To: CN=Matthew R Pike/OU=AM/O=LLY@Lilly

Date: 08/09/2002 12:22:05 PM

From: CN=Patrizia Cavazzoni/OU=AM/O=LLY Subject: Newcomer and Csernansky in the U.k.

---- Forwarded by Patrizia Cavazzoni/AM/LLY on 08/09/2002 11:21 AM -----

Dennis G West

08/08/2002 04:53 PM
To: Robert W Baker/AM/LLY@Lilly, Alan Breier/AM/LLY@Lilly, Patrizia Cavazzoni/AM/LLY@Lilly, Gary D

Tollefson/AM/LLY@Lilly

CC:

Subject: Newcomer and Csernansky in the U.k.

I had requested follow-up comments through Hiram Wildgust on the recent trip to the U.K. and previously sent you the report from the BAP meeting. Here are comments from a Janssen organized meeting. Nothing new in content but the audience reaction is interesting.

A holding action???

The points that I have been making with key schizophrenia academicians seems to address many concerns at this time. (as per their continued requests for the body of literature that I currently use as reference)

High incidence of diabetes in schizophrenics (previously and currently unrecognized)

Antipsychotics appear to play a role (not clearly defined)

Atypicals worse than typicals? (mixed signals with large outcome data bases)

Individual differences between the atypicals? (mixed signals from the literature, large variations in outcome studies methodology, most say no causality)

Previous work suggesting antipsychotic direct effect, by Newcomer and Henderson, nicely addressed by the three studies using hyperglycemic and euglycemic clamp procedures.

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Secondary drug effects (weight gain) and other risk factors must be the issue of concern to monitor

What academicians are asking for is that Lilly issue a consistent and believable drug usage approach for olanzapine. No one questions the great degree of efficacy olz has. The fact that it is so highly efficacious keeps it as a first line treatment and makes existing side effects acceptable, so long as they know how to manage those side effects. These teachers of doctors are asking for Lilly to clearly define a way to manage this issue of weight gain and diabetes. My sense is that we have defended the causality issue but not clearly issued such position statement or guideline of use at this time.

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	Forwarded by Dennis G West/AM/LLY on 08/08/2002 04:08 F	⊃M

Hiram Wildgust

08/08/2002 11:02 AM To: Dennis G West@Lilly

cc: Neil G Archer@Lilly, Peter Beardsall@Lilly Subject: Janssen meeting feedback - Chris Fear

Dennis,

I know that in the US you have been trying to get a handle on Newcomer and obviously we gave you our feedback. Please see below some feedback that came unsolicited re his presentation at a regional meeting which Howard Pankurst attended.

I hope this is helpful and here in the UK we would be interested in what happens next.

Regards	
Hiram	
Forwa	arded by Hiram Wildgust/EMA/LLY on 08/08/2002 16:59
Howard Pankhurst	
08/08/2002 11:35	

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To: Neil G Archer/EMA/LLY@Lilly, Peter Beardsall/EMA/LLY@Lilly, Millie Ewart/EMA/LLY@Lilly, Tracey J Hall/EMA/LLY@Lilly, Philip R Knott/EMA/LLY@Lilly, David McGee/EMA/LLY@Lilly, Yelena Popova/EMA/LLY@Lilly, Hiram Wildgust/EMA/LLY@Lilly

cc: Peter Aitken/EMA/LLY@Lilly, Lesley A Allen/EMA/LLY@Lilly, Richard Croft/EMA/LLY@Lilly, GB_FF_LPG KOL@Lilly, Lisa J Parrott/EMA/LLY@Lilly, Jeremy D Wiles/EMA/LLY@Lilly

Subject: Janssen meeting feedback - Chris Fear

Dear Zyprexa Marketing

FYI

Please find below feedback from a Janssen meeting that Chris Fear attended recently.

As you can see he felt the messages put across were strong in favour of Risperidone (obviously!) but that the underlying feel was that Zyprexa will cause diabetes due to weight increase. The presentation went on and on about consequences of weight gain and therefore implied that Zyprexa is much higher risk due to this side effect.

If you wish to discuss this further with Chris (he would be happy to do so) then please let me know and I will pass on his contact numbers etc

Kind regards

Howard

PS Chris also told me this week that he believes Ziprasidone could be launched in the next 6 - 9 months. Chris is on the advisory board for Pfizer

Tortworth Court Meeting

Attended by about 30 but few consultants - disappointing for J who had two excellent speakers and seem unable (as do most others) to attract a good consultant turnout from this area. Quite a lot of nurses which is significant as I think weight data makes a particular impact upon them for a number of reasons (predominantly female, still lingering prejudice against medicine & "medical model", often naive about the meaning of data and statistical tests etc.). Nevertheless I think we all accept that nurses have a huge influence on prescribing.

Csernansky - brilliant, authoritative style of presentation. Difficult to add anything to the paper which was presented exactly as written. Well-designed study of R vs. haloperidol and effect of relapse over 1-2 years. Seems to show that R reduced relapse rate by 48% over H. This message very clear and well-received: no attempts to challenge data or design. The point was made (by chairman David Nutt, me etc.) that there are no data on other atypicals and this may be a

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"class effect" (insofar as atypicals can be seen as a class, which they're not). It seems J were the company who offered to fund so they got the data and Csernansky agreed that he may have got the same result with zyprexa/quetiapine or (God forbid!) amisulpride. Major partisan message was that R is the only drug that has long-term RCT data and can be shown to reduce relapse. Also made point that John Geddes change his mind about atypicals (ie over BMJ paper) on the strength of these data.

Newcomer - Not quite a authoritative and, in fact, less to say on reflection, but this was the killer presentation of the evening as far as mopst of the audience was concerned. Basic presentation of the ArchGenPsych paper with some additions. Not obviously partisan but Z consistently implicated as a likely cause of type 2 diabetes or cardiac problems via weight gain. Lots of very complicated data, presented quite simply giving this black-and-white message. I think he said that there was no proven direct link between any atypical and endocrine problems but I doubt whether any member of the audience will have heard this. This was a very visceral presentation about the risks of weight gain and made a huge impact on me such that I though carefully before prescribing Z or Q over the next fortnight. The effect has worn off a bit now and I've spent some time thinking about what he actually said rather than the emotional impact of being implied that my prescibing of Z could seriously limit my patients' health/life (not said but implied). I know Newcomer has spoken to BAP but not sure where else. I think if I were with J, I'd be throwing some cash at this chap to get his message more widely know.

Without doubt, this was the most effective pharmaceutical meeting I have been to for some years.

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