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12/01/2003 05:24:17 PM Date:

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Weight Task Force minutes and next steps **Subject:**

bipolar wt.ppt; Issues and questions.ppt; KINON.Schizophrenia.WeightTaskForce.v2.ppt **Attachments:**

At Lilly we continue to find ways to help clinicians and patients with the proper use of our products. It is in this spirit that the weight task force met today. How do clinicians see the problem of weight gain associated with olanzapine, and what do scientific data support? Is there any discordance between the two views, and how can we address these?

Thanks for your participation in the meeting.

Attached are slides presented today. Please do not use these externally without obtaining clarification (as some of them require further review and validation).

Five major action items came out of the meeting today:

- 1. Internal communication (periodic) to ensure expertise (common knowledge base) on topic of weight is maintained throughout Zyprexa team. This has been done previously; we just need to continue this periodically. This may require some consolidation and sorting of available slide set to focus on weight gain. Periodic task force meetings will continue as well.
- 2. Market research on the following questions should be consolidated (to better understand how practicing clinicians answer these questions):

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-Does weight gain lead to metabolic issues (v. direct effect)?
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-Is weight gain predictable?

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- -How widespread is the the problem of olanzapine wt gain related discontinuations in clinical practice?
- -Are there some patients who should be discontinued due to weight gain during olanzapine treatment?
- -Is weight gain manageable?
- -Is weight gain dose-dependent (in clinically efficacious range)?
- -Are atypical antipsychotic agents comparable in -their association with weight gain?
- 3. A Review of what has been done so far (tactically) is necessary to ascertain what has worked well, and what hasn't.
- 4. Further analyses/studies are required including examination of lipids soon after initiation of weight gain (to speak to "transient effect" on lipids), histograms of weight change in patients with low and with hi baseline BMI, addition of weight change curves of other drugs (from our long-term studies), relationship of weight change to efficacy (irrespective of treatment condition), weight change is studies with polypharmacy, and weight change patterns in observational studies (The meeting today didn't cover resourcing, particularly stat, for these efforts, so this may be considered action item 4.1).
- 5. To ensure transparency, as well as provide external validation, involvement of external thought leaders, as work of task force continues.



Issues and questions.ppbipolar wt.ppt KINON.Schizophrenia.WeightTaskForce.v2.ppt