

To: CN=Michael E Bandick/OU=AM/O=LLY@Lilly; CN=Alan Breier/OU=AM/O=LLY@Lilly; CN=John C Lechleiter/OU=AM/O=LLY@Lilly; CN=Steven M Paul/OU=AM/O=LLY@Lilly; CN=Mauricio F Tohen/OU=AM/O=LLY@Lilly; CN=Denice M Torres/OU=AM/O=LLY@Lilly; CN=Albertus vandenBergh/OU=AM/O=LLY@Lilly; CN=Kathleen L Wishner/OU=AM/O=LLY@Lilly
Date: 02/08/2004 10:23:36 PM
From: CN=James A Harper/OU=AM/O=LLY
Subject: ADA

Colleagues:

At the ADA Research Foundation Board meeting this weekend (which was in conjunction with the Scientific Meeting in San Francisco), I raised my concerns as a Vice Chair of the Research Foundation regarding the integrity of the process leading to the recent consensus paper on antipsychotics. I requested an audit of the process, and challenged the ADA to reconsider it's policies on two counts: 1. Should the ADA ever take a position contrary to FDA without overwhelming cause? And, 2. The ADA , given it's status, has a special and obligation to ensure that any position it takes is based on totally sound, rigorously reviewed scientific evidence. To take a position based on hastily generated "opinion" is irresponsible.

With respect to the audit I asked for a focus on the process with special attention to the scientific rigor. Questions I requested the audit to address include:

Was there time to conduct a critical review of the volume and complexity of the data?
Was there an critical assessment of the studies and presentations including the methodological strengths and limitations of each?
Was there a relative weighting assigned to each study based on the above in assessing the relative value of each in reaching the conclusions?
Was there an adequate assessment of the subtleties of the dose/efficacy relationship of the therapies included in the paper?
To what degree were the presentations based on anecdotal impressions, small studies and limited personal experience versus a comprehensive, fact based review of all the available studies and data?
Was there any evidence of bias in the presentations?
Were the conclusions rushed?
Are the conclusions consistent with the total body of evidence?

Also:

At what point did the agenda change from a workshop focused on an epidemiological review of the increased risk of diabetes associated with mental illness, and especially schizophrenia (which was the original objective as I understand it) to a relative comparison of atypical antipsychotics?

Who made this decision and why?

My request to all of you is to look critically at the questions I have asked the audit to address. Are these the right questions and do you have any

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additions, deletions or modifications???

I would appreciate your input asap so I can provide highlight areas on which the auditors should focus, if an audit does, in fact, occur.

Thanks,

Jim

To: CN=Michael E Bandick/OU=AM/O=LLY@Lilly; CN=Russell L Barton/OU=AM/O=LLY@Lilly;
CN=Michael W Magdycz/OU=AM/O=LLY@Lilly; CN=Cherri Miner/OU=AM/O=LLY@Lilly;
CN=Michael R Sale/OU=AM/O=LLY@Lilly; CN=Mauricio F Tohen/OU=AM/O=LLY@Lilly;
CN=Denice M Torres/OU=AM/O=LLY@Lilly
CC: CN=Timothy J Barnett/OU=AM/O=LLY@Lilly; CN=Mark Enerson/OU=AM/O=LLY@Lilly;
CN=Michael Overdorf/OU=AM/O=LLY@Lilly
Date: 02/20/2004 05:37:56 PM
From: CN=Mark Enerson/OU=AM/O=LLY
Subject: Competitive Intelligence Update - includes an interview with Newcomer on the ADA paper
Attachments: Competitive Info Feb 20, 2004.doc

Please keep the distribution of the attachment limited as it may contain items that are inaccurate and only the views of one source.

As we discussed our CI plan 2 weeks ago, you mentioned that you would like more frequent updates from our vendor. The last two reports from them have been very interesting - I have compiled the notes in the attachment below.

Most of document is from an interview they had with John Newcomer, which clearly highlights his negative views of Zyprexa. The update also includes some interesting items on the competition, such as AstraZeneca pursuing generalized anxiety disorder and that studies with Seroquel and bipolar depression are done and ready to be presented at APA.

Regards, Mark



Competitive Info Feb 20, 2004.doc

Mark Enerson
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