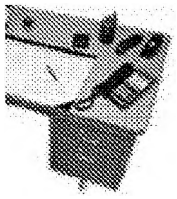

Michael Detke /AM/LLY
10/11/2005 09:59 PM

To Daniel K Kajdasz/AM/LLY@Lilly
cc Durisala Desaiah/AM/LLY@Lilly, James M Russell/AM/LLY@Lilly, PERAHIA_DAVID_G@LILLY.COM
bcc
Subject Re: Resubmitted. Your Review Required Again for Disclosure Approval Request TMIS-6GWKTM Deadline = 10/11/2005 Type = Poster

Well thought through Dan. Thanks.

I respectfully disagree with the decision about #2, as I don't see the point in being consistent with bad methodology. But I can see your point, and can live with it given that the major conclusions are not different.

As for 3 & 4, I think some minor clarification in the language would solve the problem, although I do think an opportunity was missed (i.e. we have head-to-head data with an SSRI here, why not present it).

Thus I can approve it. I assume the slightly edited version will come around, and I'll approve then.

For both of the points, a smart critic could see the stance we've taken as unduly favorable to Lilly. Using the entire treatment duration as baseline reduces the apparent number of DEAEs, and the direct comparison to paroxetine is not terribly favorable, and we've chosen not to present it. Let's continue to challenge ourselves to be as objective as possible. I'm not trying to pretend anyone is perfect at this, least of all me; let's all remind each other of it if we see what might be perceived (by any of our many eager critics) as a misstep.

Thanks.

Mike

Michael J. Detke, M.D., Ph.D.
Cymbalta & Prozac Global Medical Director
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Co-marketing statement:
1) We are sharing this information only for the purposes of co-promoting duloxetine in those regions of the world where Lilly & BI are co-promotion partners.
2) It is not to be shared to influence or direct how BI markets its brand of duloxetine in co-marketing regions.
3) It should not be considered a final determination of Lilly's brand strategy in regions where Lilly & BI are co-marketing competitors.

Daniel K Kajdasz/AM/LLY

Daniel K Kajdasz /AM/LLY
10/11/2005 05:24 PM

To Michael Detke/AM/LLY@Lilly

cc Durisala Desaiah/AM/LLY@Lilly, James M Russell/AM/LLY@Lilly, PERAHIA_DAVID_G@LILLY.COM
Subject Re: Resubmitted. Your Review Required Again for Disclosure Approval Request TMIS-6GWKTM Deadline = 10/11/2005 Type = Poster

Mike:

Thank you for your comments regarding the DCAE poster. Below please find an initial response to your questions. I'm confident David will have more to add.

1. These slides are derived from a manuscript that was recently accepted by J Clin Psych. The paper was originally submitted at the end of 2004, revised over the summer, resubmitted at the end of July and accepted several weeks ago. The slides are consistent with the recently accepted manuscript that did go through ediscloure prior to resubmission to the Journal in July.
2. You are correct that the IMT did approve the use of the final two weeks of the acute treatment period as the baseline period for determining DCAEs in April, 2004, but this was not mandated as I remember the discussion. Both David Perahia and Joel Raskin were against this approach when the IMT approval was announced to CCD (now CCST). They both felt very strongly that it was important to be consistent with the submission data. Since David is the first author on this manuscript, we agreed to stay with the approach used in the submission packages. While there are merits to the revised methodology, consistency is also important and not to be overlooked, especially regarding regulatory agencies and safety information. As a co-author and someone who respects David's opinion, I was (and still am) comfortable with the decision that was made regarding this project.
3. The references to similarities between SSRIs and SNRIs are based on the available information in the literature as well as Peter Haddad's expertise in this area. With this kind of information, I am comfortable making generalizations to the published literature, but these statement can be removed from the poster if you feel strongly. During the development of the initial manuscript, there was discussion around including DCAEs related to SSRIs, but I cannot remember the reasoning behind not including them as it was well over a year ago. David may be able to shed some light on that decision.
4. The clinician selects the severity "based upon the subject's discomfort, health risk, and/or interference with activity." We will clarify the language to indicate that the ratings are based on the clinician's assessment of the patient's self-reported AE information.

Daniel K. Kajdasz, Ph.D.
Sr. Research Scientist

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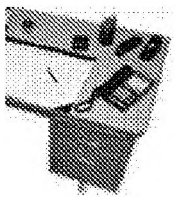
Michael Detke/AM/LLY



Michael Detke /AM/LLY
10/11/2005 03:55 PM

To Durisala Desaiah/AM/LLY@Lilly, KAJDASZ_DANIEL_K@LILLY.COM, PERAHIA_DAVID_G@LILLY.COM
cc James M Russell/AM/LLY@Lilly
Subject Re: Resubmitted. Your Review Required Again for Disclosure Approval Request TMIS-6GWKTM Deadline =

10/11/2005 Type = Poster

I'm concerned about this methodologically for a couple of reasons.

First, I thought there had been (some time ago) internal agreement that the best way to assess DEAEs was to use the last 2 weeks (approx) of treatment as the baseline. Otherwise, we saw fewer DEAEs with longer treatment, which makes no pharmacological sense.

Second, why are we concluding that the rates are similar to SSRIs and SNRIs? We have data on the former, but don't present them here, and we have no data on the later (in the database here).

Finally (minor point) in Table 5, these are reported as "self-reported" severity ratings. In fact, I'm pretty sure they are clinician ratings.

Mike

Michael J. Detke, M.D., Ph.D.
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Durisala
Desaiah/AM/LLY

To James M Russell/AM/LLY@Lilly, Michael Detke/AM/LLY@Lilly

10/11/2005 01:23 PM cc

Subject Re: Resubmitted. Your Review Required Again for Disclosure Approval Request
TMIS-6GWKTM Deadline = 10/11/2005 Type = PosterLink

Dear Jim and Mike:

Please review the attached edisclosure as we have to format and get it ready for the meeting. Appreciate it very much of yor time.

Regards,
Durisala

Tania Miles/AM/LLY

10/06/2005 12:32 PM

To Durisala Desaiah/AM/LLY@LILLY

cc

Subject Resubmitted. Your Review Required Again for Disclosure Approval Request TMIS-6GWKTM Deadline = 10/11/2005 Type = Poster

You have been identified as a reviewer on the Disclosure Approval Request linked below. Please review the request and indicate your approval/rejection by selecting the appropriate button.

Please do not respond to this email, as it will be undeliverable. If you experience difficulties in launching the attached eDAR link, you may contact Lisa Capps at 7-6748 or Janis Lewman at 7-4506. If you are experiencing IT related difficulties, please submit a ticket, via 7-7000 to the Legal/Help Group.

Thank you for your participation in the electronic Disclosure Approval Request process.

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