by Glick et al. shows olanzapine and quetiapine to be more effective, but it's not conclusive.”*
 - *“Most of the differences between drugs are all marketing BS.”*

- The ADA “Table 2” is somewhat misleading because makes the drugs look linear in their side effects with its use of plusses and minuses. It should list Clozaril & Zyprexa first with 22 lbs weight gain in 14 months, then Seroquel & Risperdal second (7 lbs.), and then Abilify and Geodon (2.2 lbs).
 - *“The efficacy ‘improvement’ of Zyprexa, even if it existed, would not justify its much higher weight gain.”*
 - *“Even if Zyprexa was a bit better, which is not shown, as a doctor, you err on the side of caution—you should start with a treatment that has low side effects and work your way up if you don’t get the benefits you want—but don’t risk the weight gain first”.*
- Lilly is “burning credibility” by denying the metabolic side effects of Zyprexa through semantics.
- Many practitioners are aware of the different metabolic profile of Zyprexa, and many would prefer straight answers from the company.
 - *“Lilly is playing a language game with the FDA pronouncements. Because the FDA class warning is about diabetes, Lilly can claim that there is no direct link with diabetes—which is true in one sense. But there is a direct link with weight gain, visceral fat, insulin sensitivity, and thus diabetes, stroke, and myocardial infarction. So while Lilly is technically correct, this is whitewash. They are, however, doing an outstanding job of politicizing and language games.”*

ASTRAZENECA – SEROQUEL

Source—AZ Marketing Executive

- AZ will no longer be pursuing trial data for borderline personality disorder
 - *“We were headed in that direction, but have stopped seeking trial data in borderline, mutilation, and personality disorders. It was a decision from the top”*
- AZ is conducting a multinational study this year to support “generalized anxiety disorder.”
 - *“To support off label uses, we are instead supporting research about use of Seroquel for generalized anxiety disorder. Don’t expect the data in 2004, though.”*

- Studies for Seroquel with Bipolar depression are done and ready to be presented APA, even though medical affairs does not report data
- AZ is developing research sites at nursing homes to study quetiapine and its effects on Alzheimer's dementia.

Source—Dr. John Newcomer

- The notion advanced by AstraZeneca that the schizophrenic brain develops diabetes on atypicals, while the non-schizophrenic brain does not develop diabetes is completely incorrect.
 - *“Body fat, caused by atypicals, is bad for all of us because it lowers insulin sensitivity.”*
- AZ is shifting its sales force to PCP to take advantage of new bipolar indications.

Source—Dr. Hirschfeld, thought leader

- “Seroquel is the big story. Its meteoric rise is due to their off-label uses.”

JANSSEN – RISPERDAL

Source—Janssen sales rep and district manager

- Janssen reps are denying that Risperdal should be part of the class warning.
- Message: Risperdal 1/3 as likely to cause diabetes as Zyprexa

Source—Janssen medical affairs

- Janssen's new message for Consta will be “Response, Remission, Reconnection.”
- A study on Risperdal for Alzheimer's dementia to be released in June

PFIZER – GEODON

Source—Dr. John Newcomer

- Pfizer could lobby directly with the states on the points that if they use Zyprexa on the Medicaid formulary, states will be have to foot the bill for statins and other health care down the road because of the additional side effects.
- Pfizer will attempt to get out of the class warning.
- Pfizer is seeking to take market share from Zyprexa based on the new ADA findings and is set for counter-detailing, speakers, and new CME.

- *“Both Pfizer & BMS have strong data showing that their drugs are low risk for lipids, glucose, and weight gain. They will use this to capture market share.”*

Source—Pfizer sales representative

- Reps are claiming that Geodon will have QTc prolongation removed from the label.

BMS – ABILIFY

Source—Dr. John Newcomer

- BMS could lobby directly with the states on the points that if they use Zyprexa on the Medicaid formulary, states will be have to foot the bill for statins and other health care down the road because of the additional side effects.
- BMS is shifting its sales force to PCP to take advantage of new bipolar indications.
- BMS is seeking to take market share from Zyprexa based on the new ADA findings and is set for counter-detailing, speakers, and new CME.
 - *“Both Pfizer & BMS have strong data showing that their drugs are low risk for lipids, glucose, and weight gain. They will use this to capture market share.”*