Zyprexa regulatory briefing

We anticipate differential labeling (re: risk for hyperglycemia, treatment emergent diabetes and related metabolic issues) with our next submission; redacted

redacted

- Expect label change in the Precaution section at a minimum, more likely as a warning
- Even FDA attempts to "class-label" could take 6-12 months to implement with other products
- Analyst community has indicated that this could be a trigger for Lilly disinvestment

There is substantial risk in opening the Zyprexa label to a public Advisory Committee discussion; that risk is not new and has been previously communicated internally. redacted

redacted

redacted Based on launch plans and sales forecasts in the U.S., as well as portfolio management decisions in other key affiliates, the redacted may no longer justify the risk to the Zyprexa label.

The position of the Zyprexa Product Team is that private negotiations (in advance of a submission) provide the opportunity to better influence the outcome, and that the timing of any outcome should be considered in the context of corporate performance (e.g. manufacturing issues, new product launches, etc.)

redacted

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