

**To:** CN=Eugen Grecu/OU=EMA/O=LLY@Lilly; CN=Roland Powell/OU=EMA/O=LLY@Lilly; CN=Mark R Russom/OU=AP/O=LLY@Lilly; US\_Zyprexa\_Brand Council  
**CC:** CN=Robert W Baker/OU=AM/O=LLY@Lilly; CN=Russell L Barton/OU=AM/O=LLY@Lilly; CN=Alan Breier/OU=AM/O=LLY@Lilly; CN=Melanie A Bruno/OU=AM/O=LLY@Lilly; CN=Patrizia Cavazzoni/OU=AM/O=LLY@Lilly; CN=Enrique A Conterno/OU=AM/O=LLY@Lilly; CN=Anthony M Fiola/OU=AM/O=LLY@Lilly; CN=James L Gahimer/OU=AM/O=LLY@Lilly; CN=Bin Gu/OU=AM/O=LLY@Lilly; CN=Jared G Kerr/OU=AM/O=LLY@Lilly; CN=Mark C Kershishnik/OU=AM/O=LLY@Lilly; CN=Timothy F Parshall/OU=AM/O=LLY@Lilly; CN=Matthew R Pike/OU=AM/O=LLY@Lilly; CN=David Ricks/OU=AM/O=LLY@Lilly; CN=Denice M Torres/OU=AM/O=LLY@Lilly; CN=Deirdre Connelly/OU=AM/O=LLY@Lilly; CN=Enrique A Conterno/OU=AM/O=LLY@Lilly; MARKETIN@Lilly; CN=Glyn Parkin/OU=AM/O=LLY@Lilly; CN=Roland Powell/OU=EMA/O=LLY@Lilly; CN=Jo A Taylor/OU=AM/O=LLY@Lilly; CN=Albertus vandenBergh/OU=AM/O=LLY@Lilly; CN=Thomas G Wellner/OU=EMA/O=LLY@Lilly  
**Date:** 10/18/2002 09:34:25 AM  
**From:** CN=Michael E Bandick/OU=AM/O=LLY  
**Subject:** Risperidone Cerebrovascular Warning in Canada

Yesterday some of you may have received a document containing a "Dear Doctor" letter that was recently issued by Janssen in Canada. The purpose of this email is to provide some background and recommendations regarding the letter.

#### **Background**

Earlier this year Health Canada requested all antipsychotic manufacturers (including Lilly) to provide safety data regarding cerebrovascular (e.g., stroke) adverse events (CVAEs). Upon review of all of the information provided, Health Canada requested that Janssen (and only Janssen) update their label. Janssen and Health Canada are still negotiating final details of the label change and Health Canada has requested that Janssen issue a Dear Doctor letter (attached) in the interim. It is likely that the Risperdal label will now contain a **black box warning** pertaining to CVAEs. In addition, physicians are advised to assess the risks of using Risperdal in elderly patients with dementia (Risperdal has an indication for this in Canada).

#### **Recommendations**

The attached letter is **NOT APPROVED** for use in the field. In addition, we need to continue to focus on our story - that Zyprexa provides the dependable control that enables a therapeutic alliance that allows physicians to help patients move their lives forward and achieve their individual potential. To that end, Zyprexa's known and manageable side effect profile is an integral part of our Brand Promise.

It would be appropriate to make mention of this information when confronted with speculation and allegations regarding our own label. While we

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do not want to speculate on potential label changes, ours or competitors, we would like to point out **actual** label changes such as the recent addition of a black box warning (**pending finalization of language**) to the Risperdal label in Canada regarding CVAE. If questioned further on the matter, suggest that the Janssen representative may be able to provide the information and get back to selling the dependable control of Zyprexa.

It would be inappropriate to use this as tool to try to influence local regulatory agencies (they will be well aware of the change) or to simply bash Janssen.

#### **Janssen Response**

We can expect Janssen to do the following in response:

- Increase focus on diabetes/hyperglycemia to divert attention from CVAEs
- Try to categorize CVAEs as "class effect"
- Introduce a discussion around falls with Zyprexa in the elderly

Janssen will go to great lengths to divert attention from this issue. Already in Canada, on the day they issued the Dear Doctor letter, they duped a local endocrinologist to "independently" write a cover letter and mailed the Sernyak, Koller and Koro articles to 23,000 physicians. This was highly inappropriate and is being handled by the Canadian affiliate in conjunction with Canadian medical and regulatory bodies. But it serves as an example of just how far they will go.

If your customers are concerned that CVAEs are a class effect or have questions regarding Zyprexa data on falls, it would be appropriate to respond with a medical letter. You may want to check that you have these materials on hand. You may contact Matt Pike if you do not have what you need.

Finally, this label change is segment specific - limited to elderly dementia - so you may want to share this information on a very limited basis with key customers involved in that segment.

#### **Summary**

The final language for the Risperdal label is not complete

The attached warning has been issued in the interim

Janssen will try to divert attention from the issue

Zyprexa underwent the same review process and was not asked to change labelling

#### **Do:**

- Share information **SELECTIVELY** as appropriate
- Affirm Zyprexa's safety profile
- Set record straight about actual product labelling
- Beware of Janssen tactics to avoid issue
- **SELL ZYPREXA!!**

#### **Don't:**

- Contact regulatory agencies
- Bash Janssen
- Speculate about potential label changes elsewhere

Mike Bandick  
Zyprexa Product Team

Tim Parshall  
Zyprexa Product Team

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Michael E. Bandick  
Director, Marketplace Management  
Zyprexa Product Team (DC 1748)  
317 277 5396 Office  
317 277 6930 FAX  
Redacted