

To: CN=Robert W Baker/OU=AM/O=LLY@Lilly; CN=Patrizia Cavazzoni/OU=AM/O=LLY@Lilly;
CN=Donald P Hay/OU=AM/O=LLY@Lilly; CN=Vicki Poole Hoffmann/OU=AM/O=LLY@Lilly;
CN=Margaret O Sowell/OU=AM/O=LLY@Lilly; CN=Patrick A Toalson/OU=AM/O=LLY@Lilly;
CN=Matthew R Pike/OU=AM/O=LLY@Lilly; CN=Katherine A Armington/OU=AM/O=LLY@Lilly;
CN=Anthony M Fiola/OU=AM/O=LLY@Lilly
Date: 02/18/2002 09:34:16 AM
From: CN=Patrizia Cavazzoni/OU=AM/O=LLY
Subject: Newcomer talk at the Nevada Psychopharm mtg

I made some comments IN RED.

I would suggest we explore ways members of audience could challenge JN's points of misinformation when he gives talks in the future.

I would also consider timely and decisive rebuttals to Jonathan Meyer's message, when he starts his lipid tour

Patrizia

----- Forwarded by Patrizia Cavazzoni/AM/LLY on 02/18/2002 09:28 AM -----

Virginia Stauffer

02/18/2002 08:41 AM

To: Robert W Baker/AM/LLY@Lilly, Patrizia Cavazzoni/AM/LLY@Lilly, Donald P Hay/AM/LLY@Lilly, Vicki Poole Hoffmann/AM/LLY@Lilly, Margaret O Sowell/AM/LLY@Lilly, Patrick A Toalson/AM/LLY@Lilly

cc:

bcc:

Subject: Newcomer talk at the Nevada Psychopharm mtg

FYI... another summary of Newcomers presentation

Ginny Stauffer, Pharm.D.

Neuroscience Disease State Specialist, Zyprexa

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----- Forwarded by Virginia Stauffer/AM/LLY on 02/18/2002 08:40 AM -----

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Michael E Shepherd

02/18/2002 08:01 AM

To: US_Zyprexa_Comp_Core@Lilly
cc:
Subject: Newcomer talk at the Nevada Psychopharm mtg

Zyprexa Competitive Team,

Here is a nice summary of Dr. Newcomers talk in the west area.

Michael Shepherd
Eli Lilly & Company
Zyprexa Product Team
317-651-3483 office
317-277-6930 fax

----- Forwarded by Michael E Shepherd/AM/LLY on 02/18/2002 07:58 AM -----

James D Ducker

02/15/2002 12:37 PM

To: John C Gilley, Mary T Silsby, Sandra L Hernandez, Amy C Gros-Louis/AM/LLY, Michael A Howa, Catherine R Anderson, Eric V Rouse, Diane I Obshleger, Eric F Sivo, Kara Rice, Maria A Brinck, Daniel G Martin
cc: W Keith Fenton@Lilly, Re Jana F Garon@Lilly, Kelly L Mehrer@Lilly, Michael E Shepherd@Lilly, Vincent P Truax III@Lilly
Subject: Newcomer talk at the Nevada Psychopharm mtg

Team,

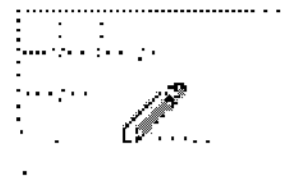
Some good competitive MIQ from Kara Rice who sat in on Newcomer's talk at recent conference. Some of your MD's may have attended, so you will definitely want to know your data on hyperglycemia/diabetes, and get the conversation back to EFFICACY.

Thank you Kara for summarizing his slanted talk.

Jim

----- Forwarded by James D Ducker/AM/LLY on 02/15/2002 12:33 PM -----

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Kara Rice
02/14/2002 04:51 PM

To: James D Ducker
cc: Sandra L Hernandez, Christopher W Jensen, Gina M Noble, Christine C Peluso, Joseph A Carrillo

Subject: Newcomer talk at the Nevada Psychopharm mtg

Here's a detailed follow up to Dr Newcomers talk at the Nevada Psychopharm Conference on 2/15.

Jim,

He was sponsored by Janseen and there were about 500 MD's at this conference. Many from the west area of the country but several from all over the country. Feel free to pass this on to the district and anyone else if you think the info is useful as many MD's heard this. He was a very good speaker and knows how to spin a story. I think he made an impact and we'll have to do some damage control b/c he presented his data in an impactful way and really scared the audience. He was artful and did this in a way so as not to look biased in bashing zy but it was clear that we looked like the villan by the end of his talk.

Topic of discussion was DM and metabolic issues w/ psychiatric pts.

Stressed the complications of obesity- mainly hy[erglycemia, insulin resistance, and increased cholesterol

Shared data comparing all atypicals to PBO for wt gain and said the data was from all the clinical trials for each drug-

OLZ causes 10x's more wt gain than PBO

Seroquel- 4x's more

Geodon - 2x's more

Risp 2x's more

An increase in glucose also maeans an increase in triglycerides. "Defects in insulin action cause problems w/ both lipid and glucose metabolism."

3 main risk factors for DM- adipocity, ethnicity, (I can't remember the other he said)

Shared CDC data on prevalence rates of DM for the nation and said "This isn't a pharmaceutical agenda, its a national health agenda and we're caught in the middle of it as psychiatrists.

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All major psych d/o's leave pts at greater risk for DM. Pts w/ depression are at greatest risk for developing DM but he focused on pts w/ Schiz.

Shared old data from typical days stressing this isn't a new issue. It was infrequent w/ haldol and prolixin, therefore when all new atypicals went for approval, FDA didn't make them do scientifically sound tests for DM- only random glucoses which isn't good enough.

Shared data from 2 studies showing the incidence of type 2 DM in pts on OLZ was 6 - 35% and pts on CLOZ was 12 - 36%.

***** These effects were reported w/ & w/o wt gain. In fact, 26% of the patients above didn't have wt gain

Shared all ADA criteria for diagnosing DM

Made a dig at Lilly's data saying we used random glucose tests w/ a 160mg cutoff and aced to ADA, that's higher than what's diagnostic for DM

Comment: I think the ML who visits JN should challenge this, by showing 126 and 140 mg/dl cutoff analyses in Allison et al. I know we have done this before, but I think we should persist. Other option would be to have challenge coming from educated member in the audience, at future events

New onset case reports and reports of DKA

Cloz 72 & 10
Olz 82 & 14
Seroq 2 & 1
Risp 1 & 1
Geodon 0 & 0

Comment: what is the source of these numbers? Numbers are not consistent with medwatch OR published reports, at least for olz

We don't have a causal rels yet but "it smells like it could be a drug rels"

DKA- gave definition. says it's currently occurring infrequently and rarely but "I have to scare you b/c it's happening and we have to be aware"

Is it really a problem to have slightly elevated glucose? Even if it's not to the level of DM?- YES

Discussed microvascular and macrovascular complications- really focusing on macrovasc d/o (i.e. athlerosclorsis)

Discussed the underdiagnosis of DM in the country. Then went on to rip our data apart by saying Insurance data base claims analysis means nothing if were missing 1/2 the cases. If pts are not even diagnosed, how can this data be true.

Comment: thi sof course would hold true only if rates of UNDERDIAGNOSIS are actually HIGHER on olz compared to other AP's. Thanks to the

services , among other, JN and J-O, is likely that rates of underdiagnosis are by now actually LOWER on olz compared to other AP's, with the possible exception of cloz

Shared data from a COGNITION STUDY- saying the study was designed to look at cognition- but olz and cloz are the worst at raising insulin levels, c peptides, etc. There's a 50 point diff btwn PBO and OLZ so if a pt has a glucose of 95 and gets a 50 pt increase, they developed DM

Comment: is this the firts-episode Lieberman study? Of course, JN is now redifining basic sattistical principles, such as definintion of MEAN and SD.

This causes a higher MI risk

Shared data from Pfizer 054 study designed to look at QTC- said triglyceride levels decreased for risp, geodon, haldol and increased for cloz and olz. Again, a sstudy designed to look at nothing at all related to trig.

Lastly, adiposity is a major issue leading to glucose dysregulation.

Told the audience that both janseen and pfizer have switching studies for pts who gained wt on other agents and the audience should believe the studies and switch pts w/ wt gain and the pt may lose weight, thus reduce their change of getting DM and cardio probs

Nowhere did he disucss efficacy. In fact, said some people are saying efficacy should supercede se's but he disagrees. Keep in mind, this talk was strictly to focus on DM and cardio issues. There are many holes in his data, esp the 2 studies he mentioned.

Hope this helps

Kara

-

To: CN=Robert W Baker/OU=AM/O=LLY@Lilly; CN=Patrizia Cavazzoni/OU=AM/O=LLY@Lilly;
CN=Starr Grundy/OU=AM/O=LLY@Lilly; CN=John R Richards/OU=AM/O=LLY@Lilly; CN=Donald P
Hay/OU=AM/O=LLY@Lilly; CN=Patrick A Toalson/OU=AM/O=LLY@Lilly
Date: 03/11/2002 10:33:41 AM
From: CN=Margaret O Sowell/OU=AM/O=LLY
Subject: Harvard Endocrinologist with insight into diabetes and antipsychotics

Hello !

I had a delightful conversation with **Dr. Arturo Rolla**, an endocrinologist based at Beth Israel-Deaconess Hospital & Harvard Medical School... I know Arturo from my days at the Brigham (across the street from him) ... he also has a good relationship with Lilly diabetes and bone....And he is a dynamic fellow!

Anyway...I was talking with Arturo about Antipsychotics and Diabetes (had heard that he might be speaking on this topic at OUS meeting)....Wondering how he got interested....To make long story short...(call me if you want long version) Arturo was through an independent assessment of the published literature has come to conclusion that this is not a good drug-bad drug issue...and that psychiatrists might benefit from some insights on current questions/issues from an endocrinologist ...It was really quite refreshing to speak with him....

Arturo indicated an interested in speaking on this topic....I told him I pass his name on to the appropriate persons at Lilly /US Affiliate.....

I also sent Arturo some of the information from SCC, clamp manuscript, and clamp slides...He wanted to call me after he's looked info over...

I think additional efforts to engage Arturo in helping us would be of tremendous value...He knows John Buse and appears to have reached many of the same conclusions that John has ...Arturo is also aware of a psychiatrist at another Harvard Hospital (the one adjacent to Charles River on Fruit Street)...who appears to have come to a very different conclusion and who is ...according to Arturo ... speading a different message...

Please get back to me with feedback....I expect Arturo will be back in touch with me in the next week or so...

Missy

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To: CN=Haya Ascher-Svanum/OU=AM/O=LLY@Lilly; CN=Robert W Baker/OU=AM/O=LLY@Lilly;
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CN=Donald P Hay/OU=AM/O=LLY@Lilly; CN=Madhav Namjoshi/OU=AM/O=LLY@Lilly;
CN=Matthew D Rotelli/OU=AM/O=LLY@Lilly; CN=Margaret O Sowell/OU=AM/O=LLY@Lilly;
CN=Zhongyun Zhao/OU=AM/O=LLY@Lilly
CC: CN=Lizheng Shi/OU=AM/O=LLY@Lilly
Date: 03/14/2002 11:39:44 AM
From: CN=Melissa Kody/OU=AM/O=LLY
Subject: Safety database studies
Attachments: safety HO studies.xls

Colleagues:

Attached is a spreadsheet describing the ongoing and new studies we've been discussing over the last several weeks. Some of the timelines are still being formalized.

I suggest that we convene our working group on an ad-hoc basis (or at least quarterly) as design issues and results/publications need to be discussed.

Please let me know if you have any additions or changes to the spreadsheet.

Thanks,

Melissa



safety HO studies.xls

Safety/Health Outcomes Database Studies

Disease area	Study	Project owner	Timeline	Comments
<i>Diabetes</i>	IMS	Danielle Loosbrock (US OR)	Complete	Manuscript to be resubmitted.
	Protocare	Christine Eickhoff (US OR)	Analysis complete. Manuscript in 4/02.	"IMS clone"
	Merck-Medco	Christine Eickhoff (US OR)	05/00/02	"IMS clone"
	Pharmetrics	Christine Eickhoff (US OR)	04/00/02	"IMS clone"
	Medicaid	Zhongyun Zhao (US OR)	?	Enhanced IMS methodology
	MarketScan	M. Kody/M. Namjoshi (GHOR)	Q3 02	opportunity to use different methodology than used in IMS research.
	Texas VA	Haya Ascher-Svanum (US OR)	Q2-Q3 02	will go beyond IMS studies to look at antipsychotic compliance/persistence rates and differences in diabetes incidence.
<i>DKA</i>	Texas VA	Haya Ascher-Svanum (US OR) with Michael Keith	?	waiting to receive RFP
<i>Lipids</i>	IMS	Zhongyun Zhao (US OR)	3/18/2002	looking at antihyperlipidemic agents.
<i>CV risk</i>	Change in CHD risk	Matt Rotelli (US) with Framingham Heart Group (FHG)	HGAJ data to FHG week of 3/11. Analyses complete by 5/02.	applying FHG algorithms to J data to establish change in CHD risk (baseline to 52 wks.).