

3AN06-556

9:00 28 AM

8:54:56AM

Summary

Gussack, E

Type
Co

3AN-06-05630CI Volume: 016

Volume 016

State of Alaska vs. Eli Lilly & Co

LOG
NOTES
ONLY

VOL. 16

CIVIL

Begin: 3-21-08
End!

PLAINTIFFS
ATTORNEY

IN THE
TRIAL COURTS

DEFENDANT'S
ATTORNEY

OF THE

STATE OF ALASKA

TYPE OF PROCEEDING

MASTER ASSIGNED	DATE ASSIGNED	DATE DISQUALIFIED	BY WHOM DISQUALIFIED

JUDGE ASSIGNED	DATE ASSIGNED	DATE DISQUALIFIED	BY WHOM DISQUALIFIED
Risdon	3-1-08		

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OTHER

In the Superior Court at Anchorage Alaska

Media No: 3AN4308-45

Judge: M. Rindner

Date: Monday, March 3, 2008

Clerk: M. Borneman

Case No: 3AN-06-5630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial – Day one

Counsel Present:

Plaintiff: Scott Allen, Esq., David Suggs, Esq., Tommy Fibich, Esq., and Ed Sniffen, AAG
Defendant: George Lehner, Esq., Brewster Jamison, Esq., John Brenner, Esq., Nina Gussack, Esq., and Andy Kantra, Esq.

Court Orders: State of Alaska's in Limine to Preclude Testimony or Argument, etc., is denied
State of Alaska's Requested Clarification of Court's Order Excluding Evidence of the
etc., granted
Eli Lilly Motion Requesting Confidential Protection of Regulatory Communication not
to Public Disclosure is Denied

Summary of Proceedings: Continue with Voir Dire on March 4, 2008 at 8:30.

8:54:56AM

On the Record

Jury Panel is Not Present

Court – list case and parties present

Kantra – first name is Andy

Court – thank you

- issues pending before the panel comes up
- jury panel is assemble and filling out the questionnaire and they will be brought to the courtroom to take up hardship issues
- will introduce you to them and them to you

Suggs – Mr. Sniffen to do introduction

Court – fine

- will start talking with the jury panel about the case and explain to them why they are here and what is going to happen for the next four weeks
- will give them the oath and send them home for the day
- have about 75 jurors coming in this morning and will have the jurors in the bench seats, back of the room
- other counsel may have to move to accommodate
- orders on remaining issue of limine, no pending motions done
- gone over the document the state has filed on opening statement
- six or seven new documents submitted by state, have objections an will get them done tonight

9:00:28 AM

Allen have some more, five or six, hands to judge

- do not know, not using all of them but judgment call at this pint

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Page 1 of 16

Court – understand and assume objections to come in

9:01:14 AM Lehner – list of 120 you initially submitted, if so, we already objected, will check

Allen – same for Ms. Joey Eski deposition and the FDA letter form January 2007

- objection to evidence itself and the Motion in Limine already granted

Court – clarified by ruling today

- Lily has filed a preadmission on some exhibits
- FDA internal documents

Lehner – packet in the hour

Court – will read new ones and objection from Lilly to old ones

- authenticity objections made at time, hard to rule in the abstract, not sure of basis as to certain documents
- number 19, 284, 320, 995, 1110, 1111, 12169

Suggs – 1145

Court – 1145 is admitted

- 1215 admitted but not ruling on completeness of document
- 1605, completeness argument on this and will admit
- 1962, 3109, admitted
- 4924, admitted but with foundation issues being preserved
- 4007, 4051, 4176, 4968, 5073, 5565, 5846 are admitted

9:06:36 AM Lehner – last one

Court – court 6218 but objections is sustained on this one, not use during opening, admitted

- 6215, need more discussion on, not admit at this time
- 7802, completeness argument and foundation
- 7822, foundation argument but admitted
- 8479, 8584 are admitted
- 8911, sustained objection
- 9281, 9731 are admitted
- 100017 foundation issue, 10061 objection sustained to this one, 10064 subject to foundation
- 10066, 10068, 10094 are admitted
- 10095 objection to this one

9:10:13 AM Allen – will pull these

Court – original ones

- attachment C, with exhibit just filed by Lilly and exhibits on Lilly's response, 10153, 1003, agree to admit notice, agree or disagree

9:11:26 AM Lehner – hearsay but can be admitted with notice

Court – agree it can be used during openings

Lehner – provide instruction

Court – understand and assume objections to come in

9:01:14 AM Lehner – list of 120 you initially submitted, if so, we already objected, will check

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Lehner – provide instruction

Court – will give instruction on openings

Lehner – not for truth of matte asserted

Allen -1926 skipped over

Court - I did and will go back and review

9:13:55 AM Lehner – will provide but same kind of document with different dates and sequence, will be able to look at all but ruling one is the same as to all

Allen – prepared to address

Court – jury coming up at about 10:30

- judge Christen asked me for copy of ruling on the preemption matters, orally done and I gave her copy of transcript, I misspoke or not transcribed right like when I talked about the product labels having been superseded by other product labels and that this wasn't a consideration of product label currently being discussed and I mentioned that wasn't a case where I felt FDA, being fully informed, told Lilly don't put warning label on the subject but it reads the opposite, it reads FDA did consider all this stuff and then rejected Lilly's additional warnings, if that is what I said, not what I intended to say
- if there's going to be a Petition for Review, just wanted to make record
- statement of the case, state filed objection but no statement from them, this is not what I expected to get, far to advocate of a piece to start the trial
- living hell and some of those things, Lilly will have to tone this down
- helpful to hve something from the state

9:18:21 AM Fibich – no objection to ours with exception, added provision on bifurcation, and he has had issue on how I said that

Lehner – no objection but for last paragraph on damages "if any" were added we'd be happy

9:19:09 AM Jamison – based on idea of parity we thought the same tone

- state says withheld information, loss of sale, etc.,
- living hell language, this case from state's own witness

Court – will not preclude in opening statement but not introduction to the jury, just let them know what this case is about

- reading from introductions
- Zyprexa number one treatment for which it is approved for
- Do not like last sentence in first paragraph
- State paying for medication should be stated as positive, take out "although"
- Why not say, Lilly denies these allegations

Jamison – wanted to include element on what has to be done, approved

Court – is that what you are doing and have the warning but not much said, state talks about UTPA claims but you do not

- first sentence of last paragraph is fine but, reading, take that out

Jamison – find in favor of Lilly

Court – save that for openings

- tell them about the case not what they should do
- make it more neutral

9:25:17AM Jamison – objection to portions that talks about the state seeks to forcibly medicate patients with Zyprexa

Court – not necessary to explain the case to jury

- will learn the state continues to pay for medication in state facilities

Jamison – understand

Court – will read objections on Exhibit C and would like guidance from you as to what do you want me to focus on, pre openings, state asking for preadmission, not sure about Lilly

- Designations depositions objections and will take up when they come in, prioritize this for me so I can make rulings on designations that might come up

9:28:23 AM Lehner – will resolve fairly quickly

- not that many outstanding
- deposition designations to be resolved by rulings you just made as you dealt with objections we made
- will get them to talk about this
- they intend to call live witnesses Thursday and Friday

9:29:23 AM Allen – right

Lehner- will get to that later in the week

Allen agree on issue on exhibits, making copies as we speak and will sit down and see if we agree

Court – if my rulings take care of a bunch of designations depositions, fine, but need to make record, standing objections allowed so nobody waives something that is objected to

9:30:52AM Allen opening statement exhibits are of concern, will prioritize

Court – will do so in evening or on weekend an want to take them in order you need them

Allen – will provide deposition excerpts this afternoon

Court – give me written list letting me know which ones to work on

Allen – doctors to be called and will play deposition and will have one video for you this week

Court – will then concentrate on designation deposition, see if this can be reduced

Lehner – will

Allen – as soon as the four are together I can meet with Mr. Lehner and Agree, if possible

Court – do not hesitate to let me know what is coming up and what needs to be ruled on, do not hesitate to tell me if I overlooked someone

Allen – thank you

9:34:25 AM

Court – foundation and authenticity objections, appropriate but I prefer to allow

- one or two other rulings less clear about
- exhibit less clear than objection

Allen – Lilly documents, ones I identified and the can not deny

Court – will check jury

Allen – if produced by defendant, takes away authenticity

Lehner – need to look at documents before I can agree

Court – disagree

Lehner – doesn't self-authenticate just because we produced them in discovery

Court –

Allen – redaction on regulatory, will live with that

Court – redaction for all sorts of things, like jury's to decide on what is going on, not to guess

- take look at some of the documents, other issue

Fibich – start at 9am

Court – need to make record

- FCC court at 1:45
- Lot of hardship and other issues to take up, takes time

Fibich – voir dire and panel tomorrow

Court - goal is for openings on Wednesday

- can go long on some days
- if short on jurors after today, will take more time

9:42:31 AM

Fibich - four hours go fast and if it pushes voir dire to Wednesday we then have four hours for openings

Court – understand

Fibich – openings statement that you approve, we do it or you do it

Court – bring them in and give them introductions, to be done by lawyers, might make jurors more willing to stay

- need something from Lilly

9:44:17 AM

Jamison – moment

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Court – will go off record and once resolved will bring panel up and start

9:44:49AM Jamison , working it now and just need to make certain all agree to it

9:45:06 AM Fibich – voir dire, challenge fro cause at he time

Court – ask to approach, correct, and we'll take up the challenge

Fibich - and in the all

Court – will go to chambers and will recorded by Mr. Borneman, make record

- they come back will parties and I meet and greet and go to my office
- one person from each side, not entire party of lawyers
- once qualified I will place 24 into the box and ask them the questions
- pas all for cause and then after 22 all passed for cause we take preempts

9:48:57 AM Fibich – 12 that will deliberate will be unknown

Court – right, 2 blind alternates

9:49:26 AM Lehner – we indicated this morning on sales representative depositions, do not believe testimony is relevant, she is heading to Hawaii with children and back March 24, 2008

Court – file motion and I'll rule

- state did not intend to call her live

Allen – will speak to legal issues later but understand we do not intend to call her first two and understand the fact of her being on vacation, we do not want to interfere but she is critical witness

- they chose her out of all the sale representatives in Alaska
- state to pay for her ticket to come and go back to Hawaii, if needed
- will be through before the 24th
- but nay need her to come back but we would pay for this

9:52:29 AM Fibich – two experts coming in and one of them has a marriage to attend in India, no room to modify

Court – will bring her back and forth to be live, obvious problems

Lehner – very young children

- Not on witness

Court – we do telephonic witnesses all the time and there are other ways to do this, video perpetuation deposition and show her this way

9:54:08AM Allen – I have family and this is reasonable but they knew when this started long time ago this witness would be out of town

Court – live or do what you can with video

Allen - just wanted it on the record

Lehner - not on witness list

Allen - incorrect

Court - unless appeal point, not make record, very willing to make record if appeal point, etc., but rather not go about things that aren't

Allen - not appeal, can we take her deposition this weekend

Gussack - leaves on the 10th

Court - why

Allen - will drop the request to do deposition in court, not cause problems

Court - inclined to say no

Allen - request is withdrawn

Court - do revisions and if not will bring up panel

Allen - foundation objections

Court - will go off record and do

9:59:04 PM

Off record

10:54:35 PM

On record

Jury Panel is Panel

Court - good morning

- everybody in a seat is a perspective juror, only
- introduction to panel, introduction of defense attorneys

Jamison - list attorneys present

Court - State of Alaska

Mr. Sniffen - list attorneys

Court - thank you for coming in this morning, jury service is greatest civic duty a citizen can do

- will proceed to selection of jury in a moment, twelve and two alternates
- voir dire process explained
- confidential area of questions, can be in private

10:59:56 PM

Jury qualifications given

Court - four week trial

- trial day is 8:30 to 1:30

Fibich - brief statement of the case given to perspective panel members

Court - Ms. Gussack

Ms. Gussack – brief statement to the perspective panel members

Court – statement of attorney is to give overview of case and to help you later on in this case, nothing said is to be considered by you as fact in this case

- questionnaire filled out, will qualify you as juror's or not
- any one of you who is not a citizen of the US of A, all are residents
- at least 18, appear to be 18
- of sound mind, all of sound mind
- natural faculty to see, smell, and touch

11:08:58 PM Ms. Woody – not able to smell

Court – thank you

- Read or speak English
- Felony
- Related to anyone parties or witnesses in this case
- Identify witnesses

Allen list witnesses to be called

11:11:09PM Randy Twenhafel

Gary Wells, may know husband

Court – fair and partial

11:11:53 PM Gussack – list witnesses to be called

Court – know any on list

Jim Cloud – I know Dr. Jackson, can be fair and impartial

11:13:40 PM Ms. Schoelhorn – I work for DHFS

Court – jury service in past year

11:15:08 PM Ms. Cain – assistant attorney general

Court – excused

Allen – fine with us your honor

Court – next

11:18:11PM Amanda Boswell – National Guard

Court – your fine

Ms. McGinnis – Depart of Mental Health Land

Court – will stay

11:17:18PM

Ted Meyer – DOT

Court - stay

Mr. Maggard - doctor

Ms. Rivas - DHSS

Court – excused

11:18:27 PM

Schoelhorn – Department of Health

Court – excused

Ms. Soto –

Court - will stay

Reineke – Public Defender

Court – will stay

11:19:21PM

Joann Wallace - Department of Corrections

Court – will stay

Mr. Mattoon

Court – will stay

Cervelli – work

Court – will stay

Twenhafel – know of Eli

Court –

11:21:16PM

Mr. Seiser – defendant in your courtroom

Court – read or seen anything on this case

Ms. Schmidt – nurse and did read...

Court – enough

Mr. Barnett – read article, made mental notes and placed on form

Mr. Wells – saw article

Reineke – read article

Court – fine, not evidence

- length of trial, questions and issues

Ms. Woody – just got back from Belize, personal hardship and bad bites from critters, I need to go to doctors for...4:30 today

- and I own and operate two businesses, I get paid when I finish the job, lectures coming up, etc.,

Court – in different parts of the state

Ms Woody - contractual issues

Court – will ask you to come back tomorrow, not excused yet

Ms Lahey – financial as I work in Peters Creek, have one other person and she is off doing other things

Court – talk with her tonight and explain situation, but come back

11:30:37PM

Sidebar begins

11:30:44 PM

Sidebar ends

Court – will excuse Ms. Lahey

Ms. Boswell two training engagements in the lower f48

Court – excused

Mr. Cervelli – article due, deadline

Court – not excused

Ms. White – own business and manger quit on me

- tanning salon

Court – excused

Ms. Peterson looking for job, interviews up and coming

Court – not excused at this time

Ms. Ramsey – personal daycare attendant

Court – excused

11:37:00 PM

Ms. Sharrer – work, baker, etc.,

Court – excused

Mr. Sowl – wife having back surgery

Court – excused

Ms. Shepherd-Bronyaur – hardship

	<p>stay at this time</p> <p>Stehr – surgery on the 26th</p> <p>Court – parties</p> <p>11:40:31 PM Sidebar begins</p> <p>11:41:05 PM Sidebar ends</p> <p>Court – excused</p> <p>Ms. Soiseth – financial advisor</p> <p>Court – stay for now</p> <p>Mr. Sudderth – work hardship</p> <p>Court – will ask you to stay at this time</p> <p>Ms. Shroud – just started new job</p> <p>Court – excused</p> <p>- anybody else</p> <p>Mr. Wofford – active duty</p> <p>Court – will stay for now</p> <p>Mr. Withers – ER doctor</p> <p>Court - parties</p> <p>11:46:30 PM Sidebar begins</p> <p>11:47:34 PM Sidebar ends</p> <p>Court – excused</p> <p>Mr. Chang leave Wednesday night for business, real estate development</p> <p>Court – excused</p> <p>Mr. Olson – construction worker, very big hardship</p> <p>Court – excused at this time</p> <p>- Parties, may I see you</p> <p>11:51:09 AM Sidebar begins</p> <p>11:51:31 AM Sidebar ends</p> <p>Court – will excuse you for the day but be back tomorrow at 8:30</p> <p>- will place 22 of you in the box tomorrow and continue with voir dire</p> <p>- confidential matters and privacy explained to panel</p> <p>- preempts explained to panel</p>
--	---

- alternates explained to the panel
- come back to the courtroom tomorrow

Jamison - lots of folks in hallway

Court - not being rude, will not speak with you nor you with them

- will be, and have been a lot of publicity on this case, do not read or view such reports or articles

11:59:52 AM

Panel is Excused at this time

11:59:26AM

Off record

11:59:52AM

On the record

Outside Presence of the Jury

Court - no panel members left in the courtroom at this time

- doing good on time, should have jury tomorrow
- anything anybody wants to place on the record

Fibich - need list of people excused

Court - will get to you

Allen - James Cloud, employed as expert witness for Lilly, independent

Court - question him while in box

Jamison - have worked with Mr. Cloud and is retained by client but not by me, paid by Lilly

- banking practices

Court - do it tomorrow

Allen - expert for defense

Court - tomorrow will take up exhibits

- will break at this time

12:03:18 AM

Jamison - one of the panel members made statement and would like to think of response but also avoid eliciting comments like this

Court - can ask about this and what the panel member knows about this case, don not want to lose this panel

- anything else at this time
- will break for 15 minutes
- filed in court for Motion to Preclude Joey Eski's testimony

Allen - just got copy

Court - opposition to be filed by Friday

Allen - will get something to you

Court - need at least a night to do this before I rule

Allen - have her testify

- will not require anybody to come back from vacation
- will listen to deposition and play what I have

Court - not just dealing with her ability but not testify period

Allen - will report tomorrow

Court -

Jamison - deposition transcript handed to clerk

12:08:14 AM

12:42:56 AM

Off record

On the record

Outside Presence of the Jury Panel

Court - copy of jury attendance

- pre-admitted

Lehner - first list, objection to 1215, withdrawn by Eli Lilly

Court - ok

Lehner - 1605/admitted

- 3924, objection

Court - foundation

Lehner - not contested

Court - overrule objection and ex. 3924 is admitted

- 6215, Motion in Limine objection, not contested, overrule the objection to 6215

Lehner - 7802, withdrawn/admitted

- 7822, objection/admitted
- 10017, objection/admitted
- 10064, withdrawal of objection/admitted
- 10068, left open
- 10095, Motion in Limine objection

Allen - letter notifying the label change and with new label, once it went out it was received and in possession and admitted

Lehner - relevancy goes to Motion in Limine, redundant

Allen - only evidence of the warning

Lehner - the warning itself

Court - will admit 10095

Lehner - attachment C

Allen will not use 3238 of C

Lehner – seven documents to C

- object to 1941, not admit this document irrelevant

Court – will admit 1941

Lehner – 2133

- 3238, not to be used in open
- 3278, no objection/admitted
- 10003/admitted
- 10035/admitted
- 10153, subject to Motion in Limine, hearsay objection

Court – 10153

Lehner – subject to Motion in Limine we filed on regulatory document form 2007

Court – why hearsay in light of FDA

Lehner – would withdrawal hearsay objection

Allen – told Ms. Gussack to get with us and we may agree with that

Court – inclined to find these to be public record

- 10153, deferred at this time but will overrule if objection is Motion in Limine

Lehner – 2133, doesn't relate to hyperglycemia and not to be used

Allen – but not what it is offered for

Court – understand objection

Allen – failure to warn and false and deceptive trade practices

- 2nd generation anti-psychotic
- they received this email
- black box and red box warning on diabetes

Court – black box warning is just that

Allen – yes, literal statement

- Canada is black box
- When warning issued in Japan they did not send sales representatives into the field to tell doctors of this information from Japan
- They have capability and responsibility to inform Alaskan doctors of this black and or red box warning, they say no
- Clearly indicates they had ability to inform if it benefited them

Court – if required to black box's something like Zyprexa and did not but would if competitor product

Allen – yes, that is exactly right

Court – not for use in the field

- Allen - 2133, reading, branch manager and market place manager, reading
- will tell about black box warning on the other's product, they have ability to do this
 - segment specific and to share with key customers
 - reading, exactly what they did not do in Japan
 - can do it unless they do not what to

Lehner - need to look at this document on its face

- black box warning in Canada and not to regulatory obligations of Lilly
- introduces mini-trial we seem to be embarked on, highly prejudicial

Allen - goes to state of mind and abilities

Court - will admit 2133, find it is relevant

Allen - two more matters

- CD, hands to judge, its about three minutes long

Court - not if they have not looked at it

Allen - copy of Jordan's exhibit 9 and 10, Jack Jordan, Lilly's Marketing Director

- October launch and I want to play 30 seconds of this tape
- I did not make the CCD, can view it tomorrow

Court - no ruling until I hear a position from Lilly

Allen - case decided in Warner v Kent, US Supreme Court; decided and in our favor

Court - dealt with Michigan statute and pre-approval, fraud on the FDA

- affirmed by equally divided court

Lehner - will file objection to this

Court - dealt with attachment A, preadmission and attachment C preadmissions stuff

- still have Lilly's list of tabs, and the state has objected
- if I adhere to my decision on public records, any other
- do see relevance, lot of allegations on what Lilly should of and did not do, and what they concealed
- entitled to put on defense to this
- if relevance, that would be overruled
- understand objections but will probably admit the 16 documents

Lehner - will file objections

Court - get me something tonight and I'll read it tonight and place a ruling on the record tomorrow

Allen - will be speaking tonight and think we agree on most

Court - and then what we're working on next

Allen yes

Court - and order on who should be looked at first

Allen cut down to seven hours from forty

Court - be here at 8:15

- want to get jury

11:12:31 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3AN4308-71

Judge: M. Rindner

Date: Wednesday, March 26, 2008

Clerk: M. Borneman

Case No: 3An06-5630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial day 18

Counsel Present:

Plaintiff: Tommy Fibich, Esq., David Suggs, Esq., and Ed Sniffen, AAG
Defendant: George Lehner, Esq., Nina Jamison, Esq., Andy Kantra, Esq.

Court Orders:

Summary of Proceedings: Parties have resolved trial by settlement. Jury is discharged and case is dismissed. All exhibits have been returned to counsel.

8:31:41 AM

On the record

Outside Presence of Jury

Court - list case and parties

- settlement reach yesterday
- missing one juror at this time and will bring the jury in when the juror arrives
- what about talking with jurors

Gussack - interested in talking as they are as well, in jury room

Court - together or alone, do not care and I want to talk with them

8:32:47 AM

Gussack - together is fine

Court - will explain and leave up to them if they wish to talk

- thank everybody for the way the trial was conducted, a well run trial, very competent team of lawyers, first rate
- if issue was missed, I'd be surprised
- good support work among your teams as well

8:34:48 AM

Fibich - been in front of a lot of Judges and this is my first time in Alaska, treated well by you and your support staff, thank you

- never been before a judge who works as hard as you did even during times of disagreement, good job
- very fair trial in this matter
- system needs people like you who administer justice

Court - thank you very much

Gussack - none of us have had a judge who would pick up additional work after hours, extraordinary, thank you

Court - enjoy a good cross examine and have seen a few of them in this case

- Lilly doing what about Bloomberg Motion, Lilly still owes me a brief on this Gussack – have filed but want to do supplement response

Court – talk to your lawyers given this has settled, might change your position, etc.,

8:38:39 AM

8:53:56 AM

Off record

On the record

Jury is Present

Court – ladies and gentleman I'm happy to tell you this case settled last night

- the work you provided is essential in the settlement, thank you
- this work here saved the parties and another jury from another trial and the appellant review that would of happen
- it's a win-win situation
- want to thank you for the participation
- greatest civic duty one can perform in this country
- up to now I gave admonishing not to talk about this case with anyone and you are now free from this admonishing
- you are free to speak with people if you choose, the attorney would like to meet with you, after I discharge you, in the jury room, if you wish to talk with them please stay and they will come back
- other states have trials going and sure these teams would like to hear how they performed their job
- real world feedback is helpful if you want to talk but that is up to you, but its helpful to me
- will give all a jury survey to fill out and mail back in, goes to Judicial Council
- and I will be sending you a questionnaire on how we did our job, we use the feedback to help in future juries
- during the trial there has been lot of press coverage and chambers has gotten request from newspaper organizations to get your names so they can contact you, up to now I have not given this out, general practice not to do this
- will not give out unless you do not care and advise me that I'm allowed to give this out but you most likely will be approached by media
- if you tell somebody you do not want to discuss this, anybody, and they persist in badgering you let me know, serious violation and would do something about it
- any opposition to discharge at this time?

Gussack – no

Fibich no

Court – you are discharged from jury service at this time, off jury duty for a year
- thank you

9:05:07 AM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3AN4308-70

Judge: M. Rindner

Date: Tuesday, March 25, 2008

Clerk: M. Borneman

Case No: 3AN06-5630Ci

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Settlement on the Record

Counsel Present:

Plaintiff: Ed Sniffen, AAG

Defendant: George Lehner, Esq., Nina Gussack, Esq.

Court Orders:

Summary of Proceedings: Settlement has been reached in this case. Payment of 15 million to be paid within 30 days, and releases provided. Agreement will be drafted by parties no later than March 27, 2008, which will conclude this case.

3:52:04 PM

On the record

Outside Presence of The Jury

Court – list case and parties present

- case has been settle and here to place on record
- not confidential settlement

Gussack –

- terms not confidential
- will have state present terms

3:53:44 PM

Sniffen

- will formalize settlement and release in next few days
- global release to all claims that are raised or could have been raise including fraud claims
- payment by debt to state in the amount of 15 million within thirty days
- placed in trust of State of Alaska plaintiff to draft agreement by March 27, 2008
- comments by them on the 31st
- April 5
- Any disagreement in language to be heard by Judge Morgan
- 42 states and this state to be notified of other settlement
- resolution by settlement not verdicts
- per capital by
- penalty amount s converted per capita an if better agreement reached by another state this state amount to be adjusted
- dispute resolution provision, is binding
- Alaska is forum to resolved all disagreements
- Joint public statement to be made and presented
- Assistant Attorney General

Court – document filed under sealed not returned to defendants

- Bloomberg new has motion to obtain these documents, hat happens, does the provision of documents produced in litigation apply to these documents

3:58:50 PM

Gussack - any material filed but not public to be returned to Lilly realize the pending motion
- those not present for public

Court - exhibits are public but if under seal and not made public during trial, Lilly says, they are to be returned to Lilly or remain under seal

Gussack - if public record that is what they are, public record

Sniffen - Bloomberg motion moot

Court - will want to obtain documents or not

- do have to rule on motion
- state to notify counsel for Bloomberg
- will not rush to decide this questions but this is what parties intend but subject to my decision on Bloomberg motion

Gussack - fine

Sniffen state intension as well

Court - what happens tomorrow

Sniffen - not sure

Court - they show up and will announce this resolution and then explain to them and of the vital and important role; they played in this case

- they are free to speak with anybody they wish and fee not to if they chose not to talk to people
- assume parties will want to speak with jury
- want jurors to have privacy if they wish
- number of calls from press on getting jurors names and addresses of record, will ask the jurors this question an if they tell me no I will keep it confidential

Sniffen - appropriate and make room available for us to speak with them

Court - will make room available and I also send out a questionnaire for them to answer

Gussack - Lilly would like to speak with them, if they want

Court - if they want to speak with them they can talk to anybody they wish

Gussack - supervised series of discussion with them

Court - if they wish to participate that is fine but they have done their duty and their duty ends when they are discharged, but will tell them its useful if you can talk with them

- not require them to talk but will encourage them to, if possible

Lehner - back in jury room

Gussack -

4:07:40 PM

Off record
3AN06-5630-03-25b-08

4:09:03 PM

On the record

Gussack - this agreement, Memorandum of Settlement Terms, results in a dismissal of this

Court - and Stipulation of Dismissal with payment and each side bears own costs and attorney fees

Sanders - have settlement and no buyers remorse

Court - and return al exhibits and return courtroom to its normal state

- thank you for the hard work and to Judge Christen
- great calper of attorneys, thank you

Sniffen - and thank you

Gussack - yes, we agree

Court - glad this is resolved

- trial counsel know about this

Sanders - will know shortly

Court - assume they working hard fro tomorrow

- will see everybody at 8:30
- will go on record before we bring the jury in

4:13:18 PM

Off record

one objection to this court's decision as that is overruled
we have provided four times the reason to be dissatisfied. Gussack and Sanders, who
testimony is not in fact as to Gussack's July 2001 to July 2002 to July 2003 to July 2004
the year is open to 2001 dismissal, perhaps that have been included
Hope Gussack give over specific information regarding this case involving, will do it
to Gussack and Jackson, no response, disbursement of all documents for showing
from Gussack to me would confirm any, otherwise are not relevant
I would like to see instructions to be given to parties, Gussack could have instructions
related with UTPA terms, not thinking on this and will give three more as well, thinking
possible to get instructions to Gussack and
On point as to instruct the recording clerk with UTPA case and the spring verdict
and
not comfortable with July agreement with the UTPA as it we do not have the evidence to
have to meet around perhaps the trial

Gussack - UTPA claim dismissed, nothing will be done the violation

Court - style over the trial, over and over again, the UTPA will proceed

Sniffen - will read of UTPA

Court - will, if the UTPA could bring weight with Gussack, Sniffen, etc., and for what they
have to prove

Sniffen - will read from Gussack's to which the jury will be being admitted to each of the case

In the Superior Court at Anchorage Alaska

Media No: 3An4308-68

Judge: M. Rindner

Date: Tuesday, March 25, 2008

Clerk: M. Borneman

Case No: 3AN06-5630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial Day 17

Counsel Present:

Plaintiff: Scott Allen, Esq., David Suggs, Esq., Tommy Fibich, Esq., and Ed Sniffen, AAG

Defendant: George Lehner, Esq., Nina Gussack, Esq., John Brenner, Esq., and Brewster Jamison, Esq.,

Court Orders:

Summary of Proceedings: Trial continues to March 26, 2008 at 8:30.

8:26:38 AM

On the record

Jury is not Present

Court – list case and parties present

- one late juror this morning
- gone over counter-designation and objections, Lilly asked that three cuts be added to ensure completeness, listed
- one objection to state counter-designation an that is overruled
- Lilly has provided four other witnesses to be designated, Curtis and Campana, find testimony is relevant but as to Campana Lilly goes to safety analysis that might be done the door is open to Eski deposition, portions that have been excluded
- Have not yet gone over specific designation objections field this morning, will do it soon
- As to Gilbertson and Jackson, no relevance, commissioner or ex-commissioner knowing about lawsuit or not would confuse jury, excerpts are not relevant
- Packet of half of jury instructions to be given to parties, generic boiler plate instructions
- Defect and UTPA claims, still thinking on this and will give three more packets, thinking packets, to get your positions and finalize later
- On packet as to instructions regarding defect claim, UTPA claim and the special verdict form
- Not comfortable with Lilly approach with the UTPA as if we do not know the violations its hard to have second portion the trial

8:34:48 AM

Lehner – UTPA claim instruction, nothing until we know the violations

Court – state gave me instruction each and every way the UTPA was violated

Lehner – restitution of UTPA

Court – no, three or four pages listing weight gain, diabetes, lipidemia, etc., and list what they have to prove

- special verdict form seems to track this with each way being identified in each of the year

06-0563007

Lehner – Ms. Jackson is head of the department in charge of safety and need to know when and how she learned, bucks stops with her

- goes to motive
- Mr. Gilbertson was prior commissioner prior to lawsuit being brought

Court - not person authorize to bring a lawsuit, more prejudicial than probative

Lehner – best interest of people in this state

- not even consulted

Court - should implied she should be consulted

Lehner – relevant and might have opinion or view and jury is entitled to know this

- health an welfare for population
- and she knew nothing about this and goes to motive, held job during time this lawsuit was brought

8:39:35 AM Suggs – nothing to do with duty to warn, or violation of UTPA

Court – prior ruling is kept, denied reconsideration

- where are we in this trial, Monday is state holiday

Lehner – Dr. Baker continues today and next is video tapes of about 2 hours

- David Noesges is next
- And then can rest our case

Court - Dr. Baker and David Noesges and rest is video

- depending on cross

8:42:06 AM Allen – Thursday conclusion

Lehner- sounds right

- rebuttal?

Allen – two weeks worth,

[laughing heard]

Court – thank you

- will check on jury

8:44:41 AM Off record

8:52:57 AM On the record Jury is Present

Court – all member of jury are present

- resume with Dr. Baker

8:53:28 AM Direct Exam of Dr. Baker by Mr. Kantra resumes

8:53:47 AM (treatment emergent-diabetes, is a term we use in safety that its observed during study)
(not that medication cause this condition)
(abnormal tests did not show at start but showed during course of study)
(things happen to all of us over course of time and would expect this regardless)

8:56:00 AM EI2135 – reference

8:56:57 AM Suggs – objection/OR
(knew they had asked for information from all manufactures and told us they looked at epidemiology study)

8:57:51 AM Suggs – objection, speculation/sustained
(letter did request the information)
(no, normal course of business)
(subpopulation means within the overall population taking this drug and looking at who has adverse events, are there groups more likely to have adverse reaction)
(looking for explanation if its from the drugs and why)
(continued to do more work and studies and analysis of question like who is at more risk)
(head to head studies with Olanzapine and others plus the CATIE study)
(mechanistic, we used clamp studies took at this)
(yes)

9:02:55 AM EI2958 – reference
(yes)
(page eight, change in label, I was part of group that met with FDA and we decided to accept the changes to our label)
(no, it doesn't say Zyprexa cause diabetes or hyperglycemia, no)
(yes, it is in the 2003 label)
(8661 patients, yes)
(yes, larger group than from 1996 approval)
(diabetes is listed as infrequent during trials, same as 1996 label)
(yes, hyperglycemia, too)
(yes, in that range)
(page eight, no)
(no, not an increase risk of hyperglycemia)
(blood sugar levels, in last sentence, reading)
(continuum is a range)
(higher than sum)
(two different things and this is talking about average glucose levels)
(diabetes is a disease and average glucose is not disease and we look for individual with diabetes, what we looked and found no difference from one treatment to another)
(yes)
(yes, we did)
(I did prepare a slide)

9:09:51 AM Slide TG213
(for FDA we looked at each comparison of Zyprexa to another antipsychotic and we are looking at average change in this slide)
(no difference among those three)
(Geodon is newest of drugs and one with least weight gain and we found average glucose change is more with Zyprexa, a moderate level)
(no, average change)

9:11:45 AM Slide TG213

(rates of potential diabetes, we found no difference in drugs)
(was difference in Clozapine, greater)

9:12:48 AM Reference EL29548

(First analysis on average change of blood glucose levels)
(there are some)
(couple recent clinical studies that address this like CATIE)
(rate of diabetes through treatment of and rates did not differ among atypical antipsychotics)
(yes, study just released this year by Pfizer GEODON maker, and looking at ketoacidosis)
(worse form of course of diabetes, life threatening, Ketoacidosis)

9:15:27 AM EI2958 - reference

(2007 study, it does include fasting information)
(based on number o placebo results from 2005 and 2007, last two studies done in 2007)
(analysis done in 2007)
(CATIE study and blood sugar levels, average change)
(looking at highest change, average of highest two)
(did look for patients who started with diabetes)
(no, difference than average change in glucose either)
(change in 2007 was because of FDA asking us to do this)
(we been reviewing this information as it came in and in context and labeling had been ok)
(Consensus Statement, I am familiar wit this)
(some of them are and some of them are not)
(consistent in ADA and labeling both point to higher rates of diabetes in schizophrenic patients)
(ADA does say increase risk, not what label says)
(yes, part of my job for number of years)

9:20:21 AM Suggs - objection, foundation/based on his experience

Suggs - speculations/ not can cross on this

(based on training and experience)
(quite a few ways)
(different doctors look for information through different routes and Eli provides)
(others look to medical department and we provide letters and through labeling)
(and or the sales representative)
(and doctors talk to other doctors and or engage speakers to talk about information on the drug)
(and we have a website as people like to do own research)
(medical letter is like a research paper and put together by our medical department and gives conclusion)
(scientific information provide through medical letters, yes)
(sure)
(I prepared medical letters, yes, an supervised physicians who did this too)
(practice to keep these medical records, yes)

9:25:19 AM EI2990, 2991, 2993, 2996, 3003, 3004, 3008, 2994, 2995, 2987, 2988, 2944, 2973, 3014, 3015, 3899 - ID

(familiar with these letters, yes, looking at medical letters from our US Medical Department on glucose)
(I have EI2990, 2991, 2993, 3003, 3004, 3008, 2994, 2995, 2996, 2987, 2988, 2973, 3014, 3015,

3911 and 3898)

Court – you mentioned two document the witness did not reference and he said two that you did not

9:28:58 AM (medical letter provide and mailed)

9:29:30 AM EI3932 – ID

Suggs – admitted or not, not to be on screen

(yes, signed by me)

9:31:51 AM Kantra – move to admit 3932/admitted

(dated December 27, 2000, yes)

9:32:48 AM EI2994

9:33:36 AM Court – mark is it admitted

9:33:51 AM Sidebar begins

9:34:21 AM Sidebar ends

Kantra – yes, would be better to get them all in

(yes, we prepared on weight gain and hyperglycemia, yes)

Kantra – Admit

Court - 2990, 2991, 2993, 2996, 3003, 3004, 3008, 2994, 2995, 2987, 2988, 2973, 3014, 3015, 3899, 3911 and 3898a are admitted
- and you said 2944 and 3014 referenced by Kantra but not the doctor

Kantra – yes

9:36:14 AM EI 2994 – referenced

(based on literature review and review of spontaneous reports)
(Dr. Alison analysis, yes)
(page ten, used electronic data bases, libraries catalog placed on data based)
(sure, both sides)
(no, not every article ever done, but we looked at them and used most relevant ones)
(has 72 referenced in this one)
(yes, review these letters annually)
(Dr. Wirshing report is in this reference, yes, number 41)
(page two, reading conclusions, yes, and still believe this to be true)
(several)

9:43:29 AM EL3015 – referenced
(medical letter, reading title of this ex.)
(screening not about medicine)

9:44:44 AM EI3911 – referenced
(letter to physicians in the change of label, 2000)

9:45:06 AM EI2973 – referenced
(yes)

9:45:46 AM EI3998A –
(yes, another letter)

9:46:49 AM TG12-3
(I did prepare this slide, MLR)
(no, want team to be creative)
(all three have to sign off)
(make sure conclusions are accurate and in line with Lilly conclusions)
(sometimes me or someone under me)
(regulatory and legal, they make sure what ever prepared comports with the laws and labels etc..)
(if we disagreed at this stage it would not go forward)
(would be sent back to improve)
(and after this is done went to sales force, correct)
(programs developed to control weight gain, yes)

9:51:31 AM EI3381 – ID
Court – not in, removed from screen
(yes, wellness program and in use)

9:52:56 AM Kantra – move to admit 3381/admitted
(control eating and weight)
(there were)
(number of them and some were tools we provided for sales force to provide to physicians, tracking sheets, education programs, lecture nurses, educators on diabetes, etc..)

9:56:04 AM EI2184 – ID
(material menu for sales force, in time frame of around 2002)

9:56:53 AM Kantra – move to admit 2184/admitted
(screening guidelines and risk factors for diabetes for general population)
(page six, screening recommendation for diabetes who are on atypical antipsychotics)

9:58:14 AM EI 3901 - reference

(brochure approved for sales force to be shown, from end of 2000 or 2001)
(looks like I approve this)

9:59:06 AM Kantra - 3901/admitted

(information for doctors and telling them they'd see diabetes in their patients)
(I did)

Court - questions, this document was prepared 2001

(yes)

Court - when, continued to be used today or what

(evolves are replaced overtime, this is not still be used in and in this time frame we made a couple of changes)

10:01:09 AM Continue with Direct by Mr. Kantra

(indicates 2001, still being used)

10:01:35 AM Slide TG213-3

(to monitor all patients who are on antipsychotics)

10:03:11 AM EI39801 referenced

(portion of patients on the two drugs Haloperidol and Olanzapine)
(no significant difference)
(took longer time frame and put them together)
(Haloperidol is widely used of older ones)
(yes longer term study we have)
(yes, other way we look for apportionment of patient who might develop diabetes, looking at blood glucose, increase to move them into hyperglycemia)
(no, Dr. Alison and team looked at Olanzapine and Haloperidol and the placebo and now significantly different)
(no to be seen commonly by doctor in their patients)
(more common with patient of psychiatric illness)
(found to be higher)
(number of studies that support his conclusion)
(yes, page three shows some of them)

10:10:11 AM EI3429 - ID

(yes, this is a Boucher for sales rep. to use with doctor)
(hyperglycemia and diabetes)
(late 2002 or earlier 2003)

10:11:34 AM Court - EI 3429 is admitted

(2003)
(diabetes is common and patients are at greater risk)

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(this is the adverse section of the label, directs doctors to where the information is)
 (that is right)
 (same information from few minutes ago)
 (new information also has bi-polar with Depakote an Olanzapine)
 (looks lighter but no difference)
 (it is)

Court - will break

10:15:06 AM Off record Jury is Present
 10:33:30 AM On the record

Court -

Kantra - 3014

Court -

10:36:31 AM Publish medical letters to jury
 AM

Court - you may

10:34:24 AM (yes, from Pfizer study)
 (diabetic ketoacidosis, very few and identical over course of a year)
 (it has been over tie with Lilly but not current responsibility)

10:36:03 AM EI3915, 2916, 3917, -
 - AK10165, (EI3918), 3919, 2920, 3921
 EI3922, 3923, 3924, 3925, 3926, 3927, 3928, 3929, 3930 - ID

10:40:15 AM Court - offering

Suggs - notice

Kantar - for treatment matters

Suggs - objections to

10:40:45 AM Sidebar begins
 10:43:42 AM Sidebar ends

Court - admit 3915, 3916, 3917, 3919, 3910, 3921, 3922, 3923, 3924, 3925, 3926, 3927, 3928, 3929 and 3930

10:45:19 AM EI 2954A - referenced

(1996 package insert)
 (page 16, weight gain, 5.4 KG which is about 12 pounds)
 (information from three long terms studies for original Zyprexa submission)
 (given patient population)
 (HGHJ study, yes)
 (time period for this group of patients was acute phase, six weeks to 2 and ½ years)
 (give or take about 800 patients)

10:48:08 AM Ak 1586 – referenced
(I do not know)
(I do see)
(this is subgroup of patients and subgroup of labeling)
(included to make average)

10:50:13 AM Suggs – objection

10:50:17 AM Sidebar begins

10:50:55 AM Sidebar ends

(yes, in general terms and for Zyprexa)
(yes, in general)

10:51:45 AM Suggs – objection

Court – joined when company when

(1999)
(based on how we do safety and how we reach conclusions)
(yes)

Court – will let him ask on this basis, may cross on this

Continue with Direct by Mr. Kantra

(because general safety approach to long term information is looked at as an average)
(normal approach is to look at beginning and)

10:53:33 AM Court – why, taking away extremes

(you do want to don adverse events and caption those in labeling)
(but average weight gain is supplementing to say what happen in general population)
(can compare labels)

10:54:29 AM Continue with Direct by Mr. Kantra

(sure, several ways like information on weight gain are in publications)

10:55:23 AM Ak1605 – referenced

(this is one of many outlines of laboratories information)
(this is short term, GHJ study)
(first six weeks of study I long term study of a year)
(yes,

10:57:19 AM Suggs – objections/ base on your knowledge of Lilly practices and procedure

(yes, would know)

Court – OR

10:57:45 AM Direct Continues by Mr. Kantra

(from study report and looking for something frequency or something different, gives a signal to look at as an issue in treatment)
(predefined threshold of highest and lowest at any given time and number of patients cross this)
(information available in this study and Zyprexa cause higher diabetes, need to look at consistency, its not)
(but look at it across all the studies)
(this topic or placebo)
(yes)

11:00:26 AM EI2043 – referenced

(page 74, yes, high non-fasting glucose levels)
(HGHJ but other studies also)
(no, as you see it is not significant)
(P value is .05 and below and this is twice that, not significant)
(look at top row it's 1.2 for Olanzapine versus 1.7 placebo)
(would not support a real difference)

11:03:36 AM EI 3931 – ID

(study report of HGHJ study)
(yes)
(familiar with this)

11:04:33 AM Kantra – move to admit 3931/admitted

(N.F. stands for non fasting)
(seeing summary)
(yes)
(understand the GPLZ had errors)
(number differ from one study to another but consistent with out Olanzapine analysis)
(conclusion is the same)
(exactly)
(yes, author on that publication, bi-polar n comparing)

11:08:30 AM AK7802 – referenced

(appears to be summary of number of patients who cross threshold on lab tests and calling out Olanzapine and Placebo)
(no, do not recognize this analysis but showing four patients with high non-fasting glucose, had we had this you look at it across all information you have)
(not base conclusion on this one line)
(yes, standard practice)

11:10:52 AM EI3939 – referenced

(

11:11:41 AM Kantra – 3939/admitted

(describe as same analysis but his is six patients not four)

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(validate by our statisticians)
(yes, I do)
(North American Diabetes Board is a group of experts in endocrinology, wanted their impute on Zyprexa and diabetes)
(in the submission)
(main thing I got from this is they wanted us to not stop with analyses but to continue and get more information and communicate this to others)
(talk with psychologist to help patients manage weight gain)
(October 2000, because not what our conclusion showed)
(not based on theoretical but looking at what we found in our studies and sharing with doctors on what we knew not what we suspected)
(we kept working on the question and with independent people from Lilly)
(looking at data and think of studies)
(Dr. Holman, endocrinologist and Dr. Buse and others who work on this)
(no restrictions placed on them from Lilly, no)
(we looked to them on guidance)
(number of them relevant to what we showed here, we showed them threshold and comparable rates)
(and we looked at hyperglycemia)
(we did)
(presented at scientific meetings numerous times)
(Thomas Brody is marketing profession working for Lilly)
(he did not work on Zyprexa and not aware of ways this data was shown to physicians)
(coming clean, no, but did get email from Brody)

11:21:13 AM Suggs - objection/sustained

(I understood Brody to say, coming clean, he was referring to advice from advisors on information we had)
(and to help with weight gain)
(no, lot of times it is not, weight being manageable)
(doctors did want this information and knew from studies attempts to control weight help some)

11:23:33 AM Suggs - objection, foundation/allowed as to what he took form these conversations

(yes, many conversation over many years and doctors were focus on weight, something they have seen in their patients)
(and interested in things they could do about that)
(weight gain could be substantial in some patients, yes, they were aware)

11:25:02 AM Suggs - objections, leading/or

(yes, basics information from school)

11:25:40 AM Cross Exam by Mr. Suggs

11:26:38 AM (2007 label change, yes, did talk about it)
(information on hyperglycemia different from 2003, yes)
(and on weight gain)
(and hyperlipidemia, yes)
(no, except for high glucose on atypical, 2003)
(they have not)
(2003 label change, agree)

06-0563007

(yes)

11:28:13 AM Court - sure, testimony being shown on screen

(yes, read that correctly)
(no, I participated in this)
(I did quite a bite very involved)
(I agree)

11:31:16 AM Kantra - objection/rephrase

(do not recall that)

11:31:44 AM Ak3223 - referenced

(Mr. Clewell, I do know him)
(four months after label change)
(Dr. Clewell is person who interacted with payers/ insurance)
(yes, Medicaid)
(health care professional)
(CVA, Cerebrum Vascular warning, January yes)
(did not write back say we were wrong, not that I recall)
(February 2004, sound right)
(do remember important for Lily but not the way you characterize it)

11:36:51 AM Ak3109 - referenced

(Hunter Heath)
(B2B, business to business, yes)
(B2G, business to government, yes)
(yes, read correctly)
(I was part of Zyprexa swat team, no, do not think so)
(one of them, higher risk for diabetes)
(hyperlipidemia, higher lipid increase than most others)
(not what our studies show, and dispute that, yes)
(Vicki Hoffman is clinical research at US Medical Group)
(no, do not recall)

11:41:13 AM AK 3192 - ID

(yes, do not recall getting this, need moment to read, do not remember)
(looks like I got it)

11:42:37 AM Suggs - 3192, move to admit

Kantra - no foundation

Court - not disputed, overrule objection and will admit

(I do see that, the advisors were, not sure)
(yes, that is what we found)

11:45:00 AM Ak9281 - referenced

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(no)
(1999 and trained as psychiatrist, right)

11:47:30 AM Ak8905 – referenced

(am married to Dr. Paula Trzepacz, yes)
(often work with people from marketing, yes)
(yes, in way we talked about earlier, medical impute on letters, training of sales rep.
(we assumed a subgroup)
(do recall that)
(Dr. Haze was the medical director for neuroscience, my boss at the time)
(September 199 came to Lilly)
(looks like it)

11:53:12 AM Suggs – AK7731, move to admit

Kantra – objection, truth of matter

Court – admitted as to purpose of putting Lilly on notice of this letter not for truth of content

11:53:51 AM Ak7731 – referenced

(yes, see that language)
(no, I do not know, not sure what you are referring to)

11:56:50 AM AK 4176, referenced

(yes, November 17, 1999)
(spontaneous reports and goes to Pharmacol Vigilance Department)
(registration trials done for MDA, yes)
(yes, that would be part of the diagnosis)
(and this is greater than 250mg, says that)
(do not recall this report)
(page 10, yes)
(not sure why Lilly had 250 cutoff)
(200 is cutoff for diabetes)
(and if they showed up not show for high blood glucose unless over 250)
(not necessarily, depending on cutoff)
(retrospective study by Dr. Casey, not at seminar that I recall)
(yes and, um, not included)
(fasting glucose levels, no)
(139 and is greater than the cutoff of 126 for diabetes, I agree)
(no)
(report, yes)
(regarded as secret, I see that and that stands on many of our documents)
(information given to doctors are the overall conclusions)
(not aware of this particular report)
(yes, we summaries our conclusions)
(no, the medical group, medical information group would respond to request for information)
(saw his report on what he saw in his patients)
(not accurate)
(no, depends on what you refer to diabetes issue, doctors aware of weight and diabetes)

12:10:13 PM Ak 3860 – referenced

(on Lilly log, answers that matter, company motto)
(telling the doctors the truth among other things, medicine providing answers for their patients)
(I do see)

12:12:11 PM Suggs move to admit 3860/admitted

(Medical Marketing Group, do not recognize nor anything from that group)
(no, not aware)
(yes, done without my knowledge, is weight gain with Zyprexa)
(not aware of that)
(not aware)
(possibly, but did not tell doctors, do not think so)
(no, not our strategy)

12:17:20 PM Ak 1962 – referenced

(Sell sheet is another word for brochure)
(AOC is area of concern)
(verbatim means sales rep. given answer to question to answer the sale rep.)
(no, did not coach sale reps. On this)
(Donna, do not know who that is prototypical patient, no)

12:20:30 PM Court – will break at this time

12:20:48 PM Off record

12:40:19 PM On the record

Jury is Present

12:40:22 PM Continue with Cross by Mr. Suggs

(not all schizophrenics are violent)
(John Nash, won noble prize, yes, but saw the movie, portrayed him as schizophrenic)
(Mark Twain might of been Bi-polar,)
(Hemmingway was felt to be bi-polar and Winston Churchill might have been)

12:42:42 PM Ak 1941 – referenced

(recognize some of the content)
(appears to be that)
(right, doctors should expect)
(correct, it says that)
(that is what it says)

12:46:10 PM Ak1453 – referenced

Court – not you personally but Lilly

(October 9 meeting, sounds right and on November 1, do not remember where I was)
(would depend, do not remember November 1 and would say the email)
(helpful meeting on Lilly's most important drug)
(I would expect that)

(assume I would of wanted emails to be read not that they'd be shown in courtroom in Anchorage

Alaska)
(I would have had teleconference with sales force but did not prepare their answers)

12:50:58 PM AK 8112 – ID
(do see that, yes)

12:52:17 PM Suggs – move to admit 8112/Ak8112 is admitted
(market research fact number one)
(yes, contact was with physicians, yes, our market)
(I see it and refers to rep knowledge)
(medical conclusions)
(yes)
(coaching sale reps on tone when given the diabetes message, I do not know)
(possible they were the lowest of all reps)
(part of my job was not to teach the sales how to say it)
(looked at medical information and material they had but not how to say it)

12:58:37 PM Kantra – objection, asked and answered/OR
(sometimes yes)
(editorials used for information teaching on disease topic)
(says diabetes)
(Marni Lemons is in the courtroom today, yes)
(I do see that language)
(medical letters have medical data)
(no, do not know what you mean)

1:02:43 PM

1:03:32 PM Ak1941 – referenced
(no)

1:04:56 PM EI3932 – referenced
(yes, correct, bottom line of letter, comparable)
(went out to 100's or 1000's)
(and to Alaskan physicians, no idea)

1:06:32 PM Ak 7802 – referenced
(no)
(sure, accept that)
(right, submitted to FDA)
(I do not think this was sent to FDA)
(telling reps not causally relationship)

1:08:49 PM Ak 8666 – referenced
(not just diabetes, Dr. Taylor is an endocrinologist)
(dated June 27, 2002, not aware he was saying this)
(after this Dr. Taylor left company, yes)
(Gary Tollefson is psychologist at Lilly in neuroscience)

Suggs – do not know but at least one hour

Court – still on track to conclude evidence by Thursday

- will miss everyone for the day, admonishment given to the jury

1:31:31 PM

Outside presence of jury

Court – get admitted exhibits to Mr. Borneman

- will be working on instructions and might go late tomorrow

1:32:41 PM

Allen calling Mr. Noesges

Lehner – on witness list but after video tapes

- our next live witness

Court –

1:34:02 PM

Lehner – re-reconsideration of Ms. Jackson, opened door with email

- look at email 2332 and testimony, her views are pertinent

Court – will review the email tonight

Allen – they seem to get four bites of the apple every time they get adverse ruling

Court – not motion based on same argument but opening the door, will review the exhibit

Allen – making record

Court – will let you know tomorrow on this issue

Allen – and Reggie Jackson, Jessie Jackson and the Jackson five

Court – no comment

1:37:11 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3AN4308-66

Judge: M. Rindner

Date: Monday, March 24, 2008

Clerk: M. Borneman

Case No: 3AN06-5630-Ci

Case Title: State Of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial day 16

Counsel Present:

Plaintiff: Scott, Allen, Esq., Tommy Fibich, Esq., David Suggs, Esq., and Ed Sniffen, AAG

Defendant: George Lehner, Esq., Nina Gussack, Esq., John Brenner, Esq., Mr. Kantra, Esq.,
and Mr. B. Jamison, Esq.

Court Orders:

Summary of Proceedings: Jury is sent home for the day, one juror is sick. Trial will resume tomorrow at 8:30.

8:21:28 AM

On the record

Jury is not Present

Court – list case and parties present

- one juror is sick today and will not make it in, number five
- will be here tomorrow
- trial is continued for today and pick up tomorrow
- not at point to pick up the jury instructions
- will bring in the jury when they arrive

8:22:50 AM

Allen –

Court – overrule objections to Cavazzoni deposition and Lily has made objection to State's Counter-Designation and list cuts they want played with state for completeness

- over the weekend I arrange the sate to drop off material at Cook's Health Club and came back to the office and found I did not have Lilly's original material and asked Judge Christen to call Mr. Jamison to drop off this document
- Jamison then called the office and I answer the phone and he advised he dropped it off an I said thanks, one minute, nothing else said
- Something on jury instructions, tentative package, one what I propose to do
- Lily has proposed a lot of jury instructions talking about the FDA and inclined not to give most or all of those instructions
- Lilly not relieved of its obligations based on allegations in this case, need more time to think this through
- Reviewed the Upjohn case on the warning instruction, think supreme court decision supports my decision of not preempting the FDA warnings

8:27:27 AM

Fibich – time for conference on the jury instructions

Court – either going to do it one Wednesday, late or even Thursday morning and bring the jury in late

Fibich – they intend to bring by deposition commissioner of Health and Human Services, we object

Court – do not have cuts

Lehner – three outstanding are brief

Court – bring in the cuts as I have time

8:29:45 AM

Off record

8:43:32 AM

On the record

Jury is Present

Court – ten members are present

- Ms. Mitchell called in and is sick, will be here tomorrow
- Ms. Ilutsk called in and said she was late but told her not to come in
- Not able to do the trial and will dismiss for the day
- Back tomorrow at 8:309
- Admonishment
- Enjoy your day

8:45:13 AM

Outside the presence of the jury

Court – cuts to be provided by Lilly today and objections to Cavazzoni

- in recess

8:45:52 AM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3An4308-65

Judge: M. Rindner

Date: Friday, March 21, 2008

Clerk: M. Borneman

Case No: 3AN06-5630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial Day 15

Counsel Present:

Plaintiff: Scott Allen, Esq., David Suggs, Esq., Tommy Fibich, Esq., and Ed Sniffen, AAG

Defendant: George Lehner, Esq., Nina Gussack, Esq. John Brenner, Esq.

Court Orders:

Summary of Proceedings: Trial continues to March 24, 2008.

8:30:30 AM

On the record

Outside presence of Jury

Court -

8:30:40 AM

Lehner - Ms. Cavazzoni to be taken up

Court - state to respond in wiring

Suggs - no need

Court - read brief, need to hear from state

Jamison - very well

Court - history about this case and predicated about MDL deposition, no need for all the deposition and then move this along, all because of MDL, hasn't this been the flavor to move this along and get it done, bifurcation, etc.,

8:32:27 AM

Suggs - agree to waived the rules, deposition to be used against parties

Court - but history and regardless if noticed on this case or not

- deposition in this case taken by lot of people
- to extend there is argument Dr. Cavazzoni given notice and waived

Suggs - not there on behalf of Alaska's interest and they said she'd be live

Court - and you said you'd not call Dr. Hobson, changes made, and question is fair is fair

- could of retaken as part of your ten, right

Suggs - could of but did not

Court - everybody on notice of the use of MDL deposition

06-0563007

Suggs – nothing about waiving the rules, no waiver of this
- nothing says waiving the rules here, not in their deposition

Court – discussion of the need to re-depose and to ask for permission

Suggs – yes, but not waiving rule 32

8:36:21 AM Jamison – was waiver but also order of this court, attached as exhibit C, reading from
- their concern was not to use but to redo some MDL deposition, they did not like the way they aware taken and they could of re-depose, gave them ten
- ten freebies, happen on purpose

Suggs – language from January 8, 2007, you'll, you will, six months after this deposition
- right to use deposition but under rule 32 they have to be represented

Court – Dr. Cavazzoni status

Jamison – not to be here

Lehner – in Indianapolis, single mother

Court – telephonic deposition to fill this gap in

8:38:43 AM Lehner – the gap, use the MDL deposition or not

Court - question is notice and able to cure this

Lehner – deposed twice on all generic material, nothing Alaskan specific

Court – they would of list as one of the ten, not use all of the ten

Suggs – no, we did not use all ten

Court – did not use for Alaskan purpose and you chose not to do this

Suggs – June 2006, not there for Alaska

Court – ended up with ten freebie rule after she was depose
- could of gone back and

Suggs – no need because of rule 32

Court - on the witness list at opening, etc.

8:40:48 AM Off record
8:42:55 AM On the record

Court

Suggs – have objection but will withdrawal it

Court – need to deal with objections and counter objections

8:43:20 AM Gussack - will make sure you have what is in dispute

Court - plan for today

Lehner - Dr. Beasley deposition and Tollefson and then Dr. Baker live

Court - and jury instructions

Gussack - conference?

Court - when Lilly is done with their case and then rebuttal from state, will send jury home for a day to do this, if needed

- will have whole day, jointly, for closing and then instruct jury, if not will bring back the next day
- have given jury instructions before the closing, I have not done this but have heard of this

Allen - worth it

Court - but will consider this

Allen - 12 minutes of rebuttal

Gussack - length of their cross, case might end Wednesday, estimated

Fibich - will not call but five witnesses in rebuttal, 12 minutes of rebuttal

Court - all depends on cross

Fibich - thank you on this issue and we need to know when they think they will rest

Court - dependant on the cross

- Cavazzoni needs to be dealt with

Allen - unlikely I will object

Suggs - I laughed

Gussack - 12 minutes of rebuttal being held in reserve

Court - based on Eski, I figure

- will review the calendar

8:50:08 AM Off record

8:59:12 AM On the record Jury is Present

Court - good morning

8:59:25 AM Lehner - will call Dr. Charles Beasley by video deposition

9:00:39 AM Dr. Charles M. Beasley, Jr., video deposition starts

10:02:20 AM Video ends

Court - in recess

06-0563007

(practicing psychiatrist at time of joining Lilly, 13 years)
(yes)
(after potential drug that may be helpful is developed, all testing happens in lab)
(then we test in animals, mice and rats, and if they pass this we go to other animals species)
(several years)
(before we test in humans we make contact and talk with regulatory people)
(we file IND and this goes to FDA and if no objection we go to human dose)
(very low dose and watch what happens and if all goes well we move up to higher doses
(blood sugar levels, sure)
(phase two is where testing is started in patients we think the drug will help with)
(can people tolerate wider scale testing and finding a more definitive dose)
(phase three is bigger trials, is there enough evidence to show it works and approval by FDA)
(1000 or more patients)
(submission, NDA, new drug application, all information to FDA and proposal for drug label, sent to them and they review this information)
(FDA is given boxes and boxes of information)
(FDA have scientist who are experts in the drugs chemical formulate, toxicology, physicians in safety, etc.)

slide...

11:53:27 AM Suggs - objection to this, email

11:53:41 AM Sidebar begins

11:54:31 AM Sidebar ends

(yes)

11:55:07 AM TG021-0002 - slide of Discovery and Development of Olanzapine/Zyprexa

Court - using what exhibit number

Kantra - slide prepared by Dr. Baker

(about four years)
(and then 9 years of trials)
(over 3,000 people)
(1995)
(all information sent in)
(they, FDA, spent a year approving this)

11:57:19 AM Ak 8905 - referenced

(yes, 8/31/2000, yes)
(not at all, other physicians at Eli Lilly examined this issue, other psychologist)
(all had job to understand side effects, etc.)
(other physicians in other countries employed in other countries doing the same)
(product team, psychologist, endocrinologist, etc.)
(all the scientist that worked on development)
(Dr. Cavazzoni and Dr. Beasley, yes)
(yes)
(July 2000, first thing I did when I came on board, reading of special submission)
(yes, as we finish with each clinical trial we submit in study report to the FDA)

3AN06-5630CI-03-21-08

06-0563007

(and looking at diabetes in patients)
 (done in United Kingdom and confirm people on antipsychotic had more diabetes to people who did not take antipsychotic, confirmed what we saw in peer review sent to FDA)
 (looked more common on atypical than 1st generation)
 (Zyprexa was new to United Kingdom and not used in this trial)
 (Zyprexa v Risperdal, this is USA study and able to make comparison and the rate in diabetes were no different)

12:34:03 PM EI2013 and 3385 ID

(article, yes, represents GPR study)

12:34:52 PM 3385 – ID

(yes, other study)

12:35:18 PM Slide TG107-2

(yes, referred to Allison clinical trial, David Allison, outside Lilly)
 (glucose in two different ways)
 (average change across the whole population, not able to say abnormal change or not)
 (showed in Olanzapine there was increase but also compared to other treatments and in one case no difference, Risperidone, but compared to placebo or haloperidol)
 (rate in individual, no difference)
 (yes)

12:38:51 PM EI 2127 – referenced

(manuscript prepared and submitted for publication, yes)
 (yes)
 (October 2003 submission to FDAA, yes)

12:40:04 PM EI2032 – ID

(have slide for this)

12:40:50 PM Slide TG107-3

(we review and provided new information on pharmacoepidemiological)
 (TED is treatment emergent diabetes)
 (this confirm what we saw before, treatment chosen is not likelihood of diabetes)
 (this also looked at risk factors and most powerful was blood glucose before getting medication)
 (elevated before start had 10 times more likelihood of getting diabetes)
 (two or more risk factor, five times s likely to get diabetes)
 (that is right and if you had weight gain during course of treatment, more likely to get diabetes)
 (yes, this was published)

12:45:04 PM EI 3801 – ID

(this is TED)
 (thinking 2005)

12:45:46 PM Slide TG107-4

3AN06-5630CI-03-21-08

(Lilly conducted two and in this 2002 submission, published, right)
(fourth submission was March 2003, yews)

12:46:47 PM Slide TG107-5

12:46:53 PM EI2033 - ID

(yes, March 2003)

12:47:55 PM Slide TG107-5

(9 million patient exposure, right)
(reviewed and Lilly found no conclusion to be drawn from this data on causation)
(June 2003, fifth submission)

12:48:45 PM EI2036 - ID

(yes, June submission to FDA)

12:49:14 PM Slide TG107-7

(since previous submission two new analysis performed by Lilly)
(that looked at clinical trials but this took in trials with people who had bi-polar disorder)
(did not find if on Olanzapine of other treatment, no likelihood of developing diabetes)
(but help up risk factors)
(TED is preexisting diabetes, not looked other studies)
(went back to those patients and look to see if diabetes got worse overtime)
(some get worse and some got better, but average was worse)
(no significant difference)
(third clinical trial, yes HGHJ, yes)
(Geodon, right)
(six month long study an comparing Ziprasidone)
(no difference in blood sugar with Olanzapine and Ziprasidone)
(more weight gain with Olanzapine than Ziprasidone)
(did review this literature)

12:53:31 PM EI2041 - ID

(yes, this looked a adverse events with diabetes and high blood pressure, conclusion was
consistent with what we had seen in earlier reviews)
(only submission that focus on that question)
(information on blood sugar elevation given to FDA, all products have periodic safety reports)
(submitted as study report)
(each of those submission are similar to new drug application and overall safety finding with the
drug)
(to include safety information)
(yes)
(package insert from 1996)

12:58:10 PM EI2954 ID

(yes, 996 label)

3AN06-5630CI-03-21-08

06-05/63007

12:59:08 PM EI2937 -ID
(200 label insert)
(yes)

12:59:42 PM EI2585 -ID
(yes)

1:00:13 PM EI2953 - ID
(yes, 9/03)
(yes)

1:00:52 PM EI2945 -
(yes)
(yes)

1:01:24 PM EI2958 - ID
(10/07 label)
(yes, aware of teleconference)
(document interaction with FDA on Zyprexa or any other)

1:02:24 PM EL2037 - ID
(note to file, yes)
(Lily to FDA)
(10/17/2002)

1:03:20 PM Suggs - may we approach

1:03:26 PM Sidebar begins

1:04:06 PM Sidebar ends
(yes, at this point)
(this is epidemiology study looking at risk of diabetes in patient with schizophrenia and if different rates among antipsychotic)
(close discussion with investigators throughout)
(end of summer 2003)
(they found similar diabetes risk with Risperidone, Olanzapine and Quetiapine)

1:06:53 PM EI2016 - ID
(right)

1:07:47 PM Reference table four
(rates of diabetes per 100 patients four would develop diabetes over the year)
(Olanzapine first on list)
(page three, 2nd paragraph, looked at rates and then did statistical analysis looking for other risks and conclusion difference are negligible)

06-0563007

(FDA label change a month after this)
 (Japanese label change, familiar)
 (contraindication means don't use this drug in this situation, diabetes patients)
 (yes, FDA advised Lilly of this, prompt but not sure how many days)
 (Japan label change took place in April)
 (my experience)

1:12:00 PM EI2044 – ID

(label change in Japan, yes)
 (Dr. Breier was leader of Zyprexa product team, globally)
 (Dr. Brophy is director of neuroscience)
 (yes)
 (two special reports on Japanese label change, we did)
 (yes)
 (yes)

1:13:53 PM EI2645

(yes, with respect to Japan label change, nine people)
 (that is right)

1:14:37 PM EI2629 – ID

(April 2002, right)
 (page six, things communicated to Lilly and showed for most of these patients, not clear what was leading to problem in them, two were fatalities)
 (other things led to their death, not Olanzapine)
 (no definitive conclusion on Olanzapine)
 (two were not even on this drug and at least four had diabetes)
 (and some patients had blood sugar that would put them in the diabetes range)
 (Lilly disagreed with this label change in Japan)
 (conclusion was wrong based on data)
 (not the right decision)
 (yes, very concerned about that because we know Zyprexa is best choice for some patients and this would mean people who had diabetes would take the choice away for the doctor, not a good thing)

Court – keep going until 1:30

1:19:13 PM Continue with Direct by Mr. Kantra

(that is right)

1:19:33 PM EI2135 – ID

(letter to Lilly on changing label, to all companies)
 (all atypical antipsychotics)
 (yes)
 (said did not understand the difference in treatment)
 (that is right, contrary to data were not sufficient for such a ranking)
 (any patient started on atypical antipsychotics should be assessed for risk factors of diabetes, as it develop during treatment)

06-0563007

(yes, good routine medical practice, even before the labeling)
(changes echo what Lily had been sharing with physicians before this time)
(we agree and accepted the request to change the label, they, FDA asked for this and we made the change)
(I played role as part of US medical group)
(we communicated Court addresses this case by changing the label)
(issued a press release to be picked up by news organizations)
(and I trained sale representatives to let all doctors they call on about this)
(made slides, medical letter for doctors)
(and Lily mailed a letter to doctors in the US of this label change)
(sent shortly after this change)

1:25:59 PM EI2972 - ID

(letter to physicians)
(conveys FDA requested this and include the press release and the package insert)
(Dr. Tohen, MD., Dr. PH. He took over from Dr. Breier)
(no, Lilly sent this as we want doctors to know this right away)
(that is right, another letter sent out at FDA request, no difference in letters)

Court - good spot for break

- admonishment to jury
- appears to be on schedule to getting this to you
- may give day off next week as we go over material
- admonishment
- Monday at 8:30

1:29:56 PM

Outside presence of jury

Court - appears I can take afternoon to deal with jury instructions, do so after hours and go late or take morning, depends on what I need to do to get this to the jury

- PJ had meeting with paralegal associations and might be nice to give demonstration of this technology

1:32:33 PM Off record

In the Superior Court at Anchorage Alaska

Media No: 3AN4308-63

Judge: M. Rindner

Date: Thursday, March 20, 2008

Clerk: M. Borneman

Case No: 3AN06-5630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial day 14

Counsel Present:

Plaintiff: Scott Allen, Esq. Tommy Fibich, Esq. David Suggs, Esq. and Ed Sniffen, AAG

Defendant: George Lehner, Esq., Nina Gussack, Esq. John Brenner, Esq.

Court Orders:

Summary of Proceedings: Trial continues to March 21, 2008.

8:35:56 AM	On the record	<u>Jury is Present</u>
	Court – list case and party present	
	- continue with Dr. Kahn testimony	
8:36:27 AM	Allen – rule 615 to be invoked	
	Court – witnesses in courtroom, excluded	
8:37:08 AM	<u>Continue with Cross by Mr. Allen of Dr. David Kahn</u>	
	(no, not change testimony from yesterday)	
	(mood stabilizer, refresh memory)	
	(mood stabilizer is not formal term but term many psychiatrist use)	
	(not scientific term, but describes range o drugs that	
8:38:42 AM	Brenner – objection, impeachment	
	(
8:38:52 AM	Brenner – objection, asked and answers	
	(drugs to stabilize mood but no scientific definition of this term)	
	(minimize risk)	
	(not aware of that)	
8:40:19 AM	Ak 1169 – reference	
	(agree with that)	
	(in general if someone doing that , yes)	
	(did not read any additional documents lat night)	
8:41:17 AM	Sidebar begins	

06-05630

Sidebar ends

(do not recall all documents sent to me)
(have reviewed the labeling, yes)
(did not make that statement)
(anything in the label, right, nothing in the label to say that)
(I do see that)
(yes, do see that language)
(and goes on but I see what you are writing/highlighting)
(I agree it does say that, FDA document but not sure what it is referring to)
(

8:44:58 AM Brenner - objection/OR

(in general, yes, they should stop but not sure what documents you are referring to)
(no opinion on this area, did not review the Viva Zyprexa material)
(in conjunction with attorneys from Pepper Hamilton)
(portion of Dr. Inzucchi testimony)
(on schizophrenia, yes)

8:47:02 AM Sides being use

(yes)
(might of seen this slide but not sure)
(Assistant Attorney General and risk factors, not on that list as risk factor for diabetes)
(I do not know if it is a risk factor)
(yes, Lilly makes diabetes drugs and can treat diabetes)
(who's who in diabetes and I'm not a who's who in diabetes or expert in this area)
(I do not know that)
(I do see that sentence)
(not what it says)
(I have no opinion)
(best of my ability)
(no, not change or modify my report a this time)
(summary of my opinion, yes)
(yes)

8:54:06 AM Allen in middle of room using easel pad, writing

(knowledge of treatment alternatives, implications of those treatments)
(yes, difference)
(knowledge means they have broad understanding of variety points of view)
(doctors have to know how to apply in patients)
(need valid, accurate and reasonable information to make the decision)
(reading from report, I agree with this, referencing schizophrenia and bi-polar disorder)
(reading out loud from report)

8:58:00 AM Brenner - objection/driftng

(yes, disease Zyprexa is used for)
(drug particular symptom being experience by patient)

8:59:17 AM Benner - objection/stuck all in there
3AN06-05630CI-03-20-08

06-0563007

(stand by that statement, yes)
(possible side affects refer to know side affects of medication, some do and some do not experience)

Court – using the word *possible*, not probable or likely

(of known side effects)

9:00:56 AM Continue with cross by Mr. Allen

(diabetes is serious as is weight gain)
(hyperlipidemia, yes)

9:01:37 AM Mr. Allen in middle of room hold up pad with 21 CFR on it

9:01:50 AM Brenner – objection

(not expert on causation)
(yes, Columbia)
(not meaning of sentence, side effects will be experience by some patients, not all)
(confused by questions, patients should be told of)

9:04:10 AM Court - when is enough information enough to tell patient

(informed an separate from causation)

9:04:35 AM Continue with Cross by Mr. Allen

(separate from side effects)
(yes, agree)
(yes, they are entitled to their opinion as I am)
(but its the patient who suffers the side effects)
(first do no harm, Hippocratic oath)

9:07:03 AM Brenner – objection/tie this in

(not sure who you represent, fine, Medicaid)

9:07:33 AM Brenner – objection/sustained

(page five of report, yes)
(other source is the phrase)
(not that I recall, review Torres deposition)
(no opinion about this)
(PDR, yes it is – handed PDR by Mr. Allen)
(not from memory)
(it says that and I have no opinion on this)
(no opinion in this area, sales representative)
(expert in how doctors assimilate information not how it is organized and provided)
(one source of information for doctors to consider)
(package insert, sales representative detail pieces...)

9:14:24 AM Brenner – objection/OR

3AN06-05630CI-03-20-08

(those came first but all in there and in order)
(no, not change my answer)

9:15:48 AM Brenner - objection, improper/assume for purpose of this question

9:16:21 AM Use of Elmo, hand written drawing/notes from Allen

(this drawing has no relationship to my testimony or my opinion
(yes, sources of information)
(that is correct)
(one description of process, yep)
(giving graphic representation and did not describe it that way)
(CME is one source of many)

Court - disagree with some doctors might not have the guidelines and or algorithms as important to some and other they do

(yes)
(many doctors may never see a detail person)

9:19:51 AM Continue with Cross by Mr. Allen

(where's Bethel)
(no, not Wasilla)

9:20:12 AM Brenner - objection

Court - asked and answered

(yes, Lily information but many doctors might not pay attention to this)
(no)
(they may get information from peer review material)

9:22:06 AM EL 3801 referenced

(yes)
(not sure who those people are but sponsor by Eli Lilly, yes, see that)
(they do have information into that, yes)
(not exclusively by Lilly)
(one participate in research)

9:23:22 AM Ak 10186 - ID

(as are many other sponsors etc.,)
(guidelines and algorithms)
(yes)
(not sure what you are referring to)
(yes, from speaker borough, yes, pharmaceutical companies are able to do this, yes)
(listed in my report)
(objection to drawing makes it appear Eli Lilly is the sole source of information, distortion of what I said)

06-0563007
Court - agree you are writing Lilly not the only source

Allen - agree

Court - deal with your concern on this

(no, distortion)
(could add all places that generate scientific hypothesis and theories)
(no, absurd diagram)
(Harvard and Columbia could have been added)
(many arrows on you diagram but could add dozens of others)
(and many sources of funding contribute to research)

9:28:36 AM Ak 1145 - referenced

(yes)
(one source of educational material among many)
(previous question you asked me, doesn't say who prepared the slides, and I would say no knowledge on who prepare and what this refers to)

9:30:20 AM Brenner - objection/no comments on testimony

(a known risk)

9:31:38 AM Brenner - objection/was a question

(yes, read correctly)
(overall goals, no idea who prepared)
(goal one, read)
(letter says that but no comment on this)
(stated in package insert)

9:33:37 AM Brenner - objection/

Court - approach

9:33:53 AM Side bar begins

9:34:31 AM Sidebar ends

(in personal experience no)
(not sure why its in the package insert but hyperglycemia and hypoglycemia are in there)
(flu, no)
(yes)
(yes, it is listed, gingivitis, not in my experience)
(libido is frequent side effect)
(vertigo, yes)
(description of events in clinical trials)
(position listed is, do not know context of this document)
(reading)
(comparable rates means side effect and may occurred with patients taking Zyprexa and in other antipsychotic or mood stabilizer)

ak10186 - referenced

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(yes)
(Zyprexa is associated with weight gain, yes, it causes weight gain)
(not sure what in the pills cause weight gain)

9:41:12 AM Ak 1453 referenced

(did not know that)
(do not know why it cause weight gain, not sure of mechanism)
(in some individuals)
(not aware they told doctors it did not cause weight gain)
(correct, should not do so)
(in some patients it is associated with weight gain, certainly a side effect)
(known side effect of Zyprexa)
(yes, learned it in medical school, with respect to)

Court – ask again

(as side effect, yes)
(learned about problems with weight gain in medical school)
(do not recall what words were connected but problems)
(sequelae means things that happen in association with each other
(heart disease, back pain, hypertension or high blood pressure, elevated blood sugar, elevated lipids and cholesterol sleep apnea, and diabetes by way of high blood sugar)
(238 days of study, gained 5.4 kg or 11 or 12 pounds)
(we do not know the cause of diabetes)
(unlink means,

Court – explained

(might not know what Eli did and not able to answer question)

9:50:42 AM Brenner – objection/right to say not able to answer an then explain

(unlink to me means, I have no idea)
(association an link is different)_

9:52:53 AM Ak1901 – reference

(Not that I recall, did not read)
(no comment on sale force training)
(no, but listed as source of information)
(they bring information to the customer)
(page two, see strategy)
(I do see that)
(used the word *neutralize* s risk of side effect)
(yes, and should know about possible side effects, yes)
(that is right)
(reading from, not being denied)

9:56:19 AM Allen – objection, non-responsive/answer question

(not able to answer on this document)
(broad statement but false an is leading to deny affect)

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(side effect a known person would experience)
(no, explained this morning one that might experience)

9:57:38 AM Brenner – objection, argumentative/it is
(if known side effect a person may experience)
(yes, and to neutralize aside effect is phrase, its wrong to deny side effect exists)
(help manage weight gain)

9:58:44 AM Brenner – objection/no
(message is a point of view)

9:59:50 AM Brenner – objection/he doesn't know an jury can decide
(yes)
(association, yes)
(logical link, I prefer to use precise term, association of link of weight gain and diabetes)
(yes, see that)

Court – objection?

Brenner – may we approach

10:01:12 AM Side bar begins
10:01:48 AM Side bar ends
(talking about Zyprexa and not general medical term)
(yes, pill cause weight gain)

10:03:33 AM Ak10205 – referenced
(did not review)
(one source of information)
(pill cause weight gain in some patient, yes)
(no, not called on by detail people, safety, policy of medical center)
(some experience as I sometimes call them for information and I want to see packet insert)
(but sometimes from the company)
(they can provide medical letters)
(not valuable, did not say that)
(yes)
(would disagree with statement, yes, cause weight gain)
(funny as she says weight gain in Zyprexa and not sure what it means)

10:07:45 AM Brenner – objection, read entire sentence/fair
(yes, in some patients)
(clear from context the patient had weight gain due to Zyprexa)

10:08:39 AM Brenner – objection, asked and answered/move on
(yes)

10:09:01 AM Brenner – objection

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Ak1110 – referenced

(not sure what I reviewed)
(impossible to say what I saw year ago)

10:10:40 AM Brenner – restrict to doctor experience/no, given article he wrote
(not necessarily cause same weight gain)

10:11:15 AM Court – again, asking him why Lily did something, said he did not know what Lilly did
Allen – able to test that knowledge)
(rationale is a reason)

10:11:43 AM Brenner – not the word/

10:12:00 AM Sidebar begins
10:12:28 AM Sidebar ends

Court – will break for now
- admonishment

10:12:41 AM Off record

10:37:41 AM On the record

jury is not present

Court – jury note, after telling Mr. Borneman, reading notes
- Ms. Sand, juror number 11

10:38:39 AM Fibich – no problem created, do so on evidence

Court – have to make record

Allen – in chambers and you speak with her only

Gussack – is concern to be explored

- copy of log note
- she has connection and record to be made

Allen – we asked at the start who they know

Court – based on witnesses

Allen – the test is different

Gussack – read again

Court - reading jury note

10:41:23 AM Allen – not the test, voir dire done and will hear evidence

Court – need to find out an be done with this

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Fibich – now will want a mistrial, phraseology is important

10:42:15 AM Gussack – objection

Court – can inquire on this

Allen – object to attorney talking to juror, we object, let the court do questions

Court –

10:45:21 AM In chambers interview begins – confidential

10:50:13 AM In chambers interview ends

Fibich – no

10:50:52 AM Parties arrive back in courtroom

10:51:04 AM On the record outside present of jury

Court – no application being made, will continue what trial

10:51:31 AM Off record

10:56:30 AM On the record jury is Present

Court – list

Cross Exam by Mr. Allen continues

(not sure how they mean that phrase)

10:57:10 AM Brenner – same objection/if he can

(not said that)

(minimize weight gain could mean to lessen weight gain, many things)

10:57:55 AM Brenner – objection/sustained

10:58:14 AM AK1169 referenced

(yes)

10:58:34 AM Ex. Ak3860 – ID

(do not recall)

10:59:38 AM Brenner – not in front of jury/hot on screen

10:59:57 AM Sidebar begins

11:01:53 AM Sidebar ends

(in mathematical terms, yes, greater than)

(no, in some patient it can cause weight gain in some patients)

(if you said that but it doesn't say that)

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Court – not question, if said to you
(not the same he said/pointed to)

11:04:16 AM Brenner – objection/can do so on cross
(yes, see that)
(yes, read correctly)

11:06:58 AM Brenner – objection/sustained
(can't answer in general)

11:07:35 AM Ex. Ak0447(4007)
(Can't recall if I saw that ex.)

11:07:52 AM Brenner – objection/laying predicate, fine
(do not know the context of this)

11:08:44 AM Ak 4007 – reference
(no reference to lunch
(Dr. Breier, do not know him)

11:10:07 AM Brenner – objection/sustained
(weight gain can be a plus to elderly)

Court - when you give this drug, Zyprexa, and informed consent, is weight gain a good thing, do you say this
(say can be problem)

11:11:02 AM Brenner – objection/OR
(in maintenance of bi-polar disorder)

11:11:25 AM Brenner – objection/sustained
(do not recall this document)
(do recall Geodon, yes)

11:12:17 AM Ex. Ak0019 – referenced
(yes, not primary care drug, no idea on context of document)

11:13:04 AM Brenner – objection/sustained
Allen – may I approach

11:13:17 AM Sidebar begins

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11:14:49 AM Sidebar ends

11:14:55 AM Continue with Cross by Mr. Allen

(do not have the survey, be great to have copy)
(yes, I do subscribe to American Journal of Psychiatry)
(no, not able to read every article)
(no, do not recall reading)
(no, do not know)
(no, do not know)
(yes, Robert Michael, is a psychiatrist with New York Presbyterian Hospital where I work)
(standard policy in every field, case now)
(recently policy, do not know)
(not sure why it was generated and can't agree or disagree with this phrase)
(no, do not agree over zealous marketing)
(yes, 1999 and information would have been a year before, 1998 or 1999)
(Lot has happen since this information gathered, in the world?)

11:19:57 AM Brenner - objection, range of events/ if he understands

(do not understand)

Court - asking you to provide your standards

(understanding of brain evolves slowly, drug use evolves over time and has there been a revolution since 1999, time will tell)
(can't recall)
(do not recall seeing that)

11:22:36 AM Brenner - objection, characterization/show document

(not sure I can say)
(if paper I might of read)
(Dr. Cavazzoni, can't recall)
(HGF study, not that I can recall)
(European label, not aware)
(Japanese warning, been aware of that, recently, preparation for this case)
(aware, do not remember exact wording)
(those came later)
(that is development)
(had not occurred at this time and not able to take into account)
(not 100 percent, did not review animal studies)
(not how I prepared this)
(a year ago, yes)
(prepared report a year ago, April or so)
(aware of FDA sending letter)
(not aware of information they had never seen before)
(editorial board for Journal of Psychiatry)
(not able to tell you)
(Dr. Hirschfeld, from Texas)
(Dr. Nasrallah, not aware)
(Dr. Paul Keck, speak for drug companies)
(not able to tell you)

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(research expert, no)
 (the PDR, yes)
 (sent to 62 people as defined in our criteria for schizophrenia)
 (page 12, Dr. Frances conclusion, his opinion and I would say there was a significant change)
 (1998 survey, year prior to publication, yes)
 (yes)
 (yes, lobotomies and ice baths, yes, that is right)
 (would not return to that, that is ridiculous to say)
 (used to generate this table, guideline five)
 (side effects these editors felt important)
 (I do stand by this)
 (not listed)
 (that is correct, the 57 experts of survey, not listed)
 (but weight gain is listed and learned about weight gain in school)
 (Clozapine and Olanzapine)
 (need to see language)
 (next page, maintenance phase, continuing patient on medication)
 (blood glucose monitoring, no, not one here)
 (not part of protocol, not use that word, the results that made statistical criteria were used here)
 (hard to monitor for)
 (blood glucose monitoring, that is correct)
 (blood monitoring, need to look at see, have to revise answer on maintenance phase)
 (reading from maintenance phase, did not do with medical monitoring)
 (general psychiatric monitoring, table is for)
 (retract earlier answer, this is about psychiatric monitoring, not medical)
 (Prodromal has to monitoring for relapse of schizophrenia)
 (footnote 14, question 14, is for psycho-social survey question 1 through 4)
 (this is not to the doctors, no, but health care providers)
 (no, graphs we used yesterday were sent to doctors, not this)
 (reading footnote 14, survey question)
 (not part of psycho-social survey, in this section where it talks about blood tests is to monitoring
 psychiatric symptoms
 (Strategies for Selecting Mediation and guidelines six, reading)
 (page 12, no different question are drawn from various sources)
 (logical sequence as to flow of decision a clinician needs to make in dealing with schizophrenics)
 (for long term treatment of schizophrenia and monitoring of schizophrenic symptoms)

11:58:05 AM Allen - need questions and answer format

(that is right, not sure why it is in certain section, but monitor)
 (plasma is blood component)
 (part of treatment)
 (page five, on side effects, footnote 11, that is right)
 (Dr. Frances and guidelines)
 (experts posed question by editors)
 (not asked in this question)
 (question 19 an 21)

12:01:39 PM Brenner - objection, answered/OR

(Cardiovascular side effects)
 (doesn't specify)
 (page 56, chart, and smack testing, this is from question 38 and section of survey that deal with

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mediation section in treatment and standard for all of us, yes)
 (reading the question, 38)
 (health needs overlap with general population)
 (page 57, psycho-social survey is put together to describe those aspect of care for psychological support, living support, etc..)

12:05:27 PM Brenner – objection/this is argumentative
 (not sure what it includes)
 (not here specifically for high blood glucose testing)
 (phase not in document)
 (every time some is admitted to hospital we take blood pressure and get baseline and do whole process to bring some in for treatment)
 (protocol for go going to ER)
 (do not ask every basic question)

12:08:12 PM Court – do not ask questions that every doctor worth his salt, monitor blood pressure
 (basic screening)
 (we asked in terms of prioritizing)

12:08:51 PM Continue with Cross by Mr. Allen
 (baseline is assume and follow up is stated in guideline, blood test annually)
 (any doctor worth his salt, Dr. Hobson, worth his salt)
 (no, did not know he changed his testing)

12:10:00 PM Court – will break jury is not present

12:10:33 PM Off record

12:32:49 PM On the record Jury is Present

Brenner – EI 3907 to be published

Court – if admitted, you may

Brenner – published
 - PDR to be mark

Allen - 2008 admitted yesterday

12:33:48 PM Brenner – EL3909, the whole book

Court - EI3909 is entire 2008 PDR book

12:34:24 PM Re-direct by Mr. Brenner
 (hyperglycemia occurred while on Zyprexa and monitored since 1996)

12:35:40 PM EI3909 on the screen
 (reading from exhibit)

12:37:51 PM EI 3907 on screen

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(problem with spin an bias, no opinion on this)

12:54:45 PM Brenner – objection

(she mad that statement, need context)

12:55:10 PM Court – being show what number

12:55:15 PM Ex. Ak10147 – referenced

(not a guideline and can't say I agree or disagree, long article)

12:56:09 PM Court – reviewing what, CATIE study

(looking at editorial from publication)

Continue with Re-Cross by Mr. Allen

(yes)

12:56:57 PM Brenner – objection/may or may not

12:57:52 PM Re-re-direct by Mr. Brenner

(yes, and recommendation)

Court – blood monitoring recommended in 1999 was what, duration

(routinely not defined)

(I monitored in 1996 and I annually had basic check up done on patient, blood test)

(routine monitoring step up blood test an if gaining weight you check thyroid)

(and evaluation based on changes you see)

(take blood if you see patient gaining weight, yes)

(if they are moving up in dress sizes or buying new cloths, 5 percent, etc.,)

(some people are 3 or 4 pounds and others put on ten pounds easily but if I se 10 pounds or more in a year I step up monitored more and have the, exercised more)

1:01:49 PM Re-re-Cross by Mr. Allen

(depends on person)

1:02:15 PM Brenner – let the judge ask the questions

Court – fair to follow up

1:02:29 PM Continue with re-re-cross by Mr. Allen

Court answer by my questions

(seen handful of patient who develop diabetes)

1:03:16 PM Court – this is not follow up

1:04:04 PM Side bar begins on jury question

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1:04:21 PM | Sidebar ends

Court - reading jury question

(annual health monitoring even without schizophrenia, use drugs that cause weight gain)
(problem with these drugs, not all drugs but most)

Court - another jury question

1:05:53 PM | Side bar beings on jury question

1:06:17 PM | Sidebar ends

Court - outside his area of expertise

1:06:30 PM | Witness steps down

1:06:48 PM | Sidebar begins

1:07:16 PM | Sidebar ends

Court - next witness is long video deposition and we will end today

- admonishment
- back at 8:30

1:08:34 PM | Outside presence of jury

Court - neglected at noon break to say all member of jury were present, they were

- issues and need to think about jury instructions
- additional instruction by close of business tomorrow

Fibich

1:09:43 PM | Lehner - demonstrative exhibits to be used with Dr. Baker, Lilly employee, on material he will be talking about, expert opinions

1:10:40 PM | Suggs - hands to judge

Lehner - deposed in this case by Mr. Suggs, various Lilly submissions to FDA

- they are relevant

Court - witness to testify as to views on these or way Lilly discounted them or not relied on

Lehner - Lilly's view is on the studies and conclusions

1:12:02 PM | Suggs - fact witness, no report

Court - will say Lilly look at the studies and this is what he thinks about it

Suggs - if phrased that way, no problem but not with mantle of expert

Court - not being offered as expert, can cross

1:13:38 PM | Lehner - Dr. Cavazzoni, not able to be live and deposition to be played but they object as no notice given

- MDL case and exhibits could be used in these proceedings

- Play deposition designation here

Suggs – Alaska not notice at that point in time, this deposition taken June 2006

- First one Alaska not even filed a suit
- Alaska not represented at this

Court – if the state was not represented, before used the opposing party has to be represented in some way

Lehner – no need to reinvent the wheel, state not participate in other depositions but we were

Court – process of notice in MDL, used or what and which cases

Suggs – list all parties and Lilly did cross notice designate in state court and Alaska not noticed at all

- will consider an agreement

Court – if you are to use in this proceeding an not noticed for this proceed will do so by agreement

- need basis for Alaska waiving notice or given notice and

Lehner – reason fro notice for you

Suggs – and not on original deposition designation list

Allen – hired by Ken Bailey two weeks before o personal injury

Court – understand question

- let me know and 2ndquestion is if you meet first threshold the 2nd might not bother me

Lehner – thank you

Court – will allow documents subject to what w just discussed

- jury instruction tomorrow

1:19:17 PM

Allen – move to admit exhibit, Ak3860

Court –

1:20:06 PM

Lehner – closed their case, not the time to offer

Court – can't you in cross offer, just given extra exhibit

Allen – do not se eye-to-eye

Court – aversion to give this with no witness

Allen – Dr. Kahn testify about weight gain being widely known but then shown not given this document, credibility of defendant

Court – not able to say he saw this or not

Allen – got middle answer but if shown entitle to give, but I don't know, doesn't make sense

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Court - Mr. Lehner

Lehner - he did not know, honest answer

- no basis to make this part of their case

Court - not admit at this time, 3860 not admitted,

Allen - mark it and make it a bill

- he talked about weight and this 3860 goes to handling weight, reading from Ak 3860

Court - want specific things not just weight gain since medical school

Allen - not telling the truth, the company

- if he said yes its in

Court - didn't get this in yet but got question on the document in

Allen - able to show at closing

Court - will keep this out without prejudice

Allen - will mark Ak3860 and submit an reject this

Court - Ak3860 is not admitted but offered at this time, can renew offer later

1:26:03 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3An4308-61

Judge: M. Rindner

Date: Wednesday, March 19, 2008

Clerk: M. Borneman

Case No: 3AN06-05630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial day 13

Counsel Present:

Plaintiff: Scott Allen, Esq., David Suggs, Tommy Fibich, Esq. and Ed Sniffen, Esq.
Defendant: George Lehner, Esq. Nina Gussack, Esq., John Brenner, Esq., Mr. Kantra, Esq.

Court Orders: Motion for Directed Verdict is Denied

Summary of Proceedings: Trial continues to March 20, 2008

- Eli Lilly filed objections to the state's counter-designation for the Wojcieszek, overrule
- Eli filed counter to Joey Eski deposition are overruled
- Tollefson, Lilly objected to counter-designation, overruled

8:34:44 AM

On the record

outside presence of jury

- Court -
- Stipulation on the PDR, will read this to jury

Allen - not signed

Lehner - gave to them last Friday

Court - proposed

Allen - provide evidence and I will look at it, not stipulate to this at this time

- we offer to put in the PDR
- they can put in stuff to the PDR
- not able to sign without facts
- no dealing with PDR or publishing company
- no evidence

Lehner - look at PDR you brought in

Allen - show me evidence

Court - do you have something

Lehner - will dig it out

Allen -

8:38:19 AM

Court - Dr. Kahn, Motion to Exclude based on Daubert, untimely and is denied
- will hear testimony and take up objections

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- Dr. Kahn is limited to scope of his report and deposition
- Allen - opposition to Motion to Strike, but they stated at page three the relevance for his testimony, reading
- have copy of Dr. Kahn's report, handed to judge, and as you see, page two, listed A through E, his opinions on blood glucose, etc.,
 - we need to object now and prevent him from going into this, not in his report

8:41:10 AM

- Brenner - stated in report, attached, things he relied on, and interrogated on this
- the guideline talks about monitoring and within the scope of his report
 - well within

Allen - show me in the report or guidelines where he discusses the weight, or lipids blood glucose

Brenner - will

- Court - in opposition to exclude, reading from
- real practice or doing this in the 90's

- Brenner - guidelines of 1998 and published in 1999 was real world practice ongoing then
- he collected the data and his practice conformed to this

Allen - show me a sentence in the report that discusses blood glucose monitoring or lipid monitoring

Court - where is it, cite

Brenner - guidelines themselves

- Court - testify there's guidelines or this is what they did
- or is this jut an article attached

Brenner - purpose of him being expert

Court - should be in deposition

Allen - or report and or guidelines

Brenner - what they asked at deposition

- Court - not just document attached as considered
- should testify as it relates to things in his report

- Brenner - in his deposition and the guidelines at page 54, 58, 60, 81, 141 to 154, 161
- item 38, survey data, translate to guidelines, reading

- Court - give me deposition testimony
- Mr. Allen you say, reading, suggest you might of known

Allen - incorrect, look at his opinion, not answered your questions, red the report, not in it

Court - notice, not just report

Allen - agree with that but they have not shown you the opinion yet

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- nothing to do with blood glucose monitoring or lipid, reading

Court - page three of Dr. Kahn's report, reading from

Allen - nothing to do with blood glucose or lipids

- maintenance page, page 16, guideline phase, reading
- not mentioned in report or guidelines

Brenner - page 56, item 38, reading

- item 39
- deposition at page 117, line 3

Court - but you can control what they are on notice

Brenner - we count on them to review the material and ask appropriate questions

Court - page 56,

Allen - rating appropriateness

Brenner - not the second line

Allen - whole report has all kinds of things not in the report

- disagree but I want to finish
- if he said read this I would be on notice but opinion and report do not reflect all the guidelines
- nothing in the report and not here, trial by ambush

Brenner - Dr. Gueriguan report

Court - will let him take this up and then cross on this

Allen - will just see how it goes

- hope we talk about page 56
- can I speak about tuberculosis

Court - if you think this is relevant

-admission of evidence and the call notes and once evidence is ruled on the state rests and then take up applications from defense

Allen - hands the judge documents

Court - hanging from last night, Noesges 9

Allen - AK 100097, move to admit/admitted with objections being preserved

Court - 10008 is previously admitted

Allen - Ak 10178, admitted

Court - objections to the PDR through 2008

Lehner - with supplement we have no objections

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Court – can admitted supplement, what's the number
Allen – let us do our exhibits and they can do theirs after

Lehner – unclear notebook as PDR as exhibit

Court – admitting this

Lehner – 10178, unreadable copy

Court – will admit, any doubt 1997 label, get better

Allen – their number EI2994

- Ak-10179, 10180, 10181, 10182, 10183, 10166, 10165, 10067, 10184, 10185, 10168, 10097

Allen – Ak 1349, admitted

- Ak, 4532,

Lehner – objection to Ak4532

Allen – admitted for notice earlier

Court – reviewing Ak 4532, will stick to that, Ak4532 is admitted

- 8042

Allen - Ak8042,

Court – Mr. Lehner the bates numbers

- concern about page 3 and they say listed as unified document when produced

Lehner – no evidence to tie this together

Allen –

Court - first two pages of Ak8042 are admitted and page three is withdrawn

Allen – Ak7822, admitted

-Ak 439, admitted

-Ak 4871, admitted

-Ak 1926,

Lehner – object to 1926, not relevant, internal document

Allen – reading from opening statement at page 130 to 140

Lehner – no testimony to offer context, no foundation for jury to consider

Allen – party can write a note on napkin and its an admission by party opponent

- relevant a it from their files, not even hearsay

Court – will admit Ak1926

Allen - Ak4361, admitted with objections

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Lehner - final draft, page three language
Allen - drafts are admissible

Court - will admit Ak 4631

9:14:01 AM Allen - Ak10035, argument for and relevant to Dr. Kahn's report
- reading from page 7

Brenner - not testifying on this

Court - let him finish

Allen - he is testifying on these matters

9:16:35 AM Lehner - may we approach

9:16:45 AM Sidebar begins

9:18:36 AM Sidebar ends

Court - 10035 is not admitted at this time
- this is off label

9:19:20 AM Allen - argument for

Court - federal government can enforced and maybe interested in this document but purposes of this trial its more probative

Allen - Ak7990, move to admit

9:20:34 AM Lehner - object to this 401, 402 basis, no evidence offered

Court - let me see 7990, will admitted with objections being preserved

Allen - Ak 2244, admitted with objections being preserved

Court - she is going to be witness

Lehner - yes or no, not sure

Court - wait and see if she shows up and bring in through her

Allen - will wait

- Ak 3223, admitted
- Ak 3872, objections is sustained, not admitted
- Ak 9578

Lehner - 401 and 402 objections

Court - will admit 9578

Allen - Ak 10090

9:29:30 AM Lehner - not part of deposition testimony, no foundation, we object under 901

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Allen - heard about non-restrictions, reading from

Court - will ruled on formulary with Eski I will rule on this

9:30:56 AM Allen - Ak 10203, relates to issue, Eski exhibit

Court - discusses Eski 7

9:32:05 AM Lehner - dealt with this

Court - deferred to later time, not admitted

Allen - Ak10204

9:32:45 AM Lehner -

Court - 10204 is admitted

- 10..... can be filed to establish a record and portions not admitted, part of record

9:33:43 AM

9:33:51 AM

Allen - overrule my offer

Court - previously done and will sustain the objections

Lehner - 10204, 2007 label, preserve motion in Limine objections

Court - all exhibits are admitted with objections preserved

9:34:56 AM

Allen - served this morning with objections to the call notes, they say irrelevant, hearsay and not probative of issues in this case

Court - no need to establish irrelevance to this degree, if call notes have issues in this case and not talking about golf, will not give to jury, but if it has relevance

Allen - just admitted 10097, their call not on policy

- evidence of call notes on weight gain, diabetes, and hyperglycemia, will see this today

Court - objections, copies of call notes for me, want to see ones being asked to admit

Allen - I do an will get, hands to judge

9:41:50 AM

Gussack - offering basis for our objections, hearsay

- sale rep. called and is business record
- see they do not rely on for content of the call note, not sure who said what to who, shorthand used
- question Eski about one or two of the call notes and she said not what that means, etc.
- narrative content of call note is not the quality evidence fro exception of hearsay rule
- 204 policy intended to ensure this shorthand used in call notes would be eliminated and new policy requires more systematic use of information in the call note, computer call note frame work, all sale rep. used, consistent terms used
- March 5 he said not use all notes, just 10/24/08 call note, we object to other notes
- look at those call notes just handed to you, word search, hard pressed to understand why they offer Martha, children or Donna used in the call notes

- they proffer this a to comparable rates and diabetes is limited
- you ruled communication with physician by sale rep. are exempt in this case
- back door attempt to get this in
- you posed, what does this have to do with the warning be adequate, nothing

Allen - what Joe Pesci said, the opposite of what she said

Court - will admit call notes when there is talk about weight gain, hyperglycemia, diabetes, etc., But use in children and if using word search weight gain etc., the core

Allen - move to admit Ak10186, used with Dr. Hobson

Court - admitted but get me copy without word comparable being underlined

Allen - yes, will do

Court - substituted to be sued

Gussack - not sued

Court - call note of call not with Hobson

Allen - this is what I used with Dr. Hobson and will get one that is not underline

- Ak10188, admitted
- Ak10205

9:51:38 AM

Court - delete those that do not have to do with weight gain, diabetes, etc.,

Allen - yes, will do and see it

- will take out muscle spasms

Gussack - objections, no testimony on these call notes

Court - general testimony on call notes by Eski

Gussack - not to whom

Court - that goes to weight and maybe relevant

Gussack - phase two issue

Court - not phase two issue, think it goes to opening when you talked about it and more then a little testimony of use by Lilly tried to neutralize the weight gain issue with Zyprexa or comparable rate issue

- warning to doctor's and Lilly says they knew about this, suggest to doctor's not to worry about his

9:55:14 AM

Gussack - document referring to are internal marketing documents

- not communicated from sale rep. to doctors in Alaska

Court - exactly that evidence you say there is not evidence on

Gussack - no, no message sent or received by doctor

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06-0563007

Court -

9:56:12 AM Allen - AK10205, admitted
- Ak10192, admitted
- Ak10200, admitted
- Ak10187, Eski's 8 deposition

Gussack - only 6 call notes use in her deposition

Allen - to avoid this will staple the six she picks, let them pick their own evidence

Gussack -

Court - would already be in

Mary Beth - not for certain

Allen - let them pick the six

Court - as to 8 go back an not double this up, things in Eski 8 that appear calls notes I have excluded

Allen - Ak10196

Gussack - state expert on this, adequacy of warning to their issue they identified

Allen - risk/benefit analysis

10:03:26 AM Gussack - not yet offer to court, relevance

Allen - risk/benefit

Court - not admit 10196

Allen

Court - 10186,
- list exhibits admitted

10:04:17 AM Allen - 100....
- call notes for later
- thank you

Court - making record, no need for apology
- does the state rest

Allen - take break first

Court -

10:06:02 AM off record
10:18:47 AM on the record

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Outside presence of the jury

Allen - Ak4046

Lehner - exclude this exhibit, irrelevant

Court - will defer on 4046

10:19:42 AM

Allen - we rest

- appreciate and say we rest in front of jury counsel
- thank you

10:20:06 AM

Lehner - Ak Civil rule 50, judgment as a matter of law

- common law failure of UTPA claims
- and UTPACA claims, not apply this statute to sale of this drug
- UTPACA should not apply
- Misrepresentation of Zyprexa in product labeling, exception and bars this claim
- In sufficient evidence on inadequate warning
- 4, state failed to articulate UTPA violation
- 5, state may not seek UTPA restitution and no injunctive relief sought
- 6, damaged claim barred by remoteness
- 7, strict liability is barred
- FDA consistently monitored and regulated the warning and communicate risk and convened
- Weight gain has risk, no need to warn
- Asking jury to substitute its judgment in place of FDA
- 2nd they failed to enumerate the elements, claims fail
- did label fail to warn on weight gain, what date
- hyperglycemia, what date
- no proof and heard Dr. Wirshing having access to all material on misleading, and he said not inaccurate or erroneous, means evidence is missing, no evidence to missing evidence on the label
- additional phrase to be on the label, no testimony on this
- supported by Dr. Gueriguan, page 181, March 1 testimony, reading
- they argue the report of Dr. Bain was inaccurate, withheld information, but that which is withheld was given to Dr. Gueriguan and he did not disagree with this evidence
- allegations that go beyond label and communication are violations of UTPA, not established
- FDA said various statement of Dr. Tollefson where he made statements to investor an FDA said outside the label, false and misleading, is the state claim to take this statement and try to use in Alaska, not made in Alaska, asking to have this statement introduced
- No link or tie up for Alaska, vague and remote, failed to prove on this claim
- What communication made is in violation of UTPA

10:31:33 AM

Court - plaintiff

10:31:39 AM

Allen - 1996 statement by Tollefson, false, deceptive and misleading and the evidence demonstrate this false and misleading statement was continued throughout the sale of this drug to doctors

- sale are the sale across the country, same training and the message must be flowed
- label, training material, comparable rate an the call notes show they reached Alaska
- messages on what they want to convene is to convene on the product and make customer feel a certain way
- Mr. Jordan use in his deposition on product positioning

06-0563007

10:34:56 AM Court – Motion for Directed Verdict the motion should be denied if it appears from the record fair minded jurors could reach different Mertz v JM, 470, P2nd 53

- will deny this motion finding there is sufficient evidence for fair minded jurors could rule in favor of plaintiff in their claims
- failure to warn on UTPA, will rely on previous decision but add it is clear the evidence establishes the wisdom of having such warning claims and UTPA claims compliment FDA regulations and evidence so far is FDA is not able to properly police the companies, they rely on the company's and need for common law claims is needed, based on evidence I have heard now
- note this in denying the motion for preemption and exception under UTPA
- no civil penalty without injunctive relief, denied
- state could of sought injunctive relief and able to seek penalties
- remoteness or state not enunciated violations of the UTPA, do not believe allegations are remote and think state has develop the UTPA claims, jury instructions
- will deny rule 50 relief
- ready to proceed

10:40:25 AM off record

10:47:41 AM On the record Jury is Present

Court - sorry for lateness of the day

10:48:09 AM Allen – the state rests

Court – now time for defense

10:48:24 AM Mr. Brenner –

10:48:59 AM David Allen Kahn, sworn

10:49:06 AM Direct Exam by MR. Brenner

(psychiatrist, Columbia Medical University)
 (duties listed)
 (medical training listed, 1979 graduation)
 (fellowship in extreme depression)
 (do have private practice, I see about 250 patients)
 (treat patients with schizophrenia an bi-polar)
 (New York State Psychiatric Institute, yes)
 (use Zyprexa, yes)
 (have been published, several dozens)
 (have served as reviewer for four or five journals, bi-polar and deliver of health services)
 (Journal of Psychiatric Practice, editorial board)
 (not testified before but ad today at 600.00 an hour)

Allen – do not object

10:53:35 AM Court – so recognized

(schizophrenia is a brain disease and is life long illness)
 {1 percent o population}

06-0563007

10:55:02 AM	<p>Use of slide</p> <p>(positive symptoms brain producing that are highly viable, delusion and hallucinations, disorganized speech and disorganized behavior)</p> <p>(but hearing voices is most)</p> <p>(disorganize speech)</p> <p>(break in language)</p> <p>(disorganized behavior, dangerous, etc..)</p>
10:56:23 AM	<p>Slide used</p> <p>(all to common and this one made News Paper, Russell Weston, 41 years old an he shot two police offices at Senate chambers)</p> <p>(Ruby satellite disk)</p> <p>(living as hermit in Montana, not far from Uni-bomber)</p> <p>(stole parent truck and gun and this tragedy ensure he shot two guards and he was shot)</p> <p>(this is video of his interview by psychiatrist)</p>
10:58:15 AM	Sidebar beings
10:58:52 AM	Sidebar ends
10:58:56 AM	Video starts
11:01:37 AM	<p>Video stops</p> <p>(describing bizarre delusions and led to this agitated behavior)</p> <p>(not talking hallucinations but speech)</p>
11:02:11 AM	<p>Slide</p> <p>(negative symptoms are brain functions missing and losing of Affection Flattening, Alogia, Avolition and Anhedona)</p>
11:03:36 AM	<p>Slide use</p> <p>(Cognitive symptoms are poor attention, poor memory, impair decision making and abstract thinking)</p>
11:04:29 AM	<p>(Co-Morbid Condition are other symptoms, that occur during illness like depression, substance abuse, smoking, hypertension, obesity, type two diabetes, suicidality)</p> <p>(type two</p>
11:05:48 AM	<p>Allen - objection as to form/sustained</p> <p>(yes, many people with schizophrenia develop these conditions, at risk due to life style issues)</p> <p>(people who are suicidal are acutely aware of life loss)</p> <p>(not all are obese)</p>
11:07:27 AM	<p>Slide use</p> <p>(long term deterioration, lack of housing, supervision an care needed, poor health and hygiene, lack of work, stigma, unemployed, etc..)</p> <p>(impact on the family, yes)</p> <p>(it is a profound loss to family)</p>

11:09:06 AM	<p>Slide use</p> <p>(bi-polar disorder is another brain disorder affecting mood)</p> <p>(elevated or angry moods, delusions of grandeur, out of control behavior, mile a minute energy, high sexual drive, high energy)</p> <p>(gets by on two hours of sleep for months at a time)</p> <p>(Depression is other side of coin, this can last for months or years extreme sadness, loss of interest in activities, disturbed sleep, self-neglect, suicide)</p> <p>(untreated 15 percent of these people kill themselves)</p> <p>(cognitive symptom, distractibility, flight of idea, poor focus, poor judgment)</p> <p>(co-morbid condition, yes, high rate of substance abuse, smoking, hypertension, heart disease and type two diabetes)</p> <p>(more common than schizophrenia and there's about 1 and 2 percent of population)</p> <p>(Depakote and Lithium is of use to these people, mood stabilizer)</p> <p>(only had 1st generation for schizophrenia)</p> <p>(before 1st generation we used forms of physical restraint, ice bath, lobotomies, etc.)</p> <p>(people in state hospital and move to return to society but not effective in treating negative symptoms)</p> <p>(side affects were weight gain, slow down their think like wet blanket over their head)</p> <p>(extra)</p>
11:19:02 AM	<p>Slid use</p> <p>(first generation antipsychotic drugs, side affects)</p> <p>(Parkinsonism is stiffness of muscles and minds is slowed down)</p> <p>(Akathisia, restless legs)</p> <p>(dopamine is blocked in the brain)</p> <p>(thought and mood and motor function and 1st generation blocked dopamine)</p> <p>(tried to block dopamine but also block motor coordination, Parkinsonism and Akathisia)</p> <p>(leads to high fever an break down of muscle, Neuroleptic Malignant Syndrome)</p> <p>(taking drug and another to counteract, not good picture)</p> <p>(Tardive Dyskinesia and Dystonia, se it in limbs, trunk of body, unable to swallow)</p> <p>(have film for jury)</p>
11:24:37 AM	Video starts
11:25:32 AM	<p>Video stops</p> <p>(4 percent a year in schizophrenia patients, shows signs of tardive Dyskinesia)</p> <p>(no treatment for this)</p> <p>(2nd generations drugs, different from 1st generation, mechanism of action)</p> <p>(not block all dopamine receptors in brain and result far less likely to develop symptoms and or overlap with other symptoms)</p> <p>(are but at far lower rate, movement with use of 2nd generation)</p> <p>(ability to take these drugs and look normal)</p> <p>(Clozapine, first drug used, side affects, white blood cells wiped out in marrow)</p> <p>(but treated negative symptoms)</p> <p>(yes, weekly blood tests for six months, weekly at first and then six months)</p> <p>(big production to be on this drug)</p> <p>(2nd generation pose similar risk, no)</p> <p>(no, weekly blood monitoring for white blood cell loss)</p> <p>(agranulocytosis, one day have fever and)</p>
11:31:32 AM	EI 3907 - ID

06-0563007

(this is publication, supplement, to Journal of Psychiatry, 1999)
(Practice Guidelines use to advise doctors on best clinical way to treat a patient)
(Steering Committee, editors, and they develop survey and this is sent to group of experts 50 to 100, and they mail back to us)
(we did guidelines tables on what to do based on assembled opinion of these experts)
(these are dated 199 and data collected over a year)
(funded by group of pharmaceutical companies)
(unrestricted educational grants, means, you go to one or more funding sources and say we have idea on educational project and we get money and do the work)
(Eli, no, role in modify in the guideline)
(published as supplement to Journal of Psychiatry)
(Texas Medication Algorithm)

11:37:36 AM Brenner - EI 3907

Allen - objection, 801

Court - EI 3907 is admitted

11:38:39 AM Use of slide, EI 3907

(newer atypical drugs were given highest recommendation for acute schizophrenia)
(pg 16, guideline 5, side affects when on antipsychotic medication)
(as to weight gain, least likely was Ziprasidone, and Risperidone)
(use of Zyprexa since it came out and we knew about weight gain from beginning)
(rated from scale of 1 to 9 and range of 1 to 3 recommended if everything else failed)
(confidence intervals)
(we asked to rate the following tests, reading of question)
(most important was weight monitoring, 96 percent rated this)
(have to monitor weight on people who are

Court - expert, critical to make expert

(term of art but called on people who we believed were experts, listed)

11:45:21 AM Continue with Direct by Mr. Brenner

(SMAC is general blood chemistry screen)

Allen - page

Court - table 38, page 56

(inclusive blood to include blood glucose checkup, yes)
(perform by me for years, good standard care)
(item 39 is real world limitations, reading)
(people who have schizophrenia are hard to get to follow advise)
(obesity has to be monitor)
(diabetes, should be on radar screen)
(and did so in 1996 and 1998)

11:48:34 AM Allen - objection, speculation, hearsay/ rephrase questions

06-0563007

11:48:54 AM (1998 and 1999, yes
Allen - accepted, withdrawal objection

11:49:26 AM Allen - objection, running objection, calling for conjecture/OR
(psychiatrist we survey there was clearly a majority opinion to screen for this)
(page 74, yes
(page 77, yes, weight gain)

11:51:20 AM Allen - do not see it on page 77
Brenner -on page 76
(since the time Zyprexa came on then market)
(aware of weight gain, yes)

11:52:07 AM Allen - objections, hearsay/can rely on hearsay
(as effective as Clozapine but without white blood cell loss but did have weight gain)
(short term and long term)

11:53:11 AM Allen - objection/OR
(weight gain in 1996, yes, health problem with associated risk, lower back pain, heart attacks,
etc.,)
(learned this in medical school)
Allen - may we approach

11:54:26 AM Sidebar beings
11:56:44 AM Sidebar ends
(
Brenner - may we approach

11:57:29 AM Sidebar beings
11:58:36 AM Sidebar ends
(
Allen - may we approach

11:59:09 AM Sidebar beings
12:01:52 PM Sidebar ends
(yes, I have)
(in my practice and at hospital...
Allen - may we approach

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12:03:00 PM Sidebar ends

(yes, patients have develop hyperglycemia, less than one hand worth of fingers)
(yes, an one case of diabetes, on Seroquel)
(peer review journals, clinical trial and review articles)
(medical conferences, doctors learn from each other and from our own experience based on what we see and from product labels)

12:05:03 PM Allen - may we approach

12:05:10 PM Sidebar begins

12:07:16 PM Sidebar ends

Court - 15 minutes

12:07:27 PM Off record

12:28:40 PM On the record

Jury is Preset

Court -

12:28:46 PM Continue with Direct by Mr. Brenner

(package insert is basics outline of key things to know about a drug)
(gives common drug interaction a patient maybe using and list of adverse events)
(they do change over time)
(letters mailed to us and I read them and find out new changes to inserts)
(trade publications)
(use of internet, yes)
(WEB MD, yes)
(PDR, familiar with that yes)
(PDR is not always up today, arrival once a year, Christmas time)
(updates do come)
(2008 PDR has information is prior to 2008 year)

12:31:58 PM Allen - objection, may we approach

12:32:05 PM Sidebar begins

12:32:43 PM Sidebar ends

(medical letters are white papers put together from pharmaceutical companies on experience they have)
(do not know what the regulatory difference is but baffling to practicing physicians, but we want to know about adverse conditions)
(warning section has neuroleptic and most do not ever see case of this)
(Geodon...)

12:35:16 PM Allen - objection

Court - this one I want you to approach

12:35:20 PM Sidebar begins

12:36:25 PM Sidebar ends

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(yes, Geodon, the warning of QTC interval is something measure on electrocardiograph, length of time electro goes through heart)
(nee to watch and it may lead to failure of heart)

12:37:54 PM Allen – objection/ that is exclude. Jury to disregard

(not seen in my practice)
(no, far to much to assimilated and most is preliminary and never will be replicated an need to be compared and must pat peer review)
(Zyprexa is first line antipsychotic)

12:39:23 PM Cross Exam by Mr. Allen

(Geodon, yes)

12:40:09 PM Ex. AK 19- referenced

(no, did not say that, but in report)

12:40:45 PM Brenner – objection, hearsay/OR

(yes)
(need report to refresh memory)

12:41:40 PM Report on screen

(they typed it up for me, Pepper Hamilton)
(and I wanted everything in it)
(more or less 30 hours)

12:43:21 PM Brenner – objection

12:43:27 PM Sidebar begins

12:44:02 PM Sidebar ends

(will not change opinion of this report, I stick by them)
(opinion A, yes, agree with that)
(describe in report, yes)
(number one, page 5, ok)
(do not know how much Eli is involved in)
(medical literature, not sure or how much)
(yes, have read articles written by Eli)
(no, not heard of this)
(no call notes read)
(or sale rep. going to doctor's no)
(pharmaceuticals companies support)
(they have advertisement booth, yes)
(do not see the word rely)
(reading from, no relied on)
(in part it was)
(colleagues, heard that expression, but nothing about ones they hired)
(not aware of that)
(slides show's not familiar with what Eli Lilly does)

06-0563007

12:50:07 PM (no)
(yes)
(no, did not review this in this case)
(in early preparation I saw some training material)
(did not depend on that but also wrote, reading from report)
(varies from physician to physician, yes)
(policy to prevent this, did not know)

12:51:53 PM Ak 1097 – reference

(no, have no idea who Noesges)

12:53:13 PM Brenner – objection/OR

(how would it related to what a doctor was told)
(I know nothing about sales aspect of pharmaceuticals)
(yes, but not know how they operate internally)
(right)
(that is right)
(no)
(no idea what Alaskan doctors knew, not my area of expertise)
(that is true)
(correct)
(context of, do not know what they were told)
(that is correct no idea what they were told)
(that is true, no idea what they told doctor's in Alaska)

12:55:59 PM Ex. Ak 19 - referenced

(no idea who Eski is)
(no, did not know about that)
(no, did not know that)
(no opinion on that)
(sir, I have no opinion on that)
(right, here giving my opinion on what I think, that is right, and this doesn't make me right)
(or other way around)
(without looking, see what you mean)
(no other way to reach opinion needs information and I agree with you)
(informed opinion, based on opinion who is holding it)
(opinion related to information)
(with valid information)
(valid information)
(certain information I do not have expertise)
(informed decision takes valid information)
(clinical may or may not be valid)
(good clinical trials)
(HDHJ study, did not know this)
(no opinion on that trial)
(need valid, accurate an true information)
(600.00 an hour, never met you before)
(deposition taken a year ago)
(few days but not sure of hours, could be 16)
(here Monday in back of courtroom with Mr. Brenner, another 16 hours)

06-0563007
1:06:02 PM

(Ms. Gussack hired me)
(source available to doctors)
(not sure if they use the information or won't not)
(sometimes they might use pharmaceutical information)
(fair and impartial, yes)
(yes)
(good accurate and well verified information)
(yes, to promote benefit and risks)
(companies should understand risk, no)
(wrong to do this, true)
(did not see that, neutralize risk)
(a known risk, yes, wrong to minimize this risk)
(or eliminate the risk)
(would be unfair and deceptive if true risk)
(not sure what drug companies are to do)
(accurate, valid information)
(depending on you to be honest)
(not able to judge all information)
(blood test was annual test that is done by anyone going to doctor but glucose is included question 38,
(Blood chemistry screen, annual routine screening, read the rest)
(SMA screen, correct)
(any of us would get this in annual physical)
(drug based chemistry test an measures 17 to 21 common chemicals, listed)
(a standard test, that is right)
(over stating benefits is wrong too)

1:12:33 PM

Ex. Ak 1169 referenced

(not seen this letter in material I reviewed)
(mechanism of action, do not know what this is, not precisely)
(there are strong theories)
(not sure what that is, yes, the PDR on Zyprexa)
(that is right, not a fact)
(that I what it says)
(that is a theory)
(tardive dyskinesia does occur in Zyprexa patients)
(yes, all carry this risk)
(I do see that and would disagree on my experience)
(FDA, not sure how things get into the package, no opinion)
(no comment on Eski testimony)

1:18:42 PM

(I do not now if it more efficacious than other drugs)
(in the package an theory on how it works, yes)
(Zyprexa has added risk, not sure what you are asking)
(Consensus Statement, ask me, aware of this panel)
(Consensus Panel says weight gain and according to panel diabetes)
(that is one source of information not the only source of information)
(my recommendation to patient to take this drug)
(can give this drug to patient if he is against it)
(Russell Weston not my patient)
(got that video from the Washington Post, never treated this patient)
(schizophrenic patient, did not diagnosis this patient)
(he was severe case)

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06-05630C

(not a lot but there are some who have jobs, family etc.)
(symptoms are positive symptoms maybe like)
(he had sever schizophrenia patient)
(need to look at patient and risk of products, he wasn't bi-polar patient)
(Zyprexa is not for bi-polar depression, several phase of bi-polar, listed)
(for acute bi-polar depression)
(but for bi-polar mania, mixed state, preventive treatment of bi-polar and schizophrenia)
(not for elderly)

1:24:47 PM Brenner - objection

1:24:51 PM Sidebar begins

1:25:11 PM Sidebar ends

(not indicated for agitate in elderly or for Alzheimer or ordinary depression)
(children, need to look at label, not sure of age cut off)
(not for ADHD or hyperactivity)
(not for anxiety)

Court - time is 1:30, how much more

Allen - do have more but good time to stop

Court - end of day

- Admonishment
- Keep open mind

1:29:30 PM

Outside presence of jury

Court - anything to take up

1:29:43 PM Lehner - designation question as to Mr. Campana, intend to ask about P&T committee but not about what it has done

Court - if you start on the P&T the door is swinging

Lehner - how far

Court - need the question

Lehner - what it does, function, and not ask him what it has done or action taken

Allen - no need

Court - want to keep out P&T testimony or what happens in the committee and efficacy of drug

- kept out as much as possible
- hope we can start close to 8:30
- witnesses

Lehner - Dr. Baker and might run video's, Dr. Baker is live

Allen - and I will narrow this done

06-05630CI

Court - still on time for Monday

Lehner - we hope

Court -

1:33:20 PM

Off record

06-05630CI

In the Superior Court at Anchorage Alaska

Media No: 3AN4308-59

Judge: M. Rindner

Date: Tuesday, March 18, 2008

Clerk: M. Borneman

Case No: 3AN-06-05630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial - Day 12

Counsel Present:

Plaintiff: David Suggs, Esq., Scott Allen, Esq., Tommy Fibich, Esq. and Mr. Sniffen, Esq.
Defendant: George Lehner, Esq. John Brenner, Esq., Nina Gussack, Esq., Mr. Jamison, Esq.

Court Orders:

Summary of Proceedings: Eski and Beasley additional designations, state objected, and I will overrule all objections. Lilly had objection to three counter designation, overruled. Overrule state objection to Eski deposition by Lilly.

8:35:55 AM	On the record	<u>Outside Presence of the jury</u>
	Court - list case and parties present	
	- jury being asked to decide what and what they have to decide it with	
	- Motion to Allow Lobbying Efforts of Lilly	
	- Responses filed, counter designation, not to be included in defense playing, played for cross an now need Lilly objections, slowing this whole thing down	
8:37:23 AM	Lehner - Charles Beasley to be played, lengthy, and I you rule on the objections on page three of their memorandum and they objected to six or eight parts of ours	
8:37:56 AM	Allen - not reviewed and will do so tonight	
	Court - thought today I was going to deal with this and bring in jury and state to finish with deposition designation and deal with motions to come	
	- and then Lilly would continue with its case with these depositions	
8:38:56 AM	Allen - willing without looking to withdrawal the objections, will not be obstreperous	
	Court - no, just need a light t so I can read the objections while state plays last video's	
	Allen - but do not want to slow this trial down	
	Lehner - and we are looking at their counter-designation an trying to get objections soon	
	Court - will do Charles Beasley today in Lilly's case	
8:41:11 AM	Allen - lobbying to be addressed, now	
	- opening statement by Lilly, page 132 to page 134 talking about Alaska having no restrictions on Zyprexa	

- March 12, 2008 they talked about restrictions, Dr. Hobson, reading from jury transcript
- Opening the door in openings and on the 12th
- Page 62 to page 68, asking of Dr. Hobson, reading from transcript of the 12th
- State P&T and legislature from keeping this in place
- Effort to stop this and argument was we did nothing to stop them but evidence shows not done due to their action committee, need this evidence to come in

Gussack - highly prejudicial and not probative

- they seek to enter lobbying efforts from 2003/2004 in which Lilly another pharmaceutical companies, etc., all were interested in having legislature not have restraints on these drugs, all
- Dr. Hobson not lobbied by Lilly as to mental health medicine nor the state with respect to Zyprexa

Court - why is 2003 and 2004 remote, in the middle of the, Prozac lost

Gussack - 2000

Court - this is big drug for Eli Lilly and trying to down play warning on Zyprexa that would give some kind of additional warnings that would affect sales of this drug

- Why if in this period, why remote

Gussack - effects of determinations of P&T committee or Dr. Hobson

Court - not allowed evidence to come in, what we are talking about, could this be given to jury

Gussack - our ability to challenge his conduct with portions of his testimony in court here

Court - P&T committee, reading from document

- all explored an there was committed in the state to look at this and they did not

Gussack - not to look at and impose restrictions but question to Dr. Hobson was if he gave his views on Zyprexa

- Dr. Campana's testimony brought up on screen, reading
- Page 233, line 4 and 5, reading
- Page 234, reading
- Political pressure came from psychiatrist
- We asked about Dr. Hobson personal opinion

Court - what would you have the do given my rulings

- ask him if he was lobbied in 2002, violation of rule

Gussack - they are not shy to press the rulings and could of asked Dr. Hobson this question, this was the time to ask this

- no evidence here that Dr. Hobson was lobbied
- protected lobbying efforts

8:54:41 AM

Allen - cited correct testimony but the fact is the evidence hadn't come in an the Eski exhibits will show part of the lobbying is what she discussed

- hands to judge Eski ex. 3, 5 and 6
- lobbying efforts is to go to doctors and prepare them letters to send to relevant P&T committed to keep this from happening
- she said police involved, they do this , part of lobbying - Partners in Crisis

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- and National Mental Health, this is part of their plan, look at ex. 5
- we depose Ms. Eski and she was recruiting doctors to put their signature on but that is the lobbying efforts

8:57:29 AM

Court – how does this relate to the warnings

Allen – as to warning and the risk benefit analysis, unfair, deceptive trade practices

Court – lobbying violation of UTPA, then we have issues

Allen – no

Court – relates to warning, how

- hit home run and jury finds for you, what are violation o UTPA

Allen – label, failure to warning o each

Court – each marketing effort a penalty

Allen – that is for Mr. Steel

- they imply the drug is safe and efficacious
- P&T could of limit the drug in this state
- Risk benefit and they say if P&T saw this they could of restricted the drug, facts do not show that
- P&T and Medicaid did not have full risk of this drug and had they had this information, elevated blood glucose, diabetes, restrictions on the drug in Japan, evidence from HGF study on glucose, evidence from 1999 of animals studies etc., and conclude reasonable association with their product and hyperglycemia and if P&T had this information they would of acted
- Did not act as they did not have all the evidence but also they engaged in efforts to keep them from reviewing at all – carve out

Court - thought there wasn't a carve out

Allen – not a full review of all, different review and Campana will testify that one reason was they were lobbied

- must allow me to rebut this
- rebuttal of their evidence and argument

9:03:27 AM

Court – rebuttal and trying to figure out some type of testimony on not being carved out or what the P&T committee limited to, all drug companies

Allen – if we made efforts large and with all drug companies, less admissible it becomes

- 70 percent of Medicaid pays from this drug – Zyprexa
- 4.8 billion in annual sales not worried about some other pill
- speaks to admissibility, court was right in the analysis and the rulings
- 12 minutes of testimony to rebut this

9:05:27 AM

Gussack – state charged with health and well being of citizen, open access refers to have all mental health medication available

- nothing done in 2003 and 2004, during time of lobbying efforts, see minutes of P&T committee from 2004 – on the screen

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9:06:52 AM Court – under advisement, can play before trial is over
 - concerns is I do not want a mini trial on lobbying an for what

9:07:24 AM Gussack - that is right as we have to have witnesses to explain open access
 - return to the question, has nothing to do with adequacy of warning

9:07:56 AM Court – if irrelevant it was irrelevant when you asked about P&T committee question
 - safety and efficacy, I wrote note

9:08:24 AM Gussack - they injected motive and our right to counter this

Court - grabbing with fairness of trial

Allen – do not mini trial, but they can talk about it in opening and on the 12th and then again 13th, but keep our evidence out
 - 12 minutes of rebuttal, I have right to do so

Court – need time to think, not allow before you rest

Allen – due process and fundamental fairness, they opened the door
 - I have only 12 minutes of testimony to rebut this

Court - question of do I interject the side issue into this trial an would confuses the jury

Allen – they heard no restrictions, one way street of evidence

9:11:09 AM Court – under advisement
 - jury to decide what, do not leave case at end of the day leaving this for jury number two
 - how do we see this jury deciding this case

Ed Sniffen - jury to decide evidence supports violations on UTPA and penalty and number of violations

Court – they have to tell me the violations from this jury
 - and how did they violate the UPTA, product labels? Going to doctors? Or what
 - could wait for jury number two or for me to say how many labels was there, each label or what
 - every time a prescription is written there is a label, so is it for each label or each doctor
 - they could be thinking the lobbying was violation

9:15:05 AM Sniffen – do not burden jury as we think judges responsibility, jury to hear evidence about the violations is and special verdict form will instruct them on failure of warning in violation of UTPA
 - and then we will present evidence on every prescription

9:16:12 AM Gussack – state and Lilly agree penalties is for the court to follow this jury deliberations and that hearing will require evidence not yet developed and might be the data base not yet examined by Lilly

9:16:48 AM Court – can figure out range of violations with help of case law on amount of each violations
 - but if I do not know the violation, how can I or who is to decide violation of UTPA
 - state is saying product label is violation but doesn't the jury decide or someone
 - call notes, advertising, they may think this is the violation
 - need to know actual violation to rule

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Sniffen – something for the court not for jury, jury can decide if the evidence satisfies the UTPA
- Anchorage Nissan case, but they sell pills, each is violation

Court – if they decide the prescription is the violation or if they say UTPA I can figure out the violate but not sure I can

Sniffen – we say you can
- Look at out statute AS5. 51(b)
- equitable powers of the court in separate hearing
- not for jury

Court – and as I have UTPA action on your own, still need to know what the violation is from this jury
- would present evidence all over again on violation

Sniffen – once jury makes findings on warning it will flow logical

Court – warning where, not just product label but also warnings on the calls, marketing, doctors, that warning?

Sniffen – if we come forward with lack of information as we allege

Court - state going to ask those findings are UTPA violations

Sniffen - all conduct is violation as are prescriptions
- violations when made representation to doctors and maybe for each patient

Court - getting into phase two then

Sniffen – just have to prove commerce to mislead on this product

Court - but penalty for each violation, need to know how many violations there were

9:25:13 AM Sniffen - for the court later not for jury
- not for this phase of trial
- second phase is actual damages, obtainable loss due to his conduct

Court - if they say they violated but I do not know the behavior, what is phase two going to decide

9:26:21 AM Steele – three parts to figure this out
- 1, has to be a decision if practice is unfair or deceptive
- 2nd, have to know what triggering event and what is the number of triggering events
- 3, what is the fine

Court – triggering in event, different term

Steele - court decides triggering event, question of law
- need to look at commercial endeavor

Court – answer own questions, telling me triggering event

Steel - I will
- practice unfair and deceptive, nature of commercial transaction we are involved in

- case is clear the judge decides the triggering event, debt letter to consumer
- unfair is the lie in the form letter, jury decides this is the letter and they ask if it was a lie when the letter was written or the label written
 - lying on weight gain, diabetes
 - we are asking, with respect to sales and marketing, was Lilly guilty of unfair practice on how it sold and marketing Zyprexa
 - every single year and jury can say yes, unfair selling in 1996, 1997, 1998, 1999 and 2000
 - next questions is for the court to decide triggering event
 - commercial transaction is for paying for prescriptions, selling in unfair ways, the triggering event
 - every letter is violation

Court – it because the letter is sent out

- need to identify the triggering event from this jury
- they might decide all was from sales and marketing in violation of UTPA or they can decide something else, but not leave for phase to on the triggering event

9:34:12 AM Steele – scheme like this the only thing that can be proved is deceptive in sales and marketing

- deficient in failure to warn
- every UTPA violation and failure to warn focuses on conduct of defendant

Court – violation of the Act, some things did and some did not

- each act is violation or grouped by physicians or each prescription

9:36:08 AM Steele – characterize in categories as to labels, marketing to physicians or

- labeling, PDR, direct marketing conduct of drug reps, information they put out, groups like this would work
- we think every prescription

9:37:26 AM Lehner – question for jury is was the labeling warning inadequate and if so at what time

- ex caption ruling as to UTPA not there
- direct marketing to physicians, depends on proof

Court – proof by Lilly to control the weight gain, hyperglycemia, etc. information and done in Alaska and efforts made to neutralize this information

- is that a violation to, state says yes

Lehner – encompassed in warning and we argue any acts by Eski are covered by dismissed portion of the claim

Court – no, exclude that portion from her that did this

9:40:08 AM Lehner – if other acts is there proof adequate to be given to jury

Court – special interrogatory

Lehner – was labeling adequate or inadequate

Court - special interrogatory on label, and deceptive each year and keep marketing from the jury

9:41:45 AM Sniffen – we will propose a special verdict form as they will

- separate proceeding to determine number of violations, not for another trial but not in this case

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Court – see if phase to is even needed
Sniffen – to include sale of Zyprexa by year
Court – want jury to get information for them to decide this

9:43:20 AM Sniffen – will relate to evidence put on
Steele – not failure to label but failure to warn
Court - and the UTPA case an this is my concern
- here we have had a lot of stuff other than just labels
- special verdict form for the jury to answer an tell us how it was violated or we have to put this evidence on for the 2nd jury

9:45:07 AM Allen - coming in a minute
Court – start getting me jury instructions and special verdict forms

9:45:51 AM Off record
9:54:05 AM On the record Jury is Present
Court – deposition of playing
Allen – call oral video Daivd Noesges

9:54:46 AM Video deposition of David Noesges
10:07:33 AM End video deposition
Allen - exhibit to jury and the court: Ak 1901,
Court – 1901 consistent with prior rulings admitted
Allen – Ak10092
Court – subject to prior rulings, Ak10092 admitted
Allen – AK10093/ subject to prior rulings, admitted
Allen – AK10097/admitted subject to prior rulings.....reserved for later decision

10:09:19 AM Lehner – not raised in this deposition
Allen – goes to marketing and sales, he was head of sales
Court - need foundations, etc.,
Allen – discussed in Eski
Court – approach

10:09:57 AM Sidebar begins
10:12:03 AM Sidebar ends
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Court - will reserve on AK10097
Allen - Ak1970/subject to prior rulings, admitted
- Ak1962, publish to jury
- Michael Bandick to be called to stand, video deposition

10:14:37 AM
10:15:02 AM
10:29:46 AM
Video deposition of Michael Bandick
Video deposition ends
Allen - concludes
Lehner - and supplements to be played
Court - you may
Video deposition of Dr. Michael Bandick, plays, defense showing
Video ends
Lehner - concludes our portion
Allen - AK2133, subject to previous rulings, admitted
- Ak 10003, admitted
- Ak 2368, admitted
- Ak 320, admitted
- Ak 1111, admitted and may be published
- Will publish just admitted exhibits 2133, 10003, 2368, 320..
Lehner - side
10:39:36 AM
10:40:44 AM
Sidebar begins
Sidebar ends
Court - 2133, 100003, 2368 maybe published
Allen - and 320
Court - may publish 320, keep track
- Beasley found?
Lehner - not arrived yet
Allen - call by oral video Dr. Gary Tollefson, 20 min.
10:42:23 AM
11:03:07 AM
Gary Dennis Tollefson, video deposition begins
Video ends
Allen - we offer AK1169, admitted subject to rulings
- Ak6100, admitted subject to prior ruling
- May we publish to jury
Court - you may and what is left
Allen - Ms. Torres and Dr. Breier and that will conclude our witness

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	Court – will break	
	- admonishment to jury	
11:05:37 AM		<u>Outside presence of Jury</u>
	Court – gone over counter designation to Lily designation, to be played after Eli play Tollefson	
	- Wojcieszek, objection to three and are all overruled	
	- Counter-designation, no Lilly response received	
	- Waiting on Beasley volume two	
	Lehner – will not get to that part of Beasley today	
	Court – will se	
	Allen – document to be admitted on Bandick, up to court	
	Court – in recess	
11:12:59 AM	Off record	
11:28:40 AM	On the record	<u>jury is present</u>
	Court –	
	Allen - calling by oral deposition Ms. Denise Torres	
11:29:38 AM	Mary Beth Rivers, sworn as deposition reader	
11:30:20 AM		
11:30:23 AM	Video deposition of Ms. Denise Torres, video starts	
11:40:01 AM	Video ends and Mr. Allen and Mary Beth are reading the questions and answers	
11:41:05 AM	Section 33 begin reading	
11:46:24 AM	Conclude reading and the video will resume	
11:46:45 AM	Video resumes, Denise Torres	
11:49:05 AM	Ends video portion	
	Allen – reading of one section, I can do it from page 136	
11:49:46 AM	Ends offer of Ms. Torres	
11:49:54 AM	Lehner – brief clip to be played by us	
11:49:58 AM	Video starts of Ms. Torres	
11:57:31 AM	Ends	
	Allen – offers AK8564, admitted with objections being preserved	
	- Ak 10096, admitted with objections being preserved	
	- Ak 9624, admitted with objection being preserved	
	- Ak 1145 to be published later	
	- Ak 9054, admitted with objections being preserved	
	- Ak 3924, admitted with objections being preserved	
	- AK 946, admitted with objections being preserved	
	Court – list may publish all to include 1145	

Allen - will now call Allen Breier, our last witness to be called

12:03:29 PM

Sidebar begins

12:04:12 PM

Sidebar ends

12:05:03 PM

Video deposition of Dr. Allen Breier begins

12:51:54 PM

Ends video deposition

Allen - have documents

Lehner - and we have additional portions of Dr. Brier to play

12:52:13 PM

Video deposition of Dr. Breier continues, defense

1:11:02 PM

Video ends

Lehner - concludes

Allan - Ak 10017 to be published

- no more witnesses to be called, we rest

Court - will let the jury retire for the day

- be back at 9am
- admonishment

1:13:43 PM

Outside presence of jury

Court - looked at Eski and Beasley additional designation and the state objected and will over rule all objections

Lilly had objection to three counter designation, overruled

- Also overrule state objection to Eski deposition by Lilly
- Eski and Wojcieszek
- Ak10097 is hanging, Eski 9

Allen - numerous document like that

Court - take up in the morning

- no application until exhibits are admitted
- show and deal with this in the morning
- and application in the morning as well

1:16:57 PM

Allen - will do as we have fair amount

- want all PDR's and the call notes that are in the data base, not just Eski's

Court - go over with counsel and get as may agreed to as possible and then take up the ones we have issues with

Lehner - send us document numbers

Allen - get the document to you

- it's the call notes

Fibich - rebuttal witness to be called, time they will be done

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Gussack - we are currently engaged in analysis of witnesses to be called, will provide when we have

Court - tomorrow

Allen - we know

Gussack - and Beasley by deposition

Court - how long is the case, Friday or Tuesday

Gussack - hope for Monday or Tuesday

Court - not holding you to this but they have rebuttal witnesses to be brought to town, if needed

1:21:23 PM Lehner - conference for jury questions

Court - can do after hours, if needed

- or spend day doing this, send home the jury
- full day for closing
- sooner I get additional jury instructions and FDA regulation, if wanted
- can go through it this weekend if I have it

1:24:17 PM Allen - to be done

Court - normal time an take up the matters

1:24:41 PM Off record

In the Superior Court at Anchorage Alaska

Media No: 3AN4308-58

Judge: M. Rindner

Date: Monday, March 17, 2008

Clerk: M. Borneman

Case No: 3AN06-05630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial Day II

Counsel Present:

Plaintiff: Scott Allen, Esq., David Suggs, Esq., Tommy Fibich, Esq. and Mr. Sniffen

Defendant: George Lehner, Esq., Nina Gussack, Esq., John Brenner, Esq., Mr. Jamison, Esq., and Mr. Kantra, Esq.

Court Orders:

Summary of Proceedings: Trial continues to March 18, 2008 at 8:30.

8:25:39 AM

On the record

outside presence of jury

Court – list case and parties present

- Lilly witness out of order and then deposition testimony

Allen – yes, plus additional video

- will meet and get exhibits straight after court
- Denise Torres deposition, lines given, move to reconsider
- Ability to play Joey Eski deposition am the restriction on Zyprexa

Court – Lilly file response on civil penalties, need something quickly from the state

Fibich – this morning

Court – Lilly objection to the Breier deposition

Lehner – they add 123 minutes

Court – three counter designation and two objections

- page 136 of Torres

Lehner – goes to what you ruled on before

Court – off label use can be used but not promoted and this says percentage of off label use nothing about Lilly promoting off label, but merely has percentage

Lehner – true statement

Court – testimony as to benefit and risks and benefits depends on these of the drug compared to risk

- different than bi-polar and schizophrenia, relevant

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Lehner - no claim this has to do with the benefits of this product

Court - assess the warning in context of benefit and use of

Lehner - no, not asked that but if the label warns on the risk

Court - will allow the jury to be read Torres' page 136, line 6 through 115
- motion to go with the memorandum on lobbying efforts

Fibich - copy of the brief on the civil penalties
- exhibits to publish

Court - will advise jury of calendar and what exhibits have been admitted
- will bring in jury when they are ready
- Mr. Inzucchi is out of order, defense witness

8:34:01 AM

Off record

8:43:11 AM

On the record

Jury is present

Court - have defense witness to take out of order and then resume and end with plaintiff case
- at conclusion of day, Friday, I admitted exhibits and we will now publish

Fibich Ak 12215, 8905, 4517, 1213, 10140, 4532, 5522, 10142, 10141, 10008

Court - Dr. Kinon's exhibits, may publish

Kantra -

8:45:38 AM

Silvio Inzucchi, sworn

Direct Exam by Mr. Kantra

(Strafford, Connecticut)
(I'm an endocrinologist)
(disease of metabolism, blood)
(we treat diabetes)
(several thousand diabetes patients over the years)
(many have mental disorders, yes)
(schizophrenia patient, 20 to 30 percent)
(I do a lot of teaching and some research about 50 percent of time is with patients)
(pills or agents)
(Yale School of Medicine, my employer)
(Director of Fellowship Program)
(heart, liver, kidney, etc.)
(thyroid, diabetes, anything dealing with hormonal)
(Yale Diabetes Center, yes)
(get patients from primary care physicians, referrals)
(type one and type two)
(some have bi-polar and schizophrenia, most challenging ones)
(we perform consultation)
(Yale psychiatric Center, do consultation for diabetes and other hormonal condition)
(Alaska Psychiatric Institute is analogous to Connecticut Mental Health Center)
(degree at Harvard Medical School, 1981 through 1985)

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(Harvard to Yale)
(board certified in endocrinology and metabolism)
(American Diabetes Association, yes, member for couple of years)
(national committee that meets twice annual to set agenda for next year on how to manage diabetes)
(sure, standard of care incorporate diagnosis of diabetes, who to screen and then how to treat and which medication to use)
(editorial board for Diabetes Care, Assistant Attorney General journal)
(one is Diabetes, scientific journal but the one that focus humans is Diabetes Care, leading journal for diabetes)
(been publish, I have and would say 200)
(text books, written them, yes)
(written two major chapters over the last couple of years)
(how diabetes is express in different populations, an interest of mine)
(have testified in court before, twice)
(two cases)
(first one over ten years ago)
(am compensated for time, 450 an hour)

8:57:22 AM Kantra – offer as expert in develop, diagnosis, treatment and complication of diabetes, etc.,

8:57:42 AM Suggs – voir dire of witness

(not an epidemiologist, no.. not trained but do use this)
(do not prescribe Zyprexa)
(do have patients on Zyprexa, yes)
(yes, but not everyone on Zyprexa has diabetes)
(prescription of psychiatric medication is field unto itself and patients with mental illness is hard to get on right medication an someone referred to me with diabetes, I do not change the mental medication)
(never taken anyone off Zyprexa)

8:59:47 AM Court – voir dire, not cross

(that is correct)
(no original research on Zyprexa and association of Zyprexa, no)
(do not recall but have written on screen of diabetes and discussed in terms of metabolic diseases)
(did prepare a report for this case, and deposited)

9:01:14 AM Kantra – objection/save for cross

9:01:26 AM Court – will recognize Dr. Inzucchi as expert for develop, treatment, and complication of diabetes, etc.,

9:01:50 AM Suggs – objection for causality as it relates

Court – will wait to hear questions

9:02:08 AM Direct Exam continues

(association of Zyprexa and diabetes)
(did prepare a slide)

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9:02:38 AM

Slide on screen

(Zyprexa does not cause type 2 diabetes because Zyprexa does not affect the body's ability to make or use insulin)
(as to glucose matters, yes)
(hyperglycemia is term to say high blood glucose)
(no)
(70 to 100 is normal range of blood glucose, at fasting)
(diabetes is 126)
(gray zone from 100 to 126)
(normal situation at meal times blood sugar can climb 20 to 40 points an increase in blood glucose by end of meal but in diabetes the blood sugar stays high and doesn't come down)
(normal fluctuation in all of us)

Court - fasting blood glucose hyperglycemic
- questions

(yes, pre-diabetes, the gray zone)
(depends on what time of day the measurement has been taken)
(lot of people can get above 126)
(fasting state of after eating)
(diabetes, not wrong to say hyperglycemia but measure on two occasions)

9:08:25 AM

Continue with Direct by Mr. Kantra

(yes, random blood glucose blood test)
(can use either random or fasting)
(threshold point is higher when measure random)
(cutoff is 200)
(insulin is a hormone and insulin has to assert action in the cells of the body and the way the body response to insulin is insulin sensitive)
(insulin sensitive is lessen as we age, doesn't work as well as we age)
(cells of body do not response to hormonal signal)

9:11:28 AM

Reference TG15

Court - refers to what

Kantra - internal reference point for us

(glucose is main energy source for the body an found in food, stages)
(we eat the bred and goes to the stomach and acid chops up carbohydrates so it can be absorb, sugar)
(blood carries this energy to the other parts of the body)
(blood is stored in the liver)
(liver is like sponge and we eat more glucose than we need and the liver holds this an releases in small amounts throughout the day)
(sugar is use by body as fuel and the brain, heart has to absorb this glucose to survive)
(blood sugar regulated by the pancreas)
(pancreas is production of stomach enzymes)
(pancreases releases insulin and signal is the glucose)
(pancreas measures the blood glucose and then tones to normal range)
(insulin acts as a key to allowing sugar to enter the cells in your body, binds to insulin receptor,

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nothing else)
(if sugar doesn't enter it build up in the blood and sugar won't enter the cell, no energy and the cells begins to be dysfunctional)
(insulin resistance, cells require more insulin to allow sugar to enter)
(this is fasting state)
(after we eat the sugar goes up and insulin is produce to compensate)
(in insulin resistance patient, more insulin is necessary to keep blood sugar in the normal range)
(after we eat sugar levels goes up as does insulin and then blood sugar comes down as does insulin)
(diabetes patient, not as much insulin comes from pancreas, type one has no insulin, immune destruction of beta cells)
(have to have insulin an need to take insulin injection)
(but not what we see in type two diabetes)
(type two there is insulin but less coming from pancreas)
(and without enough insulin the blood sugar levels remain high)
(pancreas is unable to produce enough insulin)
(pancreas unable to compensate)
(diabetes is increasing in the USA, last count had 20 million patients with diabetes)
(not actually diagnosed, that is about 1/3 of the 20 million)
(silent disease as you do not have symptoms, increase urination and thirst is early sign)
(126 to 150 range is unable to be felt)
(same as for high blood pressure)
(England study taught us y tie patient is diagnosis, could be ten years)
(diabetes can be mild in some and might not progress but normal to progress)
(takes five to ten years to develop diabetes)

9:30:07 AM TG 7 - slide on screen, How Diabetes Develops

(describing/defining screen)
(take weight of and exercise)
(pancreas compensate by putting out insulin)
(resistance getting worse and insulin getting higher but no diabetes)
(pancreas stops producing insulin, do not know why)
(risk factor is a characteristic of patient that increase risk of develop disease down the road)
(risk factor is family history, weight, etc but not cause of)

9:34:38 AM referenceTG3 on screen

(overweight and obesity is risk factor for diabetes, as long as I can remember)
(family history, estimated if you have a parent your risk is 25 and two parents with diabetes is 50 percent)
(Ethnicity, yes, Hispanic, African, and natives are at risk for diabetes)
(do not agree with that, Wirshing opinion, risk in patient with schizophrenia have increased risk of diabetes)
(the risk is patients with sever mental illness are not able to comply with normal health lifestyle, etc.)
(obesity is high in this population, the risk)
(stress and diabetes is a factor, conjecture on my part)
(package labels for current antipsychotic and is warned about these types of patients)
(I think so, ability to take part in healthy lifestyle, etc., an stress is greater in these people)
(age is factor and we gain weight as we grow older)
(risk factor is accumulative family, weight, and history but doesn't mean you will get diabetes)
(10 to 15 percent of patient population have no signs of insulin resistance, beta cell deficiency)

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(do agree Zyprexa cause weight gain but not diabetes
(weight gain is only a risk factor, insulin resistance)
(2/3 of American are overweight and only seven percent have diabetes)
(have review all three of those studies)
(blood glucose increase in Zyprexa patients but compared to other medications, 2nd generation,
no chances)
(blood glucose was 3 or 4 mg increase)
(different from developing diabetes)
(5,000 patient with about 20 studies, weight gain was cause treatment)
(yes, purpose of study, no difference, like to get diabetes across treatment form)
(CATTE study was long term and have 1500 patients)
(no difference in the groups taking Zyprexa or other medications, same rate of diabetes)
(glucose gone up)
(all three studies say no)
(diabetes is serious disease)
(has to do with how sever the diabetes is, 127 is not as pre-deposed as someone with 300 or 400
(but also hypertension, risk is compounded)
(not able to control diabetes if unable to control mental illness)
(same for diet, exercise, not possible for someone in psychiatric crisis to treat diabetes)
(gold standard of medical research)
(accepted way to do medical research that leads to changes in practice)
(mechanistic study are smaller studies and asking very precise questions)
(Clamp studies, to see if drugs cause diabetes)

9:53:25 AM

Clamp test on screen

(how well a person can make insulin, Hyperglycemic clamp, High blood sugar test)
(and euglycemic clamp, asking how well a person response to insulin)
(purpose is to find out how much insulin a person can make when stimulated by high glucose
level)
(just fasting patient and observance)
(give lots of sugar an clamp are high range, range of diabetes, yes)
(and normal the insulin would go up)
(if pancreas is not healthy we see poor insulin response)
(not impair by Zyprexa, hyperglycemic clamp is very important study)
(insulin sensitivity test, give insulin to see how effective this is)
(and give glucose to build back to baseline)
(give insulin and the levels go way up but glucose would go down, not good)
(so we give them glucose and this amount is measured and can determine how much glucose t to
reflect how sensitive to insulin they were)
(if drug cause insulin resistance would be small amounts of glucose to bring back to normal)
(Lilly did do this study and found to have no change)
(normal human volunteer study and no affect of drug as to Hyperglycemic test was concerned)
(correct)
(huge limitations, not equivalent as you have to adjust for differences)
(I was confuse as some studies said all people taken the drugs were at risk but we knew this
amount mental patients)
(Olanzapine results are out there and other studies showed no results)
(more I read the more confused I got)

10:05:32 AM

Ak10140 - referenced, page six

(Wishing is expert for the state, yes)

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(200 patient study, with 30 patients on Zyprexa, and this is over two years)
 (conclusion was no statistical difference found between the groups
 (cutoff of 200mg, chart review study, no clinically significance difference in blood glucose, this study)
 (case reports are more notable when the effect is rare)
 (but when drug is associated with diabetes, its hard to say cause and effect)
 (problem with reports do not say patient taking Zyprexa but did not develop diabetes)
 (overall conclusion and Zyprexa causing diabetes, no proof it cause diabetes)
 (been on consensus statement is group of physicians come together to listen to evidence when there is controversy and then make suggests on what needs to be done)
 (we need to interpret and apply)
 (not the same as standard of care)

10:13:41 AM El 2027 – reference on the screen
 (drug treatment is insignificant to diabetes risk)
 (do read)

10:14:50 AM Suggs – objection
 Court – approach

10:14:59 AM Sidebar begins
 10:15:33 AM Sidebar ends
 (yes, have read medical labels)

10:16:06 AM Suggs – objections/ general question
 (yes, I do read labels an adverse section is one I go to early one, do no harm to patient)
 (every medication has risk and benefit)
 (purpose of is to describe risk benefit to prescriber)
 (look at down side and the risk)
 (I like to read the label itself but also in the PDR that is mailed to every physician)
 (and able to down load this information)
 (have review the Zyprexa label and the original 1996 label, yes)

10:18:51 AM Suggs – objection, doesn't prescribe
 Kantra – argument for
 Court –

10:19:14 AM Sidebar begins
 10:20:23 AM Sidebar ends

10:20:35 AM El2954 – referenced
 (from 1996 label, did review this label for this case)
 (page 16 of this exhibit, yes, weight gain reviewed)

10:21:37 AM Suggs – objection, speculation/OR
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(made clinicians aware of the weight gain)
(7 percent is significant)
(someone who read this label was informed of the side affect)
(we know about connection of weight gain and diabetes, we all know that)
(yes, the warning on diabetes had nothing to do with causation, but higher risk group, mental patients)
(rank, do not believe so)
(overall opinion, no evidence form studies I looked at that Zyprexa cause diabetes, the evidence is not there)
(not from clinically trials, meachistic study and the observations studies are all over the map)

Court - first break

10:25:13 AM

Of record

10:25:42 AM

On the record

outside presence

Court - review Lilly objection to few additional portions of the Brier deposition and I will OR the objections to the depositions designations of the state and as to counter-designation, don't need to be included in state but can be done in cross or defense case in chief

10:26:39 AM

Off record

10:49:56 AM

On the record

Jury is Present

Court -

10:50:02 AM

Cross Exam by Mr. Suggs

(do not prescribe Zyprexa)
(need to weight both risk and benefits, yes)

10:50:28 AM

Kantra - objection

(weight gain is in the 2007 label, yes)
(do not recall the number)
(5.4 kg, yes, works out to 11.8 pounds, about that)
(Lilly trial showed 24 pounds, need to look at specific trial)
(have to look at study to recall that number, 24 pounds)
(all side affects have to be looked at)
(doctor has to have all information, risk and befits)
(need to understand context of that, totality of specific drug)
(that was a single clinical trial and doctor needs to know overall)
(need to know total experience with Zyprexa and weight gain but no reason to dispute this)
(Zyprexa does cause weight gain)
(depends on baseline weight)
(every pounds gives 4 percent increase risk to diabetes, comes from general studies)
(schizophrenia patients tend to be overweight)
(24 pounds would increase diabetes, risk of diabetes is apparent)
(do not disagree with those figures)
(need to know totality of that evidence)
(depends on overall experience of that drug not individual study)

06-0563007

(Cavazzoni presented at the conference, yes)
(CATTE study published in 2005)
(hypertension and end to have high blood glucose and over overweight)
(elevated triglycerides, HDL but not total cholesterol)
(that is correct)
(diabetes is different in Japan)
(aware of more stringent labeling in Japan)
(yes, based on long term studies of type two diabetes)
(as general rule, it can occur within weeks depending on drug)
(do not consult for Lilly, providing expert testimony)
(gave deposition and provided report, not sure of hours but several dozen at 450.00 an hour)
(not sure o how many hours)
(I'm six months behind in invoices)
(bi-polar disorder is not on here nor is schizophrenia)
(have to have lean individuals who have diabetes)
(that group study long enough to see if it predispose them to diabetes)
(not sure if studies looked at control weight, have to say no)
(all schizophrenics, ask again, all patients who had risk should be assessed to include blood monitoring)
(package insert going back to 1996 says weight gain)
(did not warn on monitoring blood glucose, should be)
(not aware of other labels but risk of diabetes is listed on all labels)
(Zyprexa label, yes)
(do not know one way or the other)

Court - in the warning section

11:10:24 AM (updated earlier than 2007, think 2003)
(weight gain in 2003 discussed glucose issues an weight gain into the precaution occurred in 2007)

11:11:22 AM EL 2005 - ID

(excerpt from my repot, yes)
(beta cell in the pancreas, yes)
(do not agree with that)
(not conclusively show)
(yes, in adverse section, yes)
(CFR regulations, no)
(not aware of that, no)
(think I said should be demonstrated)

11:15:04 AM Kantra - objection/sustained

(did use the word cause, yes)
(but not sure what the law requires on causality)
(some studies have shown an association, late 1990's and early 2000)

11:16:31 AM Kantra - objection/OR

(serious hazard, diabetes is)
(studies referred to are isolated studies and assume that the purpose of that description is to look at totality of evidence and is it reasonable)

(scientific literature demonstrate also no associations)
(found by Lilly, Margaret Sowell is employee of Lilly)
(at least one or two were not)

11:18:57 AM Ak10171 - ID

(hypoglycemic clamp assessment,)

11:20:15 AM AK10172 - ID

(Evaluation of Insulin Sensitivity in Healthy Volunteers, etc., correct)
(post hoc analysis, yes)
(depends on what you look at)

11:22:02 AM AK10174 - ID

(

11:23:17 AM Ader study on the screen for jury view

AK10173 - ID metabolic Dysregulation with Atypical Antipsychotic Occurs in Absences

(hepatic insulin is measure muscle study)
(induce means to result in or lead to or cause)
(diabetogenic , to led to diabetes)
(not human study but animal)

11:27:05 AM Ak10175 - ID

(it did and I disagree with the data)
(in rats)
(phrase means insulin sensitivity and they claim these two drugs acutely impair that and lead to insulin resistance, a worse affect)
(in this rat model, correct)
(dose dependant manner, higher the dose grater affect, not necessarily, depends what your looking at)
(incorrect)
(ketoacidosis is complication of type one diabetes and suggest hormone destruction of beta cells, sever insulin deficiency)
(this one done on humans)

11:33:39 AM Ak 10176 - ID

(not endocrinology journal but have read this article)
(learned o publication and looked it up on line)
(not sure who provided to me)
(Mr. Kantra might of shown to me, do not recall)
(consequently means a consequence, it does say that)
(not linked but association, but association is not valid or casual)
(difference with Dr. Sowell clamp study)
(standard doses, yes)
(that is incorrect, I disagree with those findings)
(I see that, and *in vivo* means in living organisms)

11:38:11 AM

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(weight gain but modest)
(yes, see that language and conclusions are invalid)
(controversy as to data)
(peer review psychiatric journal)
(major methodological flaws and are invalid)
(just pointing out an exclusion of one data point from the Sowell study)
(it is risk factor for diabetes, an that means increase in that population, causal)
(not accurate statement, no)

11:49:16 AM Reference Lipid Management Article, on screen

(publish in 2003)
(not my quote and this article is about lipid, type of fat, and lipid fast in the blood stream)
(correct)
(obesity is clearly risk factor for diabetes, yes)
(risk factor, of course)
(cause is inaccurate)
(I may have and will not clarify, not accept risk factor)
(metabolic syndrome is risk factor)
(yes, am aware of such data, look at CATTE study, this is drug associated with weight gain but did not see diabetes)
(question was about diabetes and Olanzapine and diabetes)
(Olanzapine does cause weight gain)

11:58:49 AM Ak 6128 - referenced

(agree with Dr. Beasley, needs to be looked at)

12:01:07 PM AK 1453 - referenced

(internal Lilly document, no)
(did not participate in that meeting)
(not sure where I recall, one of the lawyers, maybe)
(do not recall seeing any documents)
(I submitted opinion on public information, yes)
(do not know when that started)
(not sure of involvement in Zyprexa)
(no access to internal documents)
(animals on fixed diets, cant recall if that was amongst them)
(not sure what kind of animals used, do not recall that specific study)
(do not think it says that, these are estimates, not aware of Dr. Beasley testimony)
(first time I've seen this calculation)
(first would say 90 pound of weight gain is a lot, not sole from the drug)
(more accurate to determine average not the extreme)
(not familiar with marketing strategy)
(90 pounds of drug induce weight, these are outliers, taken exception to use of drug induced)
(this is weight gain over time and it over all life time of gain this weight, not sure of short term, beta cells may accommodate)
(disagree as we do not now the answer and as endocrinologist its had to know if more rapid weight gain is more detrimental as oppose to long term weight Defendant Absent, In Custody)
}
Court -

06-0563001

12:13:36 PM	Off record	
12:34:36 PM	On the record	<u>Jury is Present</u>
	Court -	
12:34:42 PM	Continue with Cross by Mr. Suggs	
	(genetic factors fro diabetes)	
	(and if they have two factors increased for diabetes)	
	(increases risk)	
12:35:52 PM	AK 4361 - ID	
12:36:46 PM	Sidebar beings	
12:37:20 PM	Sidebar ends	
	(Issue of Management Planning Final Draft, yes)	
	(do not know of sales)	
	(if blockbuster drug, assume so)	
12:39:48 PM	Suggs - move to admit 4361	
	Lehner - foundation	
	Court - no foundation laid	
	(as a hypothetical but not demonstrated in clinical study)	
12:40:19 PM	Reference Dr. Inzucchi report	
	(not sure what document)	
12:41:11 PM	Ak 8666 - referenced	
	(do not recall seeing any internal documents from Lilly)	
	(not conclusions but internal document, do not know context)	
	(this sentence doesn't prove what I said is incorrect but merely a contention of this person)	
	(not in the package label as it is not demonstrated to be true)	
	(and the FDA)	
12:45:13 PM	AK 7802 - referenced	
	(reviewed hundreds of studies submitted to FDA, do not recall this specific page)	
	(need to know more about the table)	
	(given submission from Lilly to FDA and this study may have been included)	
	(as we talked about today the bulk of studies failed to prove causality between Zyprexa and diabetes)	
	(given hundred of pages and do not specifically recall this page)	
	(given to me by attorneys and if in the submission)	
12:49:54 PM	Kantar - objection/move on	
	(can't say one way or the other)	

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(look at data and came to my conclusion but this could be investigator or director, not mine)

12:50:43 PM Continue with Cross by Mr. Suggs

12:50:54 PM AK 2368 – reference

(Consensus Development Conference on the Antipsychotic Drugs and Obesity and Diabetes)
 (do not recall saying that)
 (yes, correct and I knew three maybe four of them, endocrinologist)
 (yes, Dr. Allison, was presenter)
 (Dr. Cavazzoni was also presented)
 (disagree with some of these conclusions)
 (no, disagreement goes to second column, risk for diabetes is in patients who take Olanzapine)
 (does it add to risk, still controversy)
 (that is what they felt, increase risk)
 (yes, associated with and talking about risk as association but not cause of diabetes)
 (focus on what data is needed to prove what was going on)
 (yes)

12:57:57 PM AK 10177 – ID

Court – being admitted

Suggs – being offer at this time, AK10177

Lehner – no objection

Court – admitted

(ABA, Antipsychotic Drugs Raise Obesity, Diabetes and Heart Risk, yes, it does say that)
 (raises the risk)
 (lead to means?)
 (that I what it says, rapid weight gain leading to diabetes)
 (language is association, not sure)
 (but Zyprexa cause diabetes not proven)
 (but in clinical trials some gain weight and some lost it)
 (yes)
 (reface to lipid levels in the blood and referring to both)
 (SGA, yes)
 (no convincing data showing causal relationship)
 (association with Zyprexa and diabetes in so far as some patient who have schizophrenia and some of those have diabetes)
 (they do point that out)
 (and should influence choice of medication, yes)

1:07:09 PM Sidebar begins

1:07:56 PM Sidebar ends

Suggs – move to publish 10177/published

1:08:35 PM Ak 10094 – referenced

(went to Zyprexa, 200mg)

06-05630CI

(not use that term in adverse data, no)
(use of relative risk)
(gold standard study, correct)
(but look at a and this is a bit misleading as some patients actually got better with Zyprexa and some got worse)
(without question)
(yes)
(problem is its non-fasting data)
(correct)
(diagnostic for diabetes, incorrect)
(many errors, not able to use these numbers I context of this trial)
(that is the cut point)
(no idea of the date of this study)
(not normal for fasting)
(does say that)
(46 percent is 2 out of 4 patients, that 50 percent and what happens)

1:17:24 PM Court - listen to question and answer that
(yes)

1:18:01 PM Continue with Cross by Mr. Suggs

1:18:08 PM Lehner - objection, relevance/sustained

1:18:58 PM Ak 10108 - referenced
FDA made Lilly to change the label)
(not heard those words)
(yes)
(yes, unaware of this, do not recall seeing this exhibit letter previously)
(well, no, pertaining to clinical trial and glucose did increase but if using hyperglycemia as threshold, this is inaccurate)
Suggs - pass this witness

1:23:24 PM Re-direct by Mr. Kantar

1:24:10 PM Ak 10175 - referenced
(HouseKecht study, study of rats, right)
(always defer to human studies)

1:25:14 PM Ak 10176 - referenced
(invalid study, correct)
(not able to compare these two lines)
(glucose up take of about 5)

1:29:22 PM Suggs - objection/testimony stands
(no, as we reviewed this morning)
(see how well it can be stimulated by hyperglycemia)

06-05630CI

(no, not refuted)
(if leading to 90 pounds of weight gain you'd see diabetes)

1:31:41 PM Suggs – objection, speculation/sustained

(symbyax is combination of drugs yes)
(2007 label seen, yes)
(think wording is associated with blood glucose elevation not inducing hyperglycemia)
(yes, diabetes is disease of the pancreas but the obesity is not use of diabetes but that I predisposing of beta cells decomposition, it's a risk factor)

Court – questions but have time limits today, do we have questions to ask
- end of the day
- admonishment

Allen resume with our case tomorrow

Court – thank you

1:37:16 PM Outside presence of the jury

1:37:26 PM Witness steps down

Court – tings to take up

1:37:44 PM Suggs – only admitted one exhibit

Court – number ID but only one admitted
- in past they have come in for notice, but these were fro the truth of the matter

Suggs – 2007 articles

Court – 10177 introduced as new evidence

Lehner – witnesses tomorrow

Court- 1:50 of video tomorrow

Lehner – maybe 2 hours

Court – after first break Lilly to prepare for their case to be put on

1:40:43 PM Fibich – statutory penalties

Court – need to read the brief, Lily raises question if this even applies and if it applies I want the jury to decide identify what violations an then we can talk about how many
- jury to answer interrogatory
- need way to calculate numbers

Fibich – will rest subject to calling Mr. Campana as to the number of violations
- call be fore we rest tomorrow

Court – will read the submission and talk tomorrow

06-05630CI

Lehner - adding witness, if they rest

Allen - subject to calling witnesses

Court - application going to be made when you rest

- if UTPA violation is found by jury and statute that deals with penalties and as enforcer of this, what does jury have to determine, or do they
- prudent is to have jury decide, because I'd rather had a record made

Lehner - correct

Court - if I decide this claim exists do I multiple by number of violations

- math at that point
- issue on deposition that need a decision

Lehner - four or five given

1:47:05 PM

Court - ruling

Allen - will not insert my into their play but might want minutes

- they can cut and get it done

Lehner - subject to cross and ruling

Allen - of course, cut you take

1:47:49 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3AN4308-56

Judge: M. Rindner

Date: Friday, March 14, 2008

Clerk: M. Borneman

Case No: 3AN06-5630-CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial day Ten

Counsel Present:

Plaintiff: Scott Allen, Esq., David Suggs, Tommy Fibich, Esq. and Mr. Sniffen, AAG

Defendant: George Lehner, Esq., Nina Gussack, Esq., John Benner, Esq. and Brewster Jamison, Esq.

Court Orders: Motion to Strike Testimony of Dr. Hobson is denied
Motion for Mistrial is denied

Summary of Proceedings: Trial continues to March 17, 2008 at 8:30.

Outside Presence of the Jury

8:23:30 AM

On the record

8:23:30 AM

Court – list case and parties present

8:23:44 AM

Allen – just handed you excerpt from John Lechleiter and your rulings, plus an email sent to me on March 8 from Adam Michaels, asking me to include page 365 of our cuts to page 366

- during deposition of Lechleiter we stopped tape twice due to error, page 110 to page 115
- will do five video deposition to day
- first time it happen I was playing and objections overruled and last time I stopped it but material was in there at their request
- if event occurs do not hold it against me but would like to present, reading page 110 to jury

8:26:24 AM

Lehner – stood up on these items as what was on the screen was the document that our objection was sustained to, jury saw Wall Street article

- last piece was to be included but not played, non-issue
- harm was document being shown
- need to get technicians to accomplish

Court – nobody in tubule and no one in trouble, I'll take some heat as had I seen all I could of avoided this

- agree with Mr. Lehner n the exhibit not being permitted
- now want to read excerpt, listed
- stock dropping due to Prozac, part of motive in this case
- more desire to promote Zyprexa, will allow that excerpt to be read and instruct them on this

8:28:51 AM

Allen – thank you

Court – if I think somebody is unduly sniping I'll let you know, not yet

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Page 1 of 15

06-05630CI

06-05630CT

- excellent attorneys and acting appropriately

8:29:37 AM Allen - have doctor Wirshing to get on
- exhibits at time of Eski need to be admitted and will move later today to get in

8:29:59 AM Court - renew motion for mistrial concerning the treatment rendered by doctors who have been or will be a witness
- did question the jurors and nothing would affect their ability to judge testimony
- read citation, Campbell v Fox, 498 N.E.2d 1145
- Reomer vs. Cortland Memorial Hospital, 152, A.D.2d 773, New York Appellate
- Haukedal vs. Saint Luke Hospital, 1993 West Law 496681, med mal
- State of Minnesota v Schwartz, 122 N.W.2d 769, criminal case, reading
- State of New Jersey v Hunt, 138 A.2d 1
- State v Rideout, New Hampshire, 725 A.2d 8, reading
- State of New Hampshire v Hunt, 138 A.2d 1
- State cited Partlow v State, 453 N.E. 2nd 259, criminal case, no mistrial
- case law doesn't support a mistrial based on the record before the court, deny motion for Mistrial
- also review case law on the Motion to Strike Testimony on Dr. Hobson
- Miller v Phillips, 959 P.2d 1247 no error to allow witness to testify
- Zaverl v Hanley 64 P.3d 809, (Ak '03)
- Dr. Hobson is not surprising but plaintiff took up challenge from defense and after hearing testifying and then asked on cross, I would of found that proper, difference in going first but will deny the motion to Strike his Testimony

8:38:10 AM Allen - Dr. Wirshing first

Court - Suggests to question
- will give jury heads up

8:38:42 AM Off record

8:49:18 AM On the record Jury is Present

Court - saw video deposition of Dr. Lechleiter and during course of that a portion of video that I indicated could be played was stopped and today Mr. Allen will read portion in to the record, its evidence
- will have live witness and then more video

8:50:37 AM Allen - will bring back video but less than two hours of video

Court - after that the state's case is done and we may go a little bit long today

8:51:36 AM Mr. Allen reads portion of Dr. Lechleiter deposition into the record

8:52:52 AM Concludes reading

Court - Mr. Suggests

8:53:29 AM William C. Wirshing, sworn

8:53:42 AM Direct Exam by Mr. Suggests
(51 and live in Los Angelis)
(doctor for over 25 years)

06-0563002

(education background)
(I like working with schizophrenia as it fascinates me and a challenge everyday)
(board certified in 1988)
(Exodus is an entity, business, with six sites, five in the Los Angeles county and one in San Diego and it is largely takes care of county patient, serious mental illness)
(VP of Continuing Research, etc.)
(ad hoc review on journal if article, two dozen over the years, I have publish in peer review)
(most all of them on schizophrenia)
(metabolic effects of Zyprexa, all of the articles I done had to do with this)
(first publish on Zyprexa and weight gain was in 1996, first article in 1998)

9:03:20 AM Lehner - objection/ will allow

Court - abstract, difference

(the difference is at conference you present condense presentation, abstract, and formalize what the project has done)
(those abstracts are then published in the proceedings of the conference an at times full papers are written)
(both publish just different formats)

9:04:52 AM Continue with Direct by Mr. Suggs

(hundreds an familiar with the literature)
(not in its entirety but did review)
(Consensus Conference of 2003, I was a presenter at that conference and spoke)
(on blood monitoring and lipids, yes)
(yes, did review internal Eli Lilly documents, attorney gave them to me)
(stamped with confidentiality)

9:07:09 AM Reference list of 2nd generation drugs in back of witness stand, on the wall

(investigated all but for Quetiapine)
(yes, obtained medications from overseas for patients)
(familiar with labeling of the drugs)

9:08:33 AM Sidebar begins

9:08:53 AM Sidebar ends

9:09:08 AM Continue with Direct by Mr. Suggs

(yes, I did)
(Olanzapine, and we did one fairly large pre-marketing analysis)
(150,000 to conduct the survey)
(goes to university)
(interacted with industry prior to drug reaching market and doing things that are unknown)
(yes, worked with Charles going back to 1993)
(Gary Tollefson, yes, spoke with him and first interaction with Dr. Tollefson was with Prozac, 1990)
(Winston was a favorite of mine at Lilly)
(continue to research on Olanzapine until 2005 or so but it was in large part of mine design, I asked for research support from Lilly to do my studies)
(many hundred of discussion on what we could agree to)

06-0563001

(Lilly paid my research facility to help on this research)
(get clinical investigators at meetings and get results and feed back from scientists and I'd be reimbursed for my participation)
(Prozac, 1989, issue if Prozac led to suicidal ideation and published on six cases explaining how this could occur)
(thought treatment consequence)
(attention of Lilly's legal team and I worked on years on cases across the world)

9:16:16 AM Suggs – offer as expert as to schizophrenia, bi-polar, and if Lilly adequately warned on risks, etc.,

9:17:02 AM Lehner – not object

Court – so recognize in the areas you just listed

9:17:26 AM Continue with Direct by Mr. Suggs

(sounds like my phrase)
(Risperdal class action suit I was involved in and nothing to do with Olanzapine)
(at the time I was think of the prototype of Clozapine, 1959, most toxic and most powerful of the antipsychotic)
(do not practice in Alaska but before I left my practice I gave Zyprexa to two patients)
(my opinion Lilly consciously, deliberate and denied the true toxic profile of Olanzapine)
(and 2nd, in their defense of this compound they have blames the patients for the toxic consequences of this drug, unconsciously to me)
(they said people with Schizophrenia are known to have increased risk of diabetes)
(blaming the patient for the condition the drug caused, emotional upsetting to me)
(yes, had concerns about weight gain)

9:23:14 AM AK 1586 – referenced

(held in Puerto Rico)
(average weight gain of 24 pounds, no, not part of this Advisory Panel)

9:25:01 AM Ak 10008 – ID, 1998 PDR/admitted

(page three, reviewed)
(I see that 5.4 kg comes out to 11.8, correct)
(less than 24 pounds)
(that sentence altered a single letter)
(said this 5.4kg)
(average weight with Zyprexa over a year is, average, enormous range an at least 24 pounds but varies depending on person)
(up to 125 pounds in the first year but on average yes, 24 pounds)
(physicians should be aware of what ever the data is)
(others things being equal the excess fat is of consideration)
(one pound of fat change is 4 percent risk of diabetes)
(five pounds of fat gains is 25 percent increase for diabetes)
(three to four times higher, 350 percent and higher for women)
(due to adiposity)

9:31:03 AM 1586 – reference, page 8

(yes, but if you increase fat, even the 5.4kg, will induce sever problems with lipid, blood pressure

06-0563001

and glucose)
(talked to Dr. Beasley, Dr. Tollefson, Dr. Winston number of time and this was early 1996)
(doctors/scientist)
(they were receptive and interested in this information)
(same as any other of our observations)
(neuro-cognitive issues, sexual function on the dug)
(JR Richards, yes, met him, he was marketing)
(told him clinical studies done on 10mg and the dug had elevated levels and they were going to give to low a does and he the weight gain and by 1996 we had instituting a bunch of strategic to control weight gain)

9:35:46 AM

Lehner - objection

(yes, and presented a plan to try and help people with the weight gain, know fact of Olanzapine)
(Richards was dismissive as we are scientific nerds)
(second article they were adamant the drug may cause weight gain but not diabetes)
(HGHJ was 1996 patient study, yes)

9:37:57 AM

AK1605 - reference

(HGHJ is second largest study ever, 1696)
(Olanzapine and Haloperidol, lasted eight weeks but then open phase for one year)
(page 11, showing 34 met criteria for being high, 2.6 of Olanzapine group and 1.7 in Haloperidol)
(red flag for diabetes, certainly is suggestive of it)
(this is only eight study and to have hyperglycemia in this amount of time is hard to explain)
(not show this data until this trial)
(cholesterol. Total lipid pool in the blood, and shows 5 of 622 patient's had 0.8 percent, thee fold difference, not show this data)
(as you increase adiposity and fat around mid section, brown fat, bad fat and associated with insulin resistance, hard to keep sugars down)
(circulation lipids the cholesterol is the way it is transported)
(increase)
(familiar with that)

9:47:04 AM

Reference 10008 page 3 of 4

(reading from)
(adverse is not warning section this is very different from warning section)
(vast majority of adverse has nothing to do with the compound)
(adverse section explained)
(weight gain, hyperglycemia and diabetes should have been in the warning section in 1996, absolutely)
(1998 article on the link between Zyprexa and diabetes)

9:50:33 AM

Ak 10141 - ID

Suggs - move to admit 10141

Lehner - consistent with rules

Court - is admitted to show this is being discussed and notice of the contents of this document
(correct, 1998)

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(for these six patients, yes, I require only believe other trials if of sufficient time etc., do not trust)
(drugs did cause this condition and as clinician I'd bet the farm on it)
(80 articles)
(well known by 1988, yes)
(published this article as my wife, Donna, likes to be first and this was one of her pet projects)
(her focus on weight and to demonstrate weight gain has to be paid attention to)
first article link weight and Zyprexa, it got attention)
(lowest quality of publication, just what we saw, case series)
(lot of focus from company and other people, increasing amount of publication in this area)
(most certainly had contact with Lilly)
(their reaction was two fold and I recall it was receptive and interesting at first)
(on follow up from corporate Mel was adamant, in my face saying weight gain doesn't cause diabetes)
(I was at a lost and this is like throwing someone down an elevator shaft but would not hurt him)
(he came back with Mr. Anderson and they showed me his data set showing no difference, impair glucose intolerance)
(torture data set)
(six months later 0.5 versus 0.2 between Olanzapine and Haloperidol in risk of diabetes)
(depends on race, gender genetic background, etc but four fold difference assuming Haloperidol cause no change)
(presented in abstract form half dozen times)
(Mr. Anderson and that was late 1998 or 1999)
(and he was adamant of no association as he believe the fit one and additional data for the second one)
10:04:35 AM (my assumption is these studies not done to look at does it cause problems with weight gain, diabetes)
(assumed they got better data and cleaned it up, did not surprise me)
(labeling, no, its in the adverse experience but has infrequent listing in this period)
(labeling never warned on this increase)
10:06:30 AM AK 988 - referenced
(page 14, I see this)
(correct, vast amount)
(unduplicated reports 194)
10:12:23 AM Ex. Ak 1215 - referenced
(Dr. Kinon response, no way to explain this as it makes no sense at all)
(no reasonable person would do this)
(Zyprexa)
10:17:19 AM Ex. AK10142 - ID
Suggs - move to admit/admitted
(this study was very long and involved looking at 92 subject in one or another control experiment over six to eight years)
(looking at weight gain on antipsychotic drugs)
10:19:58 AM Reference slide 14
(this reflects findings from my study, yes)

06-0563001

(base line weight, gender, age, race, etc., to make reasonable comparison)
(first group is no change observe or weigh loss)
(middle set of graph, FDA considers 7 percent increase in weight is clinically pertinent, pulled from sky, no basis and I like ten and that is what we used)
(on the right are people who gain more than ten percent)
(but the order has been confirmed)

Court – first break of morning

10:25:44 AM Off record

10:48:29 AM On the record

Jury is Present

10:48:30 AM Sidebar begins

10:49:00 AM Sidebar ends

Court – continue

10:49:10 AM Continue with Direct by Mr. Suggs

(yes, I've had three different types of cancer)
(would not believe had I not taken medication from three separate pharmacy companies)
(reviewed the paper twice,

10:50:52 AM Ex. Ak 3645 – ID

Suggs – move to admit

10:51:46 AM Lehner – need to look at this]

Suggs - provided 24 hours ago

Court – will allow testimony on this

(IGT is impair glucose tolerance)

10:53:56 AM Ex. AK1440 – referenced

(page two, 11/2/2000)
(yes, did write this, nastily sarcastic)
(did it with me, Scott, Donna Steve, list psychiatrist)
(Thomas Hardy, endocrinologist, very bright guy and he presented at UCLA same data set and he was clearly sent by Lilly to debrief us on this data and counter the escalating evidence on Olanzapine)
(after I talked with Tom and told him how could he say a drug that causes weight gain can't not have risk of developing diabetes and he just shook his head)
(this was 1999)

11:01:39 AM Ex. ak1453 – referenced

(Dan Casey is a professor in Oregon and usually the chair of FDA ad hoc committee, very bright man)
(he worked with my ex and publish and lecture on this topic after our publication)
(very high rates in his population, 64 percent)

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(that is in lock step of my observation on what they did)
(2003 Consensus, no worse than any others, etc., and the message is frustratingly wrong)
(we did on glucose levels, part three)

11:06:54 AM Ex. Ak 10140 – ID

Mr. Suggs – describing ex. and we move to admit/admitted

(yes, it did)
(retrospective study, we asked the question what is the effect on number of parameters, etc., and we wanted to do weight but at the VA we did not have weights, frustrating, but we asked the impact and we went back to patients and compared them to these parameters, primarily from research data base from previous ten years)
(looked at various drugs and controlling what we could like age, race, gender)

11:10:19 AM Reference slide 34

(yes, it does, explaining the graph)
(Percentage of change in glucose)
(average glucose rounds around 60 to 110)
(definition of diabetes is 126)
(this varied but control for length of time but from six months to two years, long term studies)

11:13:53 AM Reference Percent change in Triglycerides, slide

(triglycerides are main fat compound we eat and store)
(and has main affect on the pancreas)
(if you eat a McDonald's meal your triglycerides go up)

Court – mean triglycerides

(what he said)

11:15:41 AM Continue with Cross by Mr. Suggs

(yes, that is true if you compare high triglycerides diet to say low diet the person on the high diet required more insulin)
(and people who have schizophrenia are on the lower economic level and eat horribly)
(this shows increase in triglycerides and this an weight is amazing)
(and due to a drug)
(Quetiapine shows a decrease, but they did gain weight and had glucose problems)
(this effect is separate from weight gain and looks like something else was selectively happen and distinct from weight gain)

11:18:51 AM Slide Percent change in Cholesterol of value HDL

(this is the good one, if you have to have it)
(the transport system protects you from LDL, the bad cholesterol)
(if HDL drops you need to drop LDL or you have troubles)
(Olanzapine was worse offender, yes)
(published in 2002)
(Zyprexa does cause weight gain, diabetes, hyperlipidemia)
(Lilly did not adequate warn, before October 2007, they did not)

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(comparable to some and not to others)
(to be used as first line drug, fail less toxic before going more toxic)
(absolutely)

11:24:07 AM Lehner - objection, foundation/OR

(give lectures once a week and my reading suggests the rest of the world has caught up to my way of thinking)

11:24:52 AM Lehner - objection, foundation/OR

(not sure Lilly has any doctor to say this)

11:25:20 AM Ak 2368 - referenced

(on lipids, yes)
(very much so)
(animal research, epidemiology research and clinical research)
(I did to monitor patients, correct)
(also suggest first lipid to be at eight weeks and monitoring)
(for all SGA, yes, and what I've done since 1996 and suggested to Lilly)
(routine part of our research for a decade)
(I'd ask for more money if I did certain things)
(not part of label prior to 2000)
(prior to this Lilly never question me to my face)

11:30:47 AM Cross exam by Mr. Lehner

(yes, we have met before)
(phase two and three trials)
(before the drug was on the market)
(everything we talked about turned over to Lilly)
(label information is from these trials, yes)
(1996)

11:32:47 AM EI 2954 - referenced

Suggs - stipulate not from PDR

Lehner - Lilly's label, not PDR

Court - not from PDR but Lilly's first label from 1996

(reading from exhibit)
(from short terms trials, six weeks)
(I have no idea if this is accurate, but have seen this over and over again)

11:36:32 AM Reference Dr. Wirshing deposition

Suggs - show and then see if it refreshes

Court - maybe impeachment

06-0563002

Lehner – impeaching

(yes, not sure if accurate or inaccurate)
(weight gain in all antipsychotic, short term, not with Ziprasidone)
(across the group)
(in clinically under weight people does the additional of antipsychotic promote weight profile, but from people who have eating disorders, yes)
(if you gain adiposity that is not good if you gain lean muscle mass, that I good)
(on Zyprexa we had long term data that would of supported the weight gain idea, first aware of that in 1996 or 1997)
(protocol explained, I had 15 patients on Olanzapine for a couple of years before being marketed)
(as clinician there are two data sets, patient and other data set)
(mine was much smaller)
(they had I long term, not sure but 235 for Olanzapine and 118 for Haloperidol)
(most not seen before)
(not seen until coming to Alaska)

page 209 of deposition, referenced

11:44:22 AM Suggs – foundation first

Lehner- not seen documents before being presented

Court – go through deposition questions

Suggs – refreshing

Court – not , its impeachment

(right that was a year ago testimony)
(not correct)
(started this on this case a year ago, 12/06, an prior to that only saw only about 25 percent of the material dating back to summer of 2006 when attorney for a consortium of attorneys retained me as they were suing Lilly)

11:46:32 AM Ex. AK320 – referenced

(have seen this)

11:46:56 AM Ex. Ak 988 – referenced

(no, not seen)

11:47:09 AM Ex. Ak 990 – referenced

(provided by insurance company)

11:47:44 AM Ex. Ak 1110 – referenced

(Do not recognize)

11:47:50 AM Ex. Ak 1111 – referenced

06-05630CZ

(do not recognize this)

11:48:07 AM Ex. Ak 1449 -- referenced

(yes, seen before)
(yes, show by insurance companies)
(not the insurance company attorneys but from these attorney yes)
(do not recall saying I worked for insurance company's, involvement was a single day and I did not retained any documents)
(yes, oversight on my part)
(weight gain and obesity, difference yes)
(risk factor for diabetes, yes)
(learn of this in medical school)
(most common condition afflicting our society today)
(do have to remind doctors)
(direct causal relationship with Zyprexa and diabetes, no, evidence to date is Olanzapine)
(endocrinology is due to weight)
(yes)
(drugs had selective toxicity on endocrinology system, yes)
(yes, presenter and Consensus conference)
(have to reach out and get other peoples experience, better to car for patients)
(that and my clinical experience, intellectual experience)
(read label for all six antipsychotic, correct and for this litigation)
(and the 200 label and the change to the 2003 label)
(2006 label, know that was inaccurate at the time)
(long term weight gain but other than this the label was not decidedly incorrect)
(yes, I would and not in the context of leaving things out like hyper-triglyceride and change of glucose mentioned but not quantified)
(no not correct)

12:02:47 PM Reference deposition of Dr. Wirshing at page 2214

(right)
(that is correct)

Court -- will take our second break for the day

12:04:54 PM Off record

12:28:09 PM On the record Jury is Present

Court --

12:28:27 PM Continue with Cross by Mr. Lehner

(dear doctor letter, yes)
(gives updates, get them frequently)

12:29:33 PM E. EI3003 ID

Suggs -- not admitted

Court - get them admitted first before showing to jury

06-0563002

Lehner - no objections

Suggs - purpose

Lehner - he reviewed as part of expert report

Suggs - show to witness

12:30:59 PM Sidebar begins

12:33:22 PM Sidebar ends

Lehner - showing to witness

- EL 3003, 3008, 2991, 2996, 2990, 3004,

12:35:00 PM Suggs - objection as to time/

(3003, is summary of body weight changes)

12:36:34 PM Jury number 14 wants to see this on the screen

Court - at this point, no

(journal articles, Lilly data file and presentation)

(did not know Alison would be here)

12:38:04 PM (3008, body weight changes, 12 pages)

(same as last one)

(2996, Zyprexa long term treatment on weight, etc., five page documents, two of them)

Court - two appear to be identical

(ten pages each titled 2996, and appear to be five identical pages)

Continue with Cross by Mr. Lehner

(2990, weight reduction and management)

(yes and Lilly circulated to others)

(no reason to believe data was inaccurate but as far as misleading, much when you read these letters blaming weight gain on others, its drug related obesity)

(that was my sense)

(and he review those articles, not aware that demonstrate an totally disagree)

(no changes in obesity)

(as risk factor they are wrong)

(would not be the first time, FDA wrong)

(common obesity is risk factor)

(but disagree with all those others as females with schizophrenia are lower rate, inverse relationship)

Ex. EL 2399 - referenced

(in my experience the weight gain with Clozapine is resistant to change)

(and are effective to this day)

12:47:22 PM (Donna had long interest in this)

(primary goal is to prevent patients from having so many problems with the drug)

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(manageable, treatable if you paid attention to them)
(Olanzapine and Risperidone both are above)
(no longer use first generation at API, I did here that)
(and Zyprexa as first line treatment, nothing wrong that)
(I continue to use Olanzapine and do start patients no this drug)
(no, I started on Zyprexa as they had other compounds that did not work)
(yes, and deal with toxicity but for a few bad ugly things)
(if you find something that works with schizophrenics you stick to it like a pit bull with lock jaw)
(I am stagger by)
(closest thing to magic in my medical career, happens with all the antipsychotic compounds)
(but when you find the right one it is profound and gratifying)
(life they lead is dramatic an less seen by these drugs)
(family changing)
(efficacy, can't book on anything but for Clozapine)
(illness last years and usually have guidance on what gets them better)
(atypical in general are a spectrum)
(the person himself has been expose to drugs an his history is important on this)
(what has work and what has hurt them before, patient, family information)
(I'm not the kind of person you introduce me to executives)
(never done that with anybody)

12:59:33 PM Re-direct by Mr. Suggs

12:59:50 PM Lehner - objection, not offered on primary care/allowed

(antipsychotic not be administered by anybody who doesn't have the experience)
(Lilly did not adequately warn on the risk of Zyprexa, no)

1:01:13 PM Ex. EL 2996 - referenced

(no, of course not, as if you gain weight it changes glucose, it will)
(yes, misleading statement)
(no address or name not on there nor a date)
(no one signed in the six documents I see)
(there's a Zyprexa copyright)
(I do not know but my belief at FDA and folks at meeting focus on glucose as it relates to weight and this is open at this time)
(my question is no, these drugs have no direct impact apart from weight and I agree with FDA if talking about glucose directly)
(in people who gain weight in certain way)
(pancreas is of concern as it leads to insulin dependence and is different form glucose)
(FDA has change)

1:07:22 PM Sidebar begins

1:08:13 PM Sidebar ends

(1996, 2000 and 203 labels, yes, labels did not tell the whole truth or adequate warn on diabetes, no)
(nothing erroneous but did not warn about diabetes)
(or weight gain, Olanzapine has weight gain when taken)
(weight gain, weight gain, weight gain)
(relieving the symptoms doesn't relieve their obligation to warn)

06-05630C1

1:10:18 PM

Re-cross by Mr. Lehner

(no, not with certainty)

1:10:52 PM

Re-re-direct by Mr. Suggs

(but does raise the risk to diabetes)
(a definable number develop diabetes in Alaska)

1:11:35 PM

Witness steps down

Court – play Dr. Kinon

1:13:18 PM

Dr. Bruce Kinon, video deposition begins

1:31:23 PM

Video ends

Allen – admit various exhibits

Court – make this application Monday morning

- concludes our day
- admonishment to jury

1:33:43 PM

Outside presence of jury

Court - wanted to thank both side on the technology

- AK 3645, hanging

Lehner – take up on Monday

Court – fine

- Jury instruction to b taken up at some point to deal with this
- Start on this and special verdict form, start sooner rather than later
- Get proposals by end of next week and give to me as soon as possible
- Four more video deposition and assume application to be made

1:37:43 PM

Allen – get these admitted now

Court - fine

Allen – AK1110, 1215, 8905, 4517, 1213, 4532, 7668, and 5522, move to admit

Lehner – as to last one, note to discuss objection on this but did this witness authenticate, do not think same for 4532

Allen –

Court - Ak1110, 1215, 8905, 4517, 7668, 1213,

What about 4532 and 5522

Allen – self authenticate

Lehner – no

In the Superior Court at Anchorage Alaska

Media No: 3An4308-55

Judge: M. Rindner

Date: Thursday, March 13, 2008

Clerk: M. Borneman

Case No: 3An06-5630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial Day Nine

Counsel Present:

Plaintiff: Scott Allen, Esq., Tommy Fibich, Esq., David Suggs, Esq. and Mr. Sniffen AAG

Defendant: George Lehner, Esq., Nina Gussack, Esq., Mr. Jamison, Esq., John Brenner, Esq.

Court Orders:

Summary of Proceedings: Trial continues to March 14, 2008 at 8:30.

8:31:46 AM

On the record

outside presence of jury

Court - provide counsel on deposition

Allen -

Lehner - Breier and NEgeus

- OUS, objections, read in
- page 447 line 24
- page 448 to line 17
- page 458 line 2 to page 451 line 2
- same objection to this

Court - give me page and number and will read

Allen - have Dr. Breier down to about half of what we had

Court - Lilly filed motions, Motion to Strike Dr. Hobson testimony, ruled yesterday and continue to think Dr. Hobson is witness listed on Lilly's witness list and deposed

- will deny motion to Strike
- Motion for Mistrial, will read the cites

Fibich - Alaska's case, have cite and case for you to read

- Meyst v Estate Fifth Avenue, 401 P2nd 430, dealing with discretion on mistrial
- Supreme Court of Indiana case, Partlow v state of Indiana, 453 Northeast 2nd 259,
- If we are wrong they have right of appeal on this matter but if granted we have no means to determine it was appropriate
- Go on with trial and they can appeal, if needed
- All cases they cite in Motion for Mistrial

Lehner - please read

Court - will read and the motion made yesterday and we examine the jurors, made record

06-05630CI

- ruling made and denied this yesterday but now have case authority and see if I cahng3 my decision or not

8:38:48 AM

Jamison – concerns Motion to Strike Dr. Hobson, already ruled on, do not think so

- Dr. Hobson on stand and expressed opinion evidence and never disclosed to Eli Lilly
- Miller v Phillips
- Not listed on states witness list or summary of his opinion given to us
- 12/11/07 we took Hobson deposition and if we had known he was to be called we would of asked different questions, we were confident they would not call
- we were going to offer for factual material, not opinion
- Dr. Hobson was meeting with state's lawyers unbeknownst to us and shown documents, we have no idea what
- Now we have to do discovery deposition in front of jury, not fair
- Lay in the weeds and violating the rules, kept off their witness list and then call in their case in chief
- If they are allowed I will do so in the future
- Exactly what Miller v Phillips was designed to prevent
- Prejudicial and clear violation of your rule and Uniformed Pretrial Order

8:43:38 AM

Allen – disagree, you have ruled

Court – but they are saying authority and have to read Miller v Phillips

Allen – will read the case but look at citation last page of motion, cited

- Dr. Hobson said in deposition, reading
- They did not like the answers to question I asked
- Saving clause, what surprise to them but for challenging us that we would not call him, we subpoena
- Bandick, Torres I asked the same thing

Court – objection to question and you did not and you made comment on the rules being equal and need to make objection to get same ruling

Allen – Jordan had five lawyers with him an met with them extensively

- happens in all trials I've done
- do deposition and we do not do direct, their problem not mind

Court – have two cases to read an decide

8:51:17 AM

Allen – if the court is wrong we have no remedy, and if they win this is of no consequence

- they have appeal right
- we'd have to start over
- no remedy and we have the evidence

Court – both sides can appeal what I do with Dr. Hobson, if needed

Jamison – we have good clue on what Supreme court will do, Miller v Phillips. I was accused of doing the wrong move in that case, but that was different

- doctor depose and court found Kennelly could of interview and contrast that here ,we never had that opportunity

Court – will read the cases

06-05630CI

Jamison - 11/5 had the state said we would call Dr. Hobson on the label's and all opinions he given yesterday we would of done a different deposition of Dr. Hobson

Court - lot of opinion were expressed

Jamison - we did not offer into evidence in the deposition designation

- this savings clause, their 2nd late exhibit list, but never served on me or my office
- Sanders did not et it until March 3
- Filed with the court but not serviced on this office and we would of objected to this
- Surprised he was even brought to the witness stand
- Disregard to court rules, trial by ambush
- We did not know this an the trial brief would of given this
- Relaxation of pretrial rules

Court - will red deposition and the cases and make a ruling

- if Lilly did not understand the states argument, after reading what I have, is a real surprise to me

Jamison - did not know what witness they'd call

Court - will read the deposition to see if there was surprise or not an the case to see what I have to do

- good trial tactic or unfair, will decide

Jamison - do not even know what document they let him see, not provided in time of his deposition, they kept the documents from him and the m brought him in and offer opinion

Allen - just not true

Jamison - ask him if Hobson received these documents and when, on witness list

8:59:25 AM Allen - Dr. Hobson testified to facts and his opinions related to those facts and expressed in his deposition

Court - reason for me wanting to read, not helpful to further argue

Allen - My Cousin Vinny, opposite of what he said

- did not intend to call but called due to challenge issue that we did not have the guts to call him, and I issued subpoena
- never provided document one
- he had counsel an if they met with him its confidential, not worried as he testified to facts on Zyprexa and everything I used were their documents
- documents back and forth and they got our witness list, this is false on their part

9:02:19 AM Jamison - do have Dr. Hobson deposition and had they said they called we would of deposed the doctor to find out his new opinions

- he is still on cross and being consulted and I raised this
- expert opinion on things he never hinted at in his deposition and violation of rules

9:03:36 AM Court - dr. deposition is handed to judge

- will read cases and will read this deposition, Dr. Hobson
- will be back in five minutes

9:04:24 AM

Off record

9:12:08 AM

On the record

Jury is Present

Court – Dr. Hobson resumes the stand

9:12:32 AM

Cross Exam Continues by Ms. Gussack

(40 and 50's and prior to first generation of drugs)

Allen – objection, may we approach

9:13:38 AM

Sidebar begins

9:14:28 AM

Sidebar ends

(not a real deal of scientific treats but had methods of high rates of insulin and then glucose water to bring them out of it, primitive treatment)
(and lobotomize, ice baths, electro shock)
(even today electro shock issued)
(psychosis)
(Haldal, Throazine, etc., first generation of drugs, effective in positive symptoms, delusion and paranoia)
(but negative symptoms it did not help,)
(second profile they tardive dyskinesia, neurological disorder, tremor's, tongue protrude)
(no first generation at API, no, side affect profile)
(not respond to first drug of treatment an Zyprexa is the big gun and some use it as first line of choice)
(do not know for sure but someone might chose that as first line of choice)
(some have risks)
(risk association with cardiac abnormalities, yes)
(fatal blood disorder)
(Risperdal has higher than the others)
(Seroquel has hypertension, cardiac)
(agree not equally safe, yes)
(yes, all had warnings, yes)
(process of FDA for class label, no)

9:25:54 AM

Ex. EI 2034 – id

(yes)

9:27:50 AM

2003 label on the screen, ex. EI2953

9:29:03 AM

Reference 2953

(yes, label reference yesterday)
(not exactly sure what they did)

9:29:37 AM

Ex. EI 2039 – ID

(sure I did)

9:30:34 AM

Ex. EI2728 – ID

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(yes, recall, look at it again)

9:32:15 AM Ex. EI 2368 – ID

9:32:20 AM Ex. EI2157 – ID

9:32:32 AM Allen – need copy of ex. EI 2157

(correct we began monitoring, always have as admission but then we did it specifically to all 2nd generation drugs, yes)
(yes, efficacy and how Zyprexa was effective as patients stayed on it longer)
(big challenge keeping patients on their medications, it is)
(yes)

9:37:10 AM Allen – objection, misleading/can answer and you cross on it

(need to look at study, not sure)

9:37:47 AM Allen – objection, form. overrule

(yes)
(again, look at the study)

9:38:19 AM Ex. EL2056 – ID

(correct)
(yes)

9:39:27 AM EI2182 – ID

(correct not news to me as we saw that in our patients)
(weight gain over two year period, I see that)
(but knew of this since 1996, most familiar with weight gain, yes)
(yes, significant amount of weight)
(wellness program head, a component of our treatment)
(we offer cycle education classes and group of this is focus on diet and exercise to stay health)
(educate and motivate, atpment made)

9:43:29 AM PX10144 –

Court - so not P its

Gussack – Ak

9:43:49 AM AK144 – ID

9:44:18 AM Allen – need copy of this

9:44:49 AM Sidebar begins

9:46:06 AM Sidebar ends

9:46:13 AM September 4, 2001 call note from Ms. Eski – PX144??????

06-05630CI

(do not dispute, no)
(PNT committee was formed around 2004 and physicians were selected to be on it and purpose was to go through different classes of medication and come up with preferred medication list for Medicaid)
(no, I'm not)
(Pharmacy and Therapist, PNT)
(did not ask to have Zyprexa be restricted)
(Dr. Wirshing, do not know him but said hello yesterday to him)

9:49:50 AM Allen - objection, improper, may we approach

9:50:02 AM Sidebar begins

9:51:01 AM Sidebar ends

(I would agree that you try and do that)
(we have always done as prescreen, blood level glucose check)

9:52:08 AM Re-direct by Mr. Allen

(yes, always done)
(not done as to Zyprexa)
(since 2004 we have specifically monitor blood sugar and other blood indices due to their risk of this, Zyprexa)
(would come under great deal of consideration)

9:53:33 AM Gussack - objection, leading/rephrase questions

(yes)
(all drugs have risk and side affects, yes)
(need to give conformed consent, yes)
(Geodon, cardiac issues, right)
(Clozaril)

9:55:21 AM Gussack - objection, leading

(correct, that is a PDR)
(label not sent but we use the PDR)

9:56:24 AM PDR on the screen, demonstrative

Court - year

Allen - 2008

(Clozaril, yes, black box and we monitored it and considered it)
(if warned doctors can monitor but if not warn the doctor doesn't monitor and not able to handle)

9:57:47 AM Gussack - objection, leading/rephrase

(not for sure if)
(Geodon, yes, by Pfizer)
(go to Eli Lilly and to Z to get to Zyprexa, correct)
(each company listed in PDR)

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(contraindication is someone has a condition or situation and means not to prescribe the medication)
(Geodon, contraindication, they do)
(it is)
(knowing risk is important, yes)
(manage patient and allow the patient to chose if they accept this risk)
(freedom of choice)

10:01:54 AM Gussack - objection/argumentative

10:02:10 AM Gussack - objection/OR
(it is restricted)
(did not get label that I recall and never in the PDR)
(I do see that)

10:06:23 AM Gussack - objection, date of article
Allen - letter from FDA dated 12/16/03
(yes)
(Consensus Conference was held in 11/2003, yes)
(FDA testified at this conference)
(three day conference, hearings, yes)
(panel study everything they could get their hands one, I do see that)
(support and sponsored by drug companies, I do see that)
(DR. Cavazzoni and Dr. Buse did testify as well as FDA members, yes)
(Racoosin and Wirshing, I see)
(took six months to prepare a letter to doctors I do see that)
(no)

10:12:27 AM Gussack - objection, expertise, scope/OR
(no, did not know that)
(five months earlier, yes, consensus panel met)
(table two, Zyprexa and Clozaril had worse rates, yes)
(March 1, 2004, they had the results of this consensus panel, yes)
(no)

10:14:47 AM Gussack - objection, vague/if you understand
(no, and they should of, yes)
(Dr. Laughren, no, not sure what information he had)

10:17:32 AM AK 10094 and 10184 - ID
Court - will beak
- admonishment

10:18:07 AM Off record
10:36:45 AM On the record outside presence of jury
Court - issue

06-05630CI

10:36:55 AM Gussack – best to exclude Dr. Hobson, expertise
 Court – will excuse the doctor for the time being

10:37:36 AM Gussack – argumentative, leading and inappropriate question by Mr. Allen and may make him as non-expert as to FDA
 - appears he is on path to closing by way of this witness, this witness is not appropriate to have knowledge about the documents being asked about
 Court – did you not take him through FDA documents, follow up on same line

Gussack – no, we asked the witness about his views on what Lilly should or shouldn't have done And was he aware of now being asked by Allen about FDA would of like to have know or should of Lilly done differently, there is substantial difference

10:39:43 AM Allen – disagree, she showed
 Court – is leading and so please control leading and argumentative
 - can ask the were you aware of type questions
 - sustained as to FDA questions
 Allen – no problem asking were you aware
 - not even in examination until she brought them up

10:41:05 AM Gussack – thank you
 Court – understand dilemma about this and I'm ore liberal in this are but it was pushing the line, will stop
 Gussack – argumentative
 Court – thank you for not having speaking objections
 Gussack – factual not what he thought or would of wanted to know
 Court- what he was aware of not to what he thought what FDA might of wanted to have known, the line
 - had chance to review the additional lines to be added to Brier deposition, OR the objections
 Allen –

10:43:21 AM Off record
 10:44:35 AM On the Jury is Present
 Court –

10:44:58 AM Continue with Re-direct by Mr. Allen
 (yes, asked about the letter)
 (no, did not know that but am now after reveiwing the Consensus statement)
 (aware now of Dr. Laughren)

06-05630CI
11:01:19 AM Ak 10095 - ID

(new warning on hyperglycemia and weight gain, that is correct)
(and prior there was no warnings on this)

Court - showing the 2008 PDR on the screen, make it a copy and make it an exhibit

11:03:11 AM Gussack - no objection but with clarification

Allen - will make copy tonight

Suggs - in the black box there is a copy

Allen - hands to Ms. Gussack

(yes, warning form FDA letter and on hyperglycemia, yes)
(new label for Zyprexa recommend monitoring for glucose, weight, correct)
(from consensus panel from 2003, correct)
(that is correct)
(amended warning after FDA told them to, yes)

11:06:03 AM Ak 10168 - ID

Allen - move to admit /admitted without objection, maybe published

(not in current PDR, no)
(in the letter but no the PDR, you are correct)
(blood monitoring for all patient of Zyprexa, that is correct)
(base on information from three years ago)
(if at risk for high blood sugar, you do blood tests, yes)
(correct)
(published after consensus statement, right)
(not aware)
(warning on weight gain, that is correct)
(for Zyprexa, that is correct)
(and monitor for glucose control, that is correct)
(and monitor weight gain, that is correct)

11:10:27 AM Gussack -objection

(all new information not warned on, it was the first time)
(we change this practice in 2004, monitor blood glucose and at the time the PDR did not have this requirement)

11:11:31 AM Gussack - objection, expertise/can you answer on primary care doctors do you have enough knowledge to answer

(yes)

Court - question is allowed

11:12:07 AM Continue with Re-direct by Mr. Allen

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(I would expect so)
(need doctor and on the cutting edge for regular monitoring, Dr. Jennay Love)
(yes)

11:13:49 AM Gussack - no record to show lack of memory/ask question

(when I became aware, no)
(sure, would help to see deposition)

11:16:18 AM Gussack - objection

(not to the degree we are now)
(yes, change my prescribing habits)
(at that point it was establish this medication posed risk and we began to monitor)
(new warning, will again change our practice with this drug)
(warnings are extremely important)
(New England Journal of Medicine, explained to jury, the CATEE study)
(correct looked at Geodon, Risperdal, and Seroquel)
(and looked at why they quit these drugs)
(Zyprexa had intolerable side effects)
(weight gain and glucose an lipid metabolism, correct)
(Perphenazine had different rates of discontinue rate)
(Cohort is a group, study group)
(you did read that right)
(National Institute of Mental health, the study)(

Court - ask questions

(yes, reading from New England Medicine Journal)
(Olanzapine group had more weight gain, 2 pounds a month, yes)
(Eli Lilly never informed me of this weight gain, no, even after Puerto Rico)
that is correct, 2.2 pounds)

11:27:47 AM 2005 PDR referenced on the screen

(5.4kg is 11 pounds and less than 24 pounds, yes)
(but gain 2 ponds on Zyprexa, CATEE study)
(or 24 pounds a year)
(need to be reported to doctors and this has not been reported to me from Eli Lilly)
(glycosylated hemoglobin, in he blood association with diabetes)
(Geodon is Ziprasidone, correct)
(no difference)
(Dr. Carol A. Tamminga, did not know)

11:31:38 AM Gussack - objection, mischaracterized

Allen - can mark it

Court - approach

11:31:56 AM Sidebar begins
11:32:49 AM Sidebar ends

06-0563002

(sure I took a look at it but do not remember this article)

11:33:40 AM Allen in evidence already

Court - show it to him and have him read it

11:34:34 AM Gussack - objection, doesn't recall/ now having it read do you remember
(see it in the article)
(but do not recall reading it)

Court - not question on it

(yes)

11:35:53 AM Gussack - objection, not questions/

Court - explaining to the jury to other testimony, you are judges of the facts in this case an what has been testified to, give it weight if you think it happened

11:37:03 AM Ex. Ak 10147 - referenced

Court - previously admitted

(I have copy of this and somatic effects means effects that a person would feel)
(you did)
(plasma chemistry monitor is blood monitor)
(electrocardiogram, explained)

11:40:40 AM Gussack - objection, leading

11:40:50 AM Gussack - objection/allow that

(yes)
(NIMH is National Institute of Mental Health)
(saying an unbiased study an agree with it)(

11:42:05 AM Ex. AK5846 - referenced

(I do se that)
(Zyprexa as primary agent in everyday care, do not think so)

11:43:36 AM Re-cross by Ms. Gussack

(blood pressure cut in office, body tape measure, yes)
(PDR is independent commercial publication of FDA approval of drugs, yes)
(contains all companies)
(supplements every year, two of them)
(did not review the supplement - 2004 PDR)
(correct)
(there are cut off dates, yes)
(not sure cutoff date for the PDR)
(June 2003 for 2004 PDR, no reason to disagree on that)

06-0563002

(yes, to late to publish)
(PDR comes out several months before the new year, yes)
(no)
(best is to get into the 2004 PDR but if publication date is missed)
(1996 label, yes, showed weight gain)
(average of 11 pounds, thinks so, 5.4kg, right)
(yes, asked if it was 24 pounds in a year)
(I se that but CATIE was an 18 month study, yes)
(Olanzapine had lowest discontinuation, yes)
(psychopathology, defined)
(certainly, looking for reduction, yes)
(do not recall a letter or anything but specifically do recall 2003 letter)
(have to see first)

11:52:59 AM Dear doctor letter on screen, March 2004 letter

(yes)
(it appears we did receive but further recommendation in the most recent)

11:53:53 AM ()

Allen - objection

11:53:55 AM Sidebar begins
11:54:08 AM Sidebar ends

11:54:16 AM Continue with Re-Cross by Ms. Gussack

(I probably did)
(do not recall)
(at the API staff meetings, sure it was discussed at some point)
(did not look on web cite, not that I recall)

11:55:18 AM Re-re- direct by Mr. Allen

(CATIE study was 18 months but that is true percentage of patients discontinue the study)
(on average they stayed 9 months on study)

Court - jury questions

11:58:05 AM Sidebar on jury questions
12:02:54 PM Sidebar ends

Court - after conferring with attorneys the questions have been answers and some of them
maybe asked in other testimony

- doctor had concluded his testimony
- doctor is excused

12:04:02 PM Off record
12:04:40 PM On the record outside presence of jury

Court - jury questions were objected to but attorney have read them and they can later clarify if
you wish

06-05630CI

12:05:10 PM	Gussack – helpful to get copies of questions Court – will make copies
12:05:27 PM	Off record
12:26:35 PM	On the record Court – Allen – Dr. John Lechleiter by video
12:27:05 PM	Video deposition of Dr. John C. Lechleiter begins
12:40:11 PM	Video ends
12:40:15 PM	Sidebar begins
12:42:19 PM	Sidebar ends
12:42:27 PM	Video deposition of Dr. Lechleiter begins
1:15:25 PM	Video tape ends Sidebar begins Sidebar ends
1:15:45 PM	Court – dealing with previous objection on this video deposition, explaining to jury
1:16:26 PM	Allen – concludes our offer of this witness
1:16:43 PM	Sidebar begins
1:17:29 PM	Sidebar ends
1:17:34 PM	Allen – move to admit exhibits from this deposition - AK10034 Court – 10034/ admitted
1:18:32 PM	Allen AK 1079 Court – AK 1079 is admitted Allen – move to admit AK 5913/admit, subject to objection - Ak8584/admitted, subject to objection - Ak3109/admitted - AK8668/admitted - Ak918/admitted - Ak4051/admitted - Ak10017/admitted
	Court – all admitted and objections made are preserved - good time to break for the day - admonishment to jury

06-05630CI

1:22:11 PM

Outside presence of the jury

Court – objections to designations depositions, double check to make sure exclude information is presented

- do not think anything has been heard
- got a card for Mr. Venhuizen and I have signed, would like to sign considering the Motion for Mistrial

1:24:15 PM

Fibich – not an issue to us and will not raise

Gussack – status of juror

Mark – status given

Court – objections made by Lilly and indicated for each witness what objections were sustained and or Overruled

- cuts are delineated in this , but make record

1:25:50 PM

Allen – AK10169/

Court - offer as record of portions you would of liked to have played, but sustained objections to

Allen – offer as group, reject

Court – objections ruled on

1:27:10 PM

Lehner – ruling is clear

Allen – thank you

Court –

1:27:54 PM

Fibich – two members to contact jurors who have been excused, we object to this

Court – at some point when this is over they are free to speak to jurors, but at this time you are not free to speak to jurors

Gussack – no contact

Court - will send letter of thanks and a survey on the court system etc.,

1:30:03 PM

Suggs – deposition exhibits to be admitted: Wojcieszek ak10108

- ak10109
- ak10110
- ak10104

Court - Ak 10108, 10109, 10110, 10104 are admitted, Wojcieszek deposition

1:31:28 PM

Lehner – idea for tomorrow

Fibich -

In the Superior Court at Anchorage Alaska

Media No: 3AN4308-54

Judge: M. Rindner

Date: Wednesday, March 12, 2008

Clerk: M. Borneman

Case No: 3AN06-5630-ci

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial Day Eight

Counsel Present:

Plaintiff: David Suggs, Esq., Scott Allen, Esq., Tommy Fibich, Esq. and MR .Sniffen, AAG
Defendant: George Lehner, Esq., Nina Gussack, Esq., John Brenner, Esq.

Court Orders: Application for Mistrial is denied

Summary of Proceedings: Jury continues to March 13, 2008.

8:27:44 AM On the record Outside Presence of Jury
Court – list case and parties present

8:28:10 AM Lehner – PDR document, we determine supplement to the 2004 PDR which include the information Dr. Gueriguian did not find
- And maybe for the 2001 PDR
- Complete set, this set is not complete
Court – if given to jury it must be complete, stipulation on this?
Allen – no stipulation to be reached, front cover tells everybody what it is but notebook is complete as to PDR
Lehner – no
Allen – he thinks there is a supplement for 2001 and if he has it for 2004 put it in now
Court – I want complete PDR
- time of package label approved and how long it takes to get to the PDR
- schedule for publication of PDR

8:31:10 AM Lehner – strike first 12 pages of Mr. Jordan testimony played yesterday
- profit and warning but nothing on risk

8:31:51 AM Use of Elmo
- entitle to produce evidence on mood, thought and disturbance and reason is clear because one of our theory is they over emphasis the benefit, news to us
- you struck this the case and if we have to defend its another claim
- look at their fourth response and this goes to this issue
- evidence on profit and mood etc., has nothing to do with warning

06-05630ci

Court – deny motion as it goes to motive, testimony from one witness about putting profit over safety

- argument made and supported by some evidence is that Lilly losing Prozac had big money maker and needed something to replace that drug with another
- things Lilly done as to improper warning was Lilly was trying not to lose business and Zyprexa was to be the big winner
- goes to motive and is relevant to this case
- risk benefit raise in opening by defense that doctors have to weight the different benefits of the drug
- need to see more evidence

8:35:24 AM Lehner – made that point, the jury to be asked to give adequate warnings, who were they warning

Court – not making point, but articulating their point

Lehner – given to physician and other medical professional and if Lilly has to calibrate warning every time a doctor uses the drug on his own judgment you'd be putting the company in an untenable position

8:36:46 AM Court – opens door to see what they were promoting

Lehner – risk and label is independent from what a doctor may do

8:37:12 AM Court – risk benefit issue haven't been allowed but will see what evidence comes in on cross or rebuttal

- issue goes to profit, not getting into profit per se and try to keep this out but Mr. Jordan questions were a little more general, losing Prozac

8:38:34 AM Lehner – need to focus on system, nothing not do with warning

Court - happen to look at limiting instruction

- will deny striking first 12 pages of Mr. Jordan testimony but will consider a limiting instruction

8:39:55 AM Allen – rejected fax of my offer, how to mark it

- court ex. 1

Court – do not care but make clear record

- call it plaintiff exhibit, not admitted but plaintiff exhibit to make clear record, on cuts that I have ruled on
- did make record as I rejected portions, each document handed to you on objection I wrote sustained and are part of the record if sustained the lines and page number, might already have record

8:42:11 AM Allen – marked it 1061

Plaintiff 1061 is the plaintiff listing of those portions of the Jordan deposition that I sustained objections to and not played for the jury

Court – 1061 is the exhibit number, reading

Allen – offered and to be answered individually

06-05630CI

- mood, thought, and behavior is on the label and treat anyway, Ms. Gussack said

Gussack - Dr. Hobson to take stand, proffer

- Lilly is sensitive to what is being solicited here and Eski
- Nora Pennington issue
- Remoteness issue, Allen evidence reference as result of Eski testimony date back to 2003, no evidence in record to suggest any activity since that time
- To suggest impact by Lilly conduct of 2003 to current state action is misleading
- State never had Hobson on their witness list, scope of testimony

Allen - will not talk about lobbying an if I do they can object

Court - cross can develop

Allen - if too remote they have Ms. Eski

Court - will take Dr. Hobson

Allen - video deposition first

Jamison - rule 81 obligation, may not be in court at times, excused

Court - fine, the professionalism and skill is high rate, continue to act as you are and you have leave from me top come an go

- will check on jury

8:49:19 AM

Off record

9:28:21 AM

On the record

outside presence of jury

Court - just as we were to resume Mr. Venhuizen suffer a heart attack, paramedics, JS and police called

- he has been taken to the hospital, seems like he will be ok
- ready, or

9:29:20 AM

Fibich - ready if the juror's are

9:29:29 AM

Gussack - application in chambers outside of courtroom on the affects of this

Fibich - why not in here

Gussack - coverage of this jury to media

Fibich -

9:30:24 AM

Sidebar begins

9:36:07 AM

Sidebar ends

Court - on record in chambers

- will question juror's in chambers, individually

9:37:46 AM

In chambers interview with juror number 2, Ms. Wallace

9:40:54 AM

In chambers interview ends

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9:41:59 AM In chambers interview with juror number 3, Mr. Bennett
9:42:25 AM In chambers interview ends

9:43:21 AM In chambers interview with juror number 4, Ms. Steed
9:44:05 AM In chambers interview ends

9:44:38 AM In chambers interview with jury number 5, Ms. Mitchell
9:45:23 AM In chambers interview ends

9:45:50 AM In chambers interview with jury number 6, Mr. Seiser
9:46:38 AM In chambers interview ends

9:47:14 AM In chambers interview with juror number 7, Ms. Ilutsik
9:48:04 AM In chambers interview ends

9:48:52 AM In chambers interview with juror number 8, Mr. Glatter
9:49:43 AM In chambers interview ends

9:50:33 AM In chambers interview with juror number 9, Mr. Maggard
9:51:48 AM In chambers interview ends

9:52:16 AM In chambers interview with juror number 10, Ms. Feuge
9:53:06 AM In chambers interview ends

9:54:02 AM In chambers interview with juror number 11, Ms. Sand
9:54:36 AM In chambers interview ends

9:55:32 AM In chambers interview with juror number 14, Mr. Guillen
9:56:10 AM In chambers interview ends

Court - all remaining jurors have been question on this incident and the fact some of the witnesses rendered aid, all jurors said nothing would affect their ability to judge the witness
- application for mistrial is denied

9:57:45 AM Parties arriving back in courtroom

9:57:59 AM Off record
10:02:38 AM On the record jury is present

Court - Mr. Venhuizen is excused
- will resume with evidence
- will relay information on this juror as I get it
- will get a card to be signed by all and deliver to him
- ready

10:04:11 AM Allen - yes, will call by video take Joey L. Eski

10:05:22 AM Video deposition of Joey Eski, begins
Video ends at 10:11:31

10:11:31 AM Lehner - may we approach

10:11:40 AM Sidebar begins

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10:15:37 AM Sidebar ends

10:16:12 AM Video deposition of Ms. Joey Eski resumes

10:38:55 AM Video deposition ends

10:40:17 AM Court – Eli Lilly

Lehner – reserve right to play portions in our case

Court –

10:40:34 AM Raymond Hobson, sworn

10:40:46 AM Direct Exam by Mr. Allen

(never met)
(never spoke before)
(psychiatrist, Medical Director at Alaska Psychiatric Center)
(education listed)
(general psychiatry is four years and fellowship is another 2 years)
(Timberline General Hospital, Dallas, Texas from 1990 to 1996)
(duties)
(Fairbanks for three years, in Fairbanks I was at Fairbanks Memorial Hospital, Medical Director, Mental Health Unit)
(20 bed all adult unit, ages 16 and up)
(patients came in involuntary and it is a lock doctor facility)
(did administrative duties as well)
(API medical director, 80 bed facility, only state mental health facility)
(primary administrative at API)
(responsible for all clinical services, meaning treatment)
(deposition three months ago)
(President of Alaska Psychiatric Association)
(in addition I'm lead psychiatrist in pharmacy for State of Alaska)
(we do treat acute schizophrenic patients, often times)
(we hope so)

10:50:40 AM Gussack – objection/rephrase

(due to our specialty training, yes)
(familiar with package insert, yes)

10:51:38 AM Sidebar begins

10:52:17 AM Sidebar ends

10:52:24 AM Resume with Direct Exam by Mr. Allen

(yes, important to me as the PDR is large book that is updated every year telling us of the chemical make up of drug, etc.,)
(and gives warnings and adverse side affects)
(broken down to frequent, rare etc.,)

10:54:24 AM On screen use of opening statement by Eli Lilly

06-05630CI

Gussack – may we approach

Court – sure

10:54:38 AM Sidebar begins

10:55:12 AM Sidebar ends

On screen use of opening statement of Eli Lilly, reading

(yes, when prescribing you have to weight all risk and benefit, yes)

(I would like more information)

(comes down to doing best thing for patents and we need to be given all information so we can make correct decision for the patient)

(absolutely not as it puts you at disadvantage if you do not have all the information, as they learn and understand)

10:57:49 AM Gussack – objection/will allow

(diabetes is bad for me, yes)

(no, I would not)

(they should be making us aware not eliminating the concerns to make us ignore the risk)

(she is resource for us, sale representation)

(I do expect them to be truthful)

(Ms. Eski is very nice person, not here to disparage her)

(UTPA and Consumer Protection Act, no)

(no duties under this Act)

(Attorney general enforces the law in Alaska, yes)

(no)

(do not oppose Assistant Attorney General actions in this filing against Eli Lilly)

(on they have not)

(2007 label, not that I recall)

(no, I have not)

(I have recently)

(yes, I think so, different treatment nowadays)

(acute or chronic schizophrenia and bi-polar disorder)

(need to be careful to group into that, mood, thought and disorder)

(acute is early onset of symptoms and some one with chronic is person who has had it for years)

(Abilify, Geodon, Clozapine etc.,)

(look at risk factors, we do)

(warning in the insert would be important to make this decision)

11:06:31 AM Reference screen and Dr. Hobson's deposition

11:06:48 AM Gussack – objection, impeach/do not need this deposition to ask the question

11:07:19 AM (well we have to always weight the risk and benefit)

(first line therapy and prefer to use drugs with less risk and see if that is effective for the patient)

11:08:55 AM Court – leading

(yes)

(Zyprexa as first line, yes)

(subset of patients, yes, patient who doesn't respond to medical with less profile)

06-05630CI

(some one hearing voices, or paranoid delusion and or thinking someone is out to harm them and they can act out aggressively and self-destructive)
(need to be informed of the risk of a drug, yes)
(after explaining the risk of Zyprexa some families do refuse this drug)
(we do an it does make a difference)
(we do prescribe Zyprexa but we also monitor the patient)
(we now obtain weight and baseline sugar, lipid levels at time of coming in the hospital)
(and if they come back later we compare, monitor)
(we know people who take Zyprexa have a high risk of developing high fasting glucose levels)
(base line blood glucose is if a patient is not taking medication we take baseline in the morning)
(gives us level before drug or food, good baseline)
(Zyprexa raising this baseline and would not be best choice for them as it makes diabetes worse or pushing them into Frank diabetes)
(reason

11:14:20 AM Court – frank diabetes

(frank diabetes is term that establish the symptoms)

11:14:53 AM Continue with Direct by Mr. Allen

(not always the case but since October 2004 we have done it this way)
(hired new doctor and her new protocol and the risk of this medication)
(did not use this procedure at first at API or while at Fairbanks

11:15:48 AM On screen is AK ex. 2368 – ID

(have seen this)
(yes, February 2004)
(use by us, yes., recommendation listed are standard protocols followed now)
(have seen this table before, authoritative and agree with it)
(correct and is what we do at API)
(that is the recommendation, specific intervals but length of stay the follow up is done by outside providers)
(average length of stays at API is 13 days)
(must be monitor, standard for antipsychotic medications like Zyprexa)
(before 2004, the never told us to monitor blood sugar)

11:20:49 AM Court – average length is 13 days and if on this drug for 13 days and if relieving their symptoms of schizophrenia

(outpatient provider and we convene the medication they are on and for them to do monitoring)

11:21:24 AM Continue with Direct by Mr. Allen

(protocol is standardize treatment process to be don, process)

11:22:33 AM Ex. Ak 320 referenced on screen

(Japanese warning)
(yes, before monitoring of blood, yes)
(not that I recall)

06-05630CI

(not that I recall)
(I do see that)
(but not before fall of 2004, correct)
(measure blood glucose, what we do now, but prior to this Eli did not tell us and at the time we did not do it on a regular basis for Zyprexa)
(we do explain this today and then some families refuse this medication)

11:25:52 AM Gussack - objection, sidebar

11:25:58 AM Sidebar begins

11:27:03 AM Sidebar ends

11:27:08 AM Continue with direct by Mr. Allen

11:27:32 AM Gussack - objection to word wish/change the word

(I do think today protocol is better than used to be, to monitor for side effects)

Court - kind of loud Mr. Fibich

(it achieves consistent monitoring of the recommended blood value for dangerous side effects)

11:29:18 AM AK ex. 7971 - referenced

(do not think that is appropriate)

(I do see where they say no monitoring and I disagree with that)

11:30:32 AM AK ex. 5846 - referenced

11:31:02 AM Gussack - objection, admitted or not/admitted

(I do see that)

(do not)

(danger to patient without blood monitoring, they could be developing diabetes and other side effects and not be aware of it)

(in 2006, not for those side effects)

(not that I recall)

11:33:19 AM On screen, 2001 PDR

(big book, correct)

(you did read that correctly)

(it does make it appear that way, if you were to read this Olanzapine would not increase random glucose levels, like placebo)

11:36:58 AM Gussack - objection, leading/answered but go on

11:37:21 AM Gussack - repeat the

(it could be construed)

(no)

(have seen this letter from FDA to Eli Lilly, yes)

06-0563

11:30:20 AM Gussack – no testimony on him seeing this/early on he asked doctor about seeing it and he'd get back to it

Allen – this is it

Court – not sure if this is the document nor not

Allen – showing notes to Gussack
- ex. 195

Gussack - do not recall

Court - recall he indicated he previous seen but not sure when

11:39:31 AM Continue with direct by Mr. Allen

11:39:36 AM Reference AK Ex. 195

(yes)
(I do see that and I agree that language in the 2001 PDR is reassuring)
(implied safety with Zyprexa, yes)
(inconsistent with my experience and Zyprexa)

11:41:51 AM Gussack – objection/overruled

(yes)

11:42:19 AM AK ex. 990 – referenced

(not provided this document, nobody from Eli has)
(I do see that)
(yes)
(meaningful information, I do)
(I do)
(it is inconsistent)
(yes, they should share all information they hve)
(absolutely to make an informed decision)
(even if they disagree)
(January 2001)
(not that I recall)

11:46:30 AM AK ex. 7802 – referenced

(HGFU study,

Court – ex. number

Allen – 7802, reading from

(non-fasting high glucose, yes)
(I do see that)
(code is A, I do see that)
(by summer of 2002 nobody came to me with evidence in elevation of blood glucose, not that I

06-0563002

recall)
(but information I would like to have, I would)
(allows me to make an informed decision)

11:49:54 AM Ak Ex 10094 – referenced

(symbyax is combination of drugs)
(correct, greater than)

11:54:00 AM AK ex. 10094, 988 and 7802 - referenced

(we do)
(it does as it means that is a problem, does occur)

11:55:13 AM Court – will break
- admonishment to jury

11:55:37 AM Off record
12:19:58 PM On the record Jury is Present

Court –

12:20:04 PM Continue with Direct by Mr. Allen

(you did read this correct, ten fold increase from Placebo and Zyprexa)
(we would first attempt to treat different, chose medication with the lowest side affect profile)
(reason for warning section being so important)
(is causal related, yes)
(can take decades to see affects)
(best to inform patient right away, they are people not numbers)
(yes, understand you represent State of Alaska)
(diabetes is serious condition)

12:24:28 PM Gussack – objection, is that a question/thank you, it has been withdrawn

12:24:42 PM (no, he did not show that to me at my deposition)
(significantly more information that ever, yes)
(you did read that correctly)
(that is correct)
(consistent pattern developing)

12:27:37 PM Ak Ex 10095 – referenced

(Dear Doctor letter, not seen this)
(30 to 50 pieced of mail a day from many companies)
(March 2004 letter, yes, think I remember)
(label affected my practice, yes)
(comparable rates, yes)

12:30:59 PM Eski deposition ex. 8 – call note, placed on screen

(from November 14, 2001)
(FBMH is Fairbanks Memorial Hospital)

06-0

(Locum means traveling doctor)
(yes)
(do not recall the handout but they did leave me handouts)
(yes. 0.6 comparable rate, yes)
(but different than my experience now, yes)
(yes, when they admit something it matters to me, it does)
(reason for warning on a drug, yes)
(continuum, yes)
(not that I recall)
(yes, it's a good idea for them, Assistant Attorney General, to seek information)
(I would want to present as much information as I could)
(Assistant Attorney General hiring you to pursue this litigation, no, I'm not opposed to this)
(familiar with diabetes, yes)
(yes)
(yes, familiar with consequences of diabetes like leg amputation etc.,)
(blood monitoring)
(and strict diet)
(no, I do not)
(frontal lobotomy, technique used years ago to control aggressive behavior, not really done anymore, very rare)
(if you take Zyprexa off the list would they need frontal lobotomy, no)
(no, that is outlandish and would say that is false)
(much different now than a year ago)
(think there are)

12:45:18 PM Gussack – objection/overrule

(think it has been developed in patient who took Zyprexa, yes)

12:45:43 PM Cross Exam by Ms. Gussack

(subpoena yesterday or day before)
(had counsel at deposition, Mr. Sniffen, AAG and Mr. Steele, back row)
(yes, met with them for today's testimony)
(no)
(March 2006 lawsuit)
(at deposition I knew nothing)

12:47:10 PM Allen – if impeaching, improper, may we approach

12:47:18 PM Sidebar begins

12:48:00 PM Sidebar ends

Continue with Cross by Ms. Gussack

(that is correct)
(correct, read about this lawsuit in newspaper)
(correct)
(American Psychiatric Association, yes)
(oversee psychiatrist, yes, and care for patients)
(we began seeing it after using it and as early as 1996)

12:50:59 PM Allen – page and line, page and line, objection/overruled
3AN06-05630ci-03-12-08

- questions of lawyers is not evidence
- admitted and it can be used

1:15:49 PM EL 176

1:16:13 PM Allen - same objection, offer of proof
Gussack TG 176
Allen - no exhibit sticker or even
Court - 3896A
Allen - did not see, not offered
Gussack
1:17:37 PM Allen - objection it being on screen
Court - do not show until admitted
(do not recall this letter)
Allen - not able to cross
Court - get in through somebody else
(can't recall specific conversation about this)
(internal Lilly documents, correct)

1:19:52 PM Sidebar begins
1:20:44 PM Sidebar ends
(all of them, I do not know)
(studies done by Lilly on Zyprexa, no idea)
(blood glucose studies done by them, no)
(believe I have seen that, if that is the documents I saw earlier)

1:22:42 PM September 2003 label on the screen for jury view, EI2953-A
(yes)
(yes, diabetes in general population as is obesity)
(that is my understanding)
(yes, monitoring patient who use atypical antipsychotic drugs, standard part of admission)
Court - will stop now,
- admonishment to jury
- there is an article on the web on the incident this morning, do not read

1:28:41 PM Outside presence of jury
Court - will resume tomorrow with his witness

In the Superior Court at Anchorage Alaska

Media No: 3AN4308-52

Judge: M. Rindner

Date: Tuesday, March 11, 2008

Clerk: M. Borneman

Case No: 3AN06-5630

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial – Day Seven

Counsel Present:

Plaintiff: David Suggs, Esq., Tommy Fibich, Esq., Scott Allen, Esq., and Mr. Sniffen

Defendant: George Lehner, Esq., John Brenner, Esq., Ms. Nina Gussack, Esq., Mr. Kantar, Esq. and Mr. Brewster Jamison, Esq.

Court Orders:

Summary of Proceedings: Jury trial resumes March 12, 2008 at 8:30.

8:33:26 AM

On the Record

Outside Presence of the Jury

Court – orders on the designation and objection to trial deposition and ex as to Joey Eski I also revisited and sustained an objection on Tollefson

- on Eski testimony of Lilly's lobbying efforts, exempt from the formulary requirement

Allen – they tried to carve out Zyprexa and all mental health drug from review from the Pharmacy Review Committee

Court – will use that

- open access, thank you, did not believe Nora Pennington, warning claims but not evidence, I suggested the question as to warnings in this lawsuit, do not understand theory on this, as to warning claims

Allen – it doesn't but their claim the state has done nothing to restrict the drug

- rebuts their defense

Court – not heard their evidence on this

8:37:40 AM

Allen – when they say something to the jury that the state has not done anything and that people come to court everyday to get this drug administered the door is wide open by their statements to the jury

- rule 104(b), rules of evidence, additional relevant evidence can be admitted when tied together

Court – tie together when they testify

Allen – statement to the jury, entire opening argument that the state

Court – its argument.

Allen – and we want to prove the State of Alaska regardless of deceit, fraud, misrepresentation,

06-05630

and plaintiff says bias as they met with lawyers, argument, sounds like 403 material

- confusing to jury as people are free to speak with attorney

Allen – ex employees listed, if witness comes in and give testimony adverse to me, that can be damning to me and goes to credibility of witness

- if they say they met with the lawyers on numerous occasion and then I get adverse testimony, the inference is because he met with all these people
- witness testimony has been affected by this relationship
- 24 years, this is he way I have done it

8:52:11 AM Lehner – Rule 613, foundation be laid and give opportunity

- Dr. Hobson, we have their witness list, not in there
- Prejudicial to do this now, trial by ambush

8:53:05 AM Court – not surprise to me as Dr. Hobson was known to be a witness

Allen – deposed

Court - talking about order of presentation

Lehner – they did not question him at deposition

Allen – our right

8:53:40 AM Court – no surprise here as this witness was to testify

8:53:57 AM Lehner – not a surprise but prejudicial as not on their witness list

Court – will allow Dr. Hobson to testify in their case in chief

- ruling stands on talking with lawyers before deposition
- testimony on off label, as it relates to other issues in this case, maybe relevant to rebuttal
- understand deposition done when this was still an issue in this case an I do find this is difficult way to parse this out, explain to me
- most goes to off label

8:56:08 AM Allen – demonstrative exhibit being used

- not asking to go into off label matters but prove my claims under Alaska UPTA, and failure to warn
- who did they violate to Alaska or some doctors
- we say as to all doctors
- risk and benefit of product for all doctors who use this drug, admissible

Court – this is how I'm looking a questions

Allen – entitled to put in evidence of risk and benefit

- they have told you when looking at risk side you have to look at all information from Lilly to prescribers
- benefit side of equation, is different depending on prescription

Court – understand

Allen – primary care doctors prescribe Zyprexa and Ms. Gussack told the court and jury and they said for on label purposes

06-056301

- PCP campaign is for on label issue and PCP doesn't mean off label, their own admission
- 30 percent is used for other than Schizophrenia
- I accept her argument for introduction of evidence and I can present evidence on what Lily said and did to all doctors on risk and benefits including PCP doctors, on label
- Risk listed
- To include mood, thought and behavior, not off label campaign
- Ask them if mood behavior and thought is within the label, ask them

9:03:29 AM Use of Elmo – on screen

- reading from their opening statement
- reading from deposition of Jack Jordan
- when looking at the PCP and weighting this equation we have to look at what this company knew and their conduct to affect this equation

9:08:47 AM Court – portion of Mr. Jordan deposition, currently ruling is its in

Allen – yes, and looking to strike, but currently in

Court –

Allen – think on label not off label

- reason for barrier of PCP is aversion to risk
- Viva Zyprexa campaign
- Mood thought and behavior disturbance, on label bi-polar statement
- Do not think off label but on label, entire launch was for approval for bi-polar, think on label
- Do not just look at the label

Court - I remember

Allen – but sharing information and not just relying on the label

- emphasis safety and ease of use, reading from...

Court - and this is all

Allen – but struck the testimony

- Mr. Bandick testified that they marketed this drug for people as mood stabilizer and its not off label
- Ask them the question is mood, thought and behavior on label

Court – then why hasn't this testimony come in yet

- I saw it as efforts as Lilly doing things off label, but if on label it is, why isn't it in

Benner – it is on label, element of state case, they want to back door us

- this is on label, and will stipulate

Allen – stipulate to it

Benner – then comes out for both sides

Allen - will not content its off label

Court – lot of what I struck was for, only able stuff an I struck it

06-0560

Brenner – no longer germane

Allen – they agree any document with mood, thought, etc., should come in

Court – jury could hear the stipulation

Allen – 3x3 campaign/message, clear this is mood, thought and behavior, safety and ease of use

- they over emphasized the benefits, 1996 FDA letter, balance
- FDA said the labeling piece obtain violations, lack balance as to adverse events and misleading impression of Zyprexa – Viva Zyprexa campaign
- Entitled to show not to warn, unfair balance and mis-characterize their drug

9:19:26 AM

On screen

- what if doctor say they do not see these kind of patients, but do for behavior, mood and thought disturbance, on label

Court - document is in and taking out is separate

Allen - understand

9:21:25 AM

Reference Ms. Gussack opening statement on the screen

Allen – reading from

- I beg this court to go back and look at Torres, Bandick, and Mr. Jordan and see where you struck and if you struck claims of mood, thought and behavior disorder – its on label
- I want evidence of what they said on risk and benefit
- What did they say about children and Alzheimer
- Dr. John Lechleiter March 2003 memo

9:24:02 AM

On screen

- reading from
- initial ruling on this doctor was to allow me to bringing this evidence and they ask you to reconsider, and you struck it
- did the right thing the first thing, not off label

Court - sounds off label but when I strike questions, regardless of current positions, sounds like might have been off label

Allen – did not put them in a box, jury is going to be asked this questions, adequate warning

- Denise Torres will admit 40 percent of use is off label, not promotion but they knew this
- Used in children
- 500 million a year, duty to warn doctors

9:27:35 AM

Court – if Torres testimony, is as he relates it, 40 percent off label, doesn't that change the benefits depending on use

9:28:44 AM

Brenner – some doctor thinks it useful for common cold

Court - not worried about doctor and his min but what Lilly says is going on with off label

9:29:24 AM

Brenner – off rack on risk/benefits

- adequacy of warning is phase one
- and this is how a doctor uses or doesn't use the warning
- proximate cause not adequate

Court - but opening statement suggested that this had to be looked at in context for what it does for people and if that is the defense you have to know what people are using the drug

Brenner – he said eliminate the risk, reading from their opening

- but opening argument is not evidence and reason for rebuttal case, not their case in chief

Allen –

Brenner – not under Alaska law how it is analysis

- impact of warning from doctor, not this phase
- on label use is not part of their case, not an element of the case and no need to prove this
- they want to drag in this off label, back door way after your ruling

Court – if you did not violate the law, on label, do you not have to know the risks were adequately disclosed for the use of the pill

Brenner – indicated uses, yes

- off label is legal right of doctors, not in the case

9:33:24 AM

Allen – read the quote, issue of warning is how physician uses the warning

- benefit outweigh risk in particular patient
- we did not bring this issue up but they did
- with each patient, every time
- 4.6 million
- talking about Alaska UTPA, protect consumers and they have duty to tell the truth

Court – evidence become relevant is a timing issue

- give me cite to Torres where I struck the off label, I will reconsider that portion of testimony but will adhere to prior rulings and keep this information out from being played
- might be proper grounds for cross examination and may come in on rebuttal
- fine line giving here on what is to be brought up with
- goes to establish of label, despite positions, how I read questions and interject this into the case, not do so on warning
- give me cite and I'll look at it

Allen – mood, thought an behavior and you stand by the decision of Jordan

Court – when I read this deposition, I thought I should of waited

Allen - this morning by tape

Lehner – told Beasley first and then Jordan not on the list,

Allen - email about Jordan, yesterday

Lehner – and we have objections

Court – ruled on Jordan other than the reconsideration

Lehner – order of proof, Hobson coming tomorrow, do we need witness by end of this week or not

Fibich – no, do not need witness for this week

Allen - 24 hour notice given

Fibich - quasi non label yesterday in the PDR

Court - PDR, has defense reviewed

Gussack – no, and we object to PDR, not label

Court - question from juror to read this

9:41:32 AM Gussack – publication date

Court – wanted PDR label read

- will look at Jordan and make rulings
- objections from on Brier, when is he going to be used

Allen – next to last witness, you have time

Court – ruled on Tollefson

- but another one with five cuts, somebody with a T in the name, where's that witness

Allen – Sidney Taurel, will not play him

Court – will read Jordan

- have at least ten minutes

9:43:41 AM Off record

9:56:28 AM On the record Outside Presence of the jury

Court – Reconsidering for Jack Jordan, overrule all objection

9:57:18 AM Off record

10:02:13 AM On the record Jury is Present

Court -

10:02:50 AM Sidebar begins

Sidebar ends

Court – good morning

- will be out of here today by 1:30
- video tape deposition today, instruction given

10:05:04 AM Allen – adviser witness, Jack Jordan, USA marketing director for Eli Lilly

10:05:24 AM Video deposition of Jack Jordan, starts

3AN06-5630CI-03-11-08

10:13:51 AM Jury – text is out of focus
Allen – will publish when this is over

10:14:13 AM Video deposition continues of Jack Jordan
10:27:28 AM Video deposition stops
Allen – publication of previous admitted ex. 5073
Court – show to other side and make sure they are from previous rulings
Lehner - good
Court – subject to previous objection
Allen - plaintiff ex. 5073, 8479, 5846, 8632, 284, 1301, 9739
- Mr. Jordan is complete
Court – Lilly to reserve further examination for later
Lehner – yes

10:29:34 AM Sidebar begins
10:30:05 AM Sidebar ends
Allen – next video deposition
Suggs – Charles Beasley, July 26, 2006 deposition

10:30:40 AM Video starts
Court – video stops
- do we need break

11:22:44 AM Allen have about 40 minutes
Court – will break for 15 minute

11:23:01 AM Off record
11:48:34 AM On the record Jury is Present
Court – resume

11:48:50 AM Video deposition of Dr. Beasley resumes
12:25:40 PM Video deposition of Dr. Charles Beasley ends
Allen – publish to jury
Court – defense to play
Lehner – when we do our case
Suggs – AK6090, 8042,

- 1349, 1605, 988, 6998, 4858, 1449, 1453, 195, 990, 5565, 6128, previously admitted and request to publish

12:27:13 PM

Sidebar begins

12:27:59 PM

Sidebar ends

Court – base on previous ruling 6090, 8042 are both admitted and other s referenced maybe published to he jury at this time

Allen – Robin Wojcieszek is 49 minutes

12:31:08 PM

Video deposition of Robin Wojcieszek starts

1:24:17 PM

Video deposition ends

Suggs – move to admit and publish

Court – end the trial day

- 8:30 tomorrow
- admonishment

1:25:55 PM

Outside presence of jury

Court – Mr. Suggs

Suggs – tomorrow

Court – Lilly objection to Dr. Brier on the pages dealing with counter designation, jus the checked ones to be included

Lehner – yes, highlight did not turn out

Allen – can work with them tomorrow on this

Lehner – agenda

Allen - Dr. Hobson and depositions of Eski but will view ruling and may hold off
- Dr. Lechleiter, Tollefson and Bruce Kinon

Court – rulings made as to them but for Hobson

1:28:29 PM

Fibich

- notebooks on PDR, marked as 10160, offered

Lehner – will look it over tonight

Court – copies of PDR through the years for jury, will give time to look at

Fibich – stilled offered

Court – look at it as to completeness but going to jury

Gussack – evidence as to why PDR as more confusing

In the Superior Court at Anchorage Alaska

Media No: 3An4308-51

Judge: M. Rindner

Date: Monday, March 10, 2008

Clerk: M. Borneman

Case No: 3AN06-5630Cr

Case Title: State of Alaska

Vs.

Eli Lilly Company

Type of Proceeding: Jury Trial – Day Six

Counsel Present:

Plaintiff: Scott Allen, David Suggs, Esq., Tommy Fibich, Esq., and MR. Sniffen, AAG

Defendant: George Lehner, Esq., John Brenner, Esq. and Ms. Gussack, Esq. and Mr. Kantar, Esq., and Mr. Brewster Jamison, Esq.

Court Orders:

Summary of Proceedings: Trial continues to March 11, 2008 at 8:30am, jurors will arrive at 9:30am.

8:27:32 AM

On the record

Outside presence of Jury

Court – list case and parties

- Ms. Shepherd had tooth issues at voir dire and is home with problems and will be excused
- Motion to Intervene and unseal records from Bloomberg News
- Plaintiff do not oppose but defense do

Fibich – yes

Gussack – not seen the motion

Court – services indicates hand delivery to Mr. Jamison and Mr. Sanders

Gussack – not seen this

Court – by Davis Wright, will wait for opposition

- Saturday and Sunday met with parties and obtained deposition designation and made rulings and distributed to parties
- Jack Jordan, Bruce Kinon, Denise Torres, Michael Bandick, etc
- Ruled on all those and what is to be include and what exhibits are to come in and what objections overruled or sustained
- State filed letter memorandum on certain objections and rulings, as to what evidence I'm allowing in on off label usages and Eli has filed response to this, will take this up end of the day
- Just wanted to make record on the material received this weekend
- My understanding is there are two claims
- Common law, products liability and the UTPA where state issuing on its own behalf but also suing as sovereign and seeking injunction under its authority

Allen – yes

Brenner – legal issue presented but not seeking injunctive relief

7:00:00-00

Court – seeking civil penalties
Brenner – yes
Court – judge or jury question, who decides this
Brenner – thought it was with the court, not the jury

8:35:12 AM Sniffen – tricky question...
Court – reason for it
Court – rule on penalties is for the judge, but set by statute
- specific act subject to penalty is another questions
Sniffen – case

8:36:15 AM Court – might have to make findings and that doesn't have to be answer now but does by the end of the case.
- plaintiff case done by Monday
Fibich – this week
Court – and defense is how long
Lehner – four or five days

8:37:32 AM Allen – put the Dr. Gueriguian and discuss this afternoon
Court - by Monday on who is to decide what and do I make findings , etc.,
- this afternoon for the issues in the letter filed by the state an the response, plus scheduling
Lehner – another letter at noon yesterday and we have response
Court – will wait for original

8:39:20 AM Fibich – additional exhibits to add into evidence, 1941

8:39:59 AM Court – offer these with Dr. Gueriguian
Lehner – relevance objection filed
Fibich – has to due with diabetes
Court – 1941, overrule the objection and allow the exhibit, admitted

8:41:06 AM Fibich – 7971
Court –

8:42:03 AM Fibich – dealing blood monitoring
Court –

3An06-05630CI-day6, 03-10-08

06-05630CI

8:42:27 AM Lehner – relevance objection and
Court – overruled and admit 7971
Fibich – move to admit 3387
Court – 3387, admitted without objection
- ex. 9739, admitted
- 1961, admitted
8:46:37 AM - another juror called in, not sure who but advised us she has bone marrow cancer, will try and find out who..
Fibich – have to go as Dr. Gueriguan son is getting married
8:47:22 AM Court - if we lose one
8:47:41 AM Off record
8:56:56 AM In chambers interview with Ms. Mitchell, begins
8:58:52 AM In-Chambers interview ends
9:13:04 AM On the record Jury is Present
Court – good morning, juror number 12, Ms. Shepherd, has been excused
9:13:38 AM Fibich – recall Dr. Gueriguan
9:13:57 AM Dr. John Gueriguan, previously sworn
Direct Exam continues by Mr. Fibich
9:14:31 AM Ex. 10094
(this is the post New York Response by FDA to the article alleged, involving atypical antipsychotic, Zyprexa)
9:15:24 AM Brenner – objection/ if you know
(I do, as FDA thought this article was important)
(now FDA letter, 100094, reading)
(February 20, 2007 response to our January 12, 2007 letter on this article is not helpful in these concerns)
(number one, FDA has decided the safety information is not complete)
(number two, justification on safety information and completeness is biased as we have to inform prescribers
(number three, need all information from all clinical trial on Zyprexa, etc..)
(and explain any and all difference in the label in the USA and foreign countries)
9:19:37 AM Fibich – publish 10094 to be published, on the screen
9:19:51 AM Ex. 9739 – referenced
(Project BAD, August 2, 2002, yes I do)

06-05630CI

9:20:48 AM (amount budgeted is 10 million dollars)
 Brenner – objection/allow

(to be approved they have to be overstated, if that is the case an the second part is to reduce the negative aspects of what is know)
 (Eli found out 100 percent of physicians were concerned on prescribing Zyprexa due to Diabetes Mellitus)
 (inconsistent as document inform last week said fair and balance, do not overstate your advocacy)

9:23:13 AM Fibich – move to publish

9:23:26 AM Ex. 7971 – referenced, on screen

(yes, concerns, primary resource guide)
 (low risk for certain serious medical complication. Over five million given, not true and overstates the safety)
 (page two, that is true)
 (they are saying major selling points of Zyprexa, doctor viewpoint, saying no blood monitoring is necessary)
 (they are not, they are saying no blood sugar monitoring)
 (weight gain, hyperglycemia, diabetes, no its not)
 (because in this case it's the wrong thing to say a you do need blood monitoring from the very beginning)
 (short of going into Ketoacidosis)
 (methods available and very implication of patient and not expensive, everything is fine)
 (mainstay of public protection)
 (major essential test and introduce by Japan to find diabetes)
 (down laying of the risk of diabetes, its worse as you do not allow prescriber to find risk)
 (down playing is to say if below a certain level, etc..)
 (page 12, that is correct an Eli tells doctor's no, not appropriate)

9:29:21 AM Fibich – publish 7971 to jury published

9:29:45 AM Ex. 1941 – referenced

(Frequent area of concerns or FAOC, I do see this)
 (sales people being advised of question that would be asked of them)
 (reading answer into the record)
 (not fair balance, no)

9:31:59 AM Fibich – move to publish 1941 to jury/ you may

(yes, that did catch my attention - Get back to selling)

9:32:46 AM ex. 3387 – referenced

(I do have it)
 (hyperglycemia and diabetes resource guide, it is
 (page five, I do)
 (reading)
 (no)

06-05630CI

9:38:23 AM Brenner – objection/sustained
(yes, imperative that physicians concerns are being addressed by Eli, reading from exhibit
(neutralize adverse event and its improper)

9:40:13 AM Brenner – objection/overruled
(FDA doesn't want anyone being rewarded in research of saying something that is not true)
(page seven, if it addresses a concern with tools and data, nothing wrong, but if its neutralizing a
position, its inappropriate)

9:42:13 AM Fibich – we pass this witness

9:42:18 AM Cross Exam by Mr. Brenner
(good morning, sir)
(Pharmagenesis, yes, my company I run from the home)
(yes, testify and I have always been open to any client)
(not many defendant's asking for my expertise)
(I charge 600.00 an hour and I have no idea how many hours I have in this case)
(60 hours...might be 63 hours at that time)
(has been more since, no idea)
(testified many times in court, yes and given depositions)
(internal documents, yes, not sure who showed them to me but clients obtained me is Allen,
Suggs an Fibich)
(do not interpret but base answers on facts)
(no need to and I haven't)
(yes, realize nobody can read all that - millions of document)
(no, state attorney, not sure of his role but clients through them I have been given number of
documents and I told them up front if they accept my conclusions right or wrong)
(both, need to be objective)
(when I got these documents I spent large amount of time doing research on my own, analysis
both sides of question to find out who is right and wrong)
(choose a number of them for their pertinence)
(did not ask you side for any documents)
(find out from literature opinions that agree with one side or the other, to be objective)
(must be kidding)

9:47:57 AM

9:48:56 AM Ex. 10131 – referenced
(page ten, exhibit B, and this is exactly what I'm talking about, important part)
(put aside what was not pertinent and did review many more, but mainly these four but others)
(selection I used here is contribution to clarify scientific matters)
(not for all bi-polar disorder)
(and its an overview on Olanzapine)
(yes, yes, yes, these approvals done at different points of time)
(maybe but overview is not something that is comprehensive and boring)

9:53:07 AM 2954
(package insert for Zyprexa, yes)
(yes, for psychotic disorders, correct)
(yes, Japanese shared that opinion)

(Zyprexa cause diabetes, my opinion, hat treatment emergent hyperglycemia/diabetes have been show to my satisfaction as being more with Olanzapine as to other psychotic drugs)
(have review the Lily documents where comparisons were made, 1995, MDA sent to FDA and at that point the difference between Zyprexa as to other atypical and it got clearer and clearer and Lily given time and by end of the day 100 percent of prescribers was aware of the link with this drug and diabetes)
(Janssen, why)
(saw evidence to this affect)
(not that I remember)
(Quetiapine, not that I remember)
(Abilify)
(did not have access to the rest and can't be expected to have read)
(more than that)
(Dr. Brancati, do not know him personally, noting to do it but reviewed both sides of question to arrive at solid, objective answer)
(Lilly generated documents and I review other evidence where the issue was no addressed satisfactory to the author)
(not all studies can come to conclusions, and Lily did not do the proper studies)
(sir, medical officer in charge of Zyprexa did not, how can I as I did not have access)
(did not read entire MDA)
(two things apparent to me in those documents, proper studies not done and Lily says themselves, internal and external, there is no difference between placebo and Zyprexa)
(nobody of competence believes that)
(if Lilly says that in head to head comparison there is not side of hyperglycemia or diabetes and that is wrong statement to chase a wild goose)

PG1295, on the screen

10:03:15 AM

(may have, no not remember)
(do not remember reading but read other articles)
(Dr. Henderson, do not remember)
(Dr. Leslie and most I have not read)
(Dr. Lindenmayer, may have but do not remember)
(defined by pharmacology, my discipline)
(no association but correlation)
(may or may not be right but general speaking this is what experts believe)
(no hear when the good doctor made that statement, Dr. Brancati)
(gray hair an old age, causation and correlation)
(correlation doesn't, that is what people say)
(need to do studies that cause causality)
(correlation doesn't cause causality and can tell you how this can be done)
(risk factors can be dependant or not)
(risk by adding something or independent by themselves is a risk)
(high triglycerides, example)
(statistics and epidemiology data)
(certain number of people will)
(may risk factors for diabetes, one of the things yes, elevated glucose levels)
(would hve to do proper blood test to determine)
(pre-diabetic do not go on to develop, seems o be correct)
(according to Lilly, lot of people do, great risk)
(would not use Madison Avenue words ,but there are concerns with diabetes in the USA, maybe and maybe not)
(diagnosis and weight gain has been going down over decade's strong associations, and most

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type two are elderly overweight individuals)
(weight gain is factor an denied by Lilly)
(but should of told them the drug was causing above the normal weight gain)
(greater frequency)
(sedentary habits are risky for number of health issues)
(April 2007, deposition, yes)

10:13:47 AM Reference April 2007 deposition, on screen

(page 67, line 8 to 10, that is correct)
(specific case of causality, not here to address this but to answer that...do not understand, again)
(in general diabetes or drug related diabetes?)

10:15:27 AM Court - no, have to answer his question
- fie risk factors and say they will get diabetes, correct

(yes)

10:15:45 AM Cross exam by Mr. Brenner

(not seen a case like that, but possible, especially type one)
(you are right, probably)
(not able to offer opinion on what Dr. Brancati said)
(it may, in most cases an in some, no)

10:17:21 AM Pg 148 - referenced

(right, do not recall reading this)
(that is what it says)
(that I what it says and what experts call a negative study, not as important as a positive findings)
(in this case we are talking about diabetes Mellitus not a frequent event, not sure they have
enough statistical evidence but showed a positive finding)
(page 5, negative findings, not surprised)
(page 9, that is correct)
(yes)
(and very good advise, yes, from medical literature)
(of course, not, comparable rates means conclusive proven and negative finding is not
conclusive)
(de-hertin)

10:23:27 AM Sidebar begins

10:24:50 AM Sidebar ends

Continue with Cross by Mr. Brenner

EL3267 - referenced

(yes, joint research)
(Dr. John Buse, yes, do not know his reputation in the world of diabetes, right)
(suggestion may or may not b correct but they suggest this may be the case)
(yes, it is true like most issue hard to resolve, number of publication is appropriate to issue)

Court - why

(no, good people)
(not if article is positive and well done, by why is it so, despite being good people, difficult issue and this takes time)
(not sure decree of risk)
(but end of the day it's the ones that are more rigorous and supported, makes it

10:28:59 AM Cross exam by Mr. Brenner

(no, sir)
(not true in Court addresses this case particular case ad De-herthn studies could have been done in 1998 or 2002 by Lilly

10:29:54 AM Benner - strike

Court - jury disregard

(that was the finding)
(yes, it is in this study, but there are two sides to the story in the literature and issue not concluded)
(we do not know and they can't push one side and ignore the other side)

10:32:12 AM Brenner - move to strike/disregard

EL 3801 referenced on screen

(yes, that I correct)
(page 5, annualized rate of TED was about 3 percent, yes)

Court t - will break at this time
- admonishment

10:34:34 AM Off record

10:53:28 AM On the record

Jury is Present

Court -

10:53:33 AM Continue with Cross exam by MR .Brenner

(yes, mails warning letter to offending company)
(serious step to take

10:54:29 AM EL2113 - referenced

(yes, to Janssen on Risperdal)
(DDMAC, safer than other antipsychotic, I see that)

10:55:50 AM Fibich - objection relevance/overruled

(that is correct)
(page 4, violating federal law)
(FDA after marketing a drug has burden to proof drug is unsafe)
(substantial is also point at which FDA can't ignore)
(risk assessment not available at the time, correct)

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10:59:15 AM (proper decision)
(April 2004 position o FDA, correct)
(head-to-head clinical trials, yes, two compounds tested)
(did not hear...)
(some or all, fine, results on the internet)
(not many and depends on drug and company)

11:00:55 AM Fibich – objection, timeframe/fair questions

(do not know)
(looked at Cedar Website and did not find anything you are talking about)_
(no, pharmsydical..)

11:01:32 AM Fibich – objection, timeframe/ doing so now

11:02:12 AM Sidebar begins

11:03:16 AM Sidebar ends

Court - documents being placed on the wed by pharmaceutical company, disregard any question or discussion on the internet by pharmaceutical companies)

(Abilify)
(MDA content, yes)
(give good idea on 60 days for glycemic changes)
(page five, no meaning)
(yes)

11:06:48 AM PE 169 – referenced on screen

(yes, good evidence or not, statistical power)
(poster presentation, yes)

11:09:16 AM PE 164 – referenced on the screen

11:09:43 AM Sidebar begins

11:10:19 AM Sidebar ends

11:10:40 AM PE10151 referenced

(case report, yes)
(not always, depending on conclusion)
(looking for signal, its ok but not ok to be conclusive)
(this is patient who is lean and wasn't gaining weight while on Zyprexa yet destabilization of diabetes, unique case)
(provides evidence, it's a nature experiment, observation)
(yes, but A can be diabetes and B can be worsen of diabetes)
(yes, it says that)
(antipsychotic drugs cause weight gains, yes, not sure for decades but seems to be there)
(yes, with Zyprexa, reported, do not know what...difficult question)
(agree with you)

11:15:30 AM EI 2731 – referenced

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(medical officer at FDA same time as me, but I did not know of him)
(yes, short studies)
(regarding Zyprexa, says that but strictly on wording and not conclude from that)

11:17:54 AM EL 2954

(package insert for Zyprexa)

(yes)
(two paragraph follow, I agree with what you said)
(page 18, and hyperglycemia in the package insert, yes)
(doing a review article)
(David B. Allison, Ph.D., not personally know him)
(it says that)
(that is correct)
(1999 American Journal of Psychiatry)
(from 1998, that is what they say)
(discussed is to being a word as meetings you have 15 minutes to present work and 5 minutes of questions)
(better chance of being published, not subject to peer review)
(subjected to some review but not rigorous)
(perception of scientist in the field yes)

11:24:42 AM (neuroleptic drugs had weight gain, that is what it says)
(non-fasting glucose test, more surprised)
(corroboration on behalf of patient, yes)
(but exists in every single clinical trial)
(FDA was, not sure when they were aware, an have to know this is neurological agent, proper studies not later done)

11:27:19 AM PI2731, reference on screen

(that is what he said but not sure what he means and he is not an endocrinologist)
(going to another division in review at MDA doesn't occur all the time)
(no, not that I remember)
(do not recall but)

11:30:02 AM PE136 - reference on the screen

(I see that)
(perfectly alright to being with non-fasting glucose but when power and precision is not obtained, better methods needed to be used)

11:31:45 AM Fibich - object to further questions on this document/overruled

(one of his conclusion but if negative result, need different method)
(it happens)

11:33:37 AM PE 775 - referenced

(have seen this letter and what I got from this is FDA wants all data Lilly has)
(not really when you think about what happen in the future)
(to all manufacture, send everything you have)

11:35:36 AM EL 2043 – referenced

(July 31, 2000, not important how many pages, but did they obey FDA asking for all data)
(did not review it but saw it later on)

11:36:40 AM PE – 4871, referenced

(division director)
(Lilly took initiative to change label and FDA in unusual fashion is review n then saying what it thinks)
(yes)
(doing what you say but more, approval, and then before application can be approved you must perform following corrects)

EL2945-A, referenced

(not as fully as FDA wanted)
(yes, it is)
(not true, but what is given regulatory constraints of FDA, the FDA has to prove what the company wants to say is conclusively proven)
(data has to be sufficient)
(FDA at the time did not have conclusive evidence to force the companies to say this or that)

11:42:34 AM Court - conclusive an sufficient

(yes, scientifically conclusive means proven and not sure how they decided on this basis)

11:43:37 AM Continue with Cross exam by Mr. Brenner

(yes)
(Rhesus monkeys, all increase if I remember)
(Clozapine, yes, and I did say on Friday that having done that I thought, surprised, Lilly did not perform Rhesus monkey studies on Zyprexa)
(Ketoacidosis)
(seem to confused somebody, I was talking about monitoring blood glucose)
(agranulocytosis)
(if you find something out in the animal a company is required to perform trials and see fit is happening in then human)

EL2121, referenced

11:48:23 AM (appears to be that)

(Judith Racoosin, not sure what division she is I, but FDA)
(preclinical, in animals, yes)
(in the rat I assume)
(Changes Being Affected)
(if time is of the essence it is normal for FDA to alter methods and can be misused)
(this is the case and I have been involved in many of these changes and only once did FDA have informal review, not acceptable)
(its performance)
(yes, but rarely does so as changes are well know, address time related emergency)
(manufactures know if what they say makes sense and statute say drug is safe when experts agree it is safe)

(FDA lets it pass when you have expert consensus)
 (but when it feels something is not right the FDA take time and says not the way it should be)
 (FDA need assurance it had everything it had requested)
 (yes but in 2008....)

11:55:23 AM Court – do not talk about that

Continue with Cross by Mr Brenner

(depends on how you use comparable, I do not use it)
 (FDA define terms an scientist define terms)
 (best to present the data)

11:56:35 AM EL3399, referenced on the screen

(do not remember seeing this graph)
 (not sure you can say that given the numbers, more than 4500 for Zyprexa and 4500 for placebo, what does this mean)
 (can read graph but not sure what it means)
 (goes to using the word comparable rate...not being done here, is it)
 (difference in characterization)
 (comparable to be used in talks with prescribers)
 (doesn't mean slightly different and should be used but to neutralize people)
 (DDMAC, knows not to use this word)
 (I do not know)

11:59:48 AM EL2108, referenced on screen

(do not recall that it was given to me by the state)

12:01:04 PM PE 1111, referenced on the screen

(that was the problem/issue)
 (no, they did not know this, took them awhile to may be a problem and that messages was contradicted by representation from Lilly)
 (2001, I agree it says that)
 (marketing statements and doesn't address the label or being told to prescribers)
 (and Lily shot back to say don't think this is true)
 (Japanese approach to Zyprexa, yes)
 (it should and very few reasons there should be glaring difference in the labeling)
 (in part, and negotiation power with different regulatory powers vary)
 (do not understand, did they not have the data, Eli generated)
 (why is this a surprise)
 (Eli informed FDA of Japanese action, not all evidence agree)

12:06:06 PM EL 2044, reference on screen

(dated 2002)
 (not shown to me)
 (Dr. Laughren, not sure of position)
 (works at FDA, yes)
 (April 12, 2002, that is what it says)

12:07:44 PM | E12629, referenced on screen
Internal analysis of Eli Lilly, ye, but submitted to FDA and they prepared it)
(page four, and would like to know when they found this out and date of this communication to FDA)
(and Japan to Eli Lilly, I do not know)
(I need information, can tell you why)
(this is Eli Lilly analysis)
(post marketing period and not enforceable on Eli Lilly)
(very few people working compared to people working at the company)
(we can't obtained and will not ask for)
(FDA doesn't ignore but that which was not sent to it)
(FDA duty is to manage time to address public health issue it can)

12:11:05 PM | PE4436, referenced on screen
(or is it 96)
Court - by agreement 96
(and Lilly will do nothing contrary to its interest)
(that is what it says but not sure of exact verbiage)
(depends on wording, but not arrive conclusion from imprecision of this document)
(not the case, they were talking about hyperglycemia and means nothing if you do not know or present what is said about this in each case)
(reference one of the H series)
(yes, to the high level increase glucose group as compared to Placebo and referred to this as a signal)
(yes, and signal is signal)
(same data from same trial an analyzed again and not found statistical)
(six weeks)
(granted but have to look at positive findings)
(signal has to be addressed)

12:17:01 PM | E12043, referenced on screen
(page 71, that is what it says)
(as medical officer, this raises a big question, would discount as totally not practical)
(placebo not consistently more toxic than a drug, please)
(do not know but a lot)
(12 months in duration, clinical trials)
(that is fine but can't replace control)

Court - open label extensions?

12:19:52 PM | Continue with Cross by Mr. Brenner
(and put together in order they are similar or identical)
(double blinded means nobody knows who is getting a placebo or the drug)
(open label extension means both are broke, yes, and good reason)
(once you have identical efficacy of drug, not to put on drug during open extension)

Court - will break, admonishment

06-0563001

12:21:47 PM

Off record

12:42:24 PM

On the record

Jury is Present

Court -

12:42:27 PM

Continue with Cross by Mr. Brenner

(FDA Advisory Committee, and company)

(convened at request of FDA)

(when FDA is on thorn or complex issue)

(yes, you are correct no Advisory committee on this drug)

(medical letters publication letters)

12:45:03 PM

Fibich - identify this and admit so jury can view

Brenner - my option to admit but will ID them

Court - ID them and plaintiff can move into evidence, if they wish

Fibich - now move any letter be admitted for totality

Brenner - only asking if he saw them

Court - if on the screen can be admitted

- go beyond just asking seeing and if that is it, take them down and not in evidence

Fibich - identify with copies to use

Court - to happen

Fibich - and if lengthy letter want witness to see the letter

Court - if he hasn't seen the letter, no more questions

12:47:39 PM

EI 2993, identified (letter)

Court - find, but doctor needs to be here tomorrow if not done today

- yes, show to counsel first

12:48:36 PM

(I do not remember seeing this)

12:49:05 PM

EI 2996, identified (letter)

(no, not seen this letter)

12:50:18 PM

EI 2987, identified (letter)

(no, not seen or do not remember)

12:51:40 PM

EL 3012, identified (letter)

(do not remember seeing this either)

12:53:16 PM

(annual reports or periodic reports, yes, some adviser reports have to be sent within 15 days of

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received by pharmaceutical company to FDA)
(for the rest they send annual report with everything else and maybe mandate for certain drugs to
he periodic report and more frequently)
(not sure how many they have sent in but they would of sent some in, do not recall seeing)
(for every case they are sent in regular fashion or for specific fashion)
(no, but can understand why)
(did not review any of them as it did not affect my opinion)

12:55:54 PM EI 2127, identified

(page nine, need to see entire document)

Court – free to approach with out leave of asking

(EL what, you say, do not see it)
(have not seen it or remember seeing it)

12:58:10 PM EI2032, identified

(no, did not know but knew o a lot of interaction between Lily and FDA)

12:58:49 PM EI 2033, identified

(not able to answer as I may have seen a summary but no 600 page report)

12:59:32 PM EI2036, identified

(not seen this one)

1:00:24 PM EI 2119, identified

(from Dr. Boehm, yes, not seen but agree with summary)
(page seven, no difference in risk between groups)
(can't say there is not the affect)

1:02:48 PM E 2121, identified

(agree but need to see summary before I give opinion on this)

1:04:01 PM EI 2130, identified

(Dr. Boehm's Review and Evaluation of Clinical Data)
(agree with conclusions and do not remember seeing this)
(page nine, not a finding but an opinion and agree with out studies being done)

1:06:25 PM EL2773

(I know of Andrew Mosholder, MD)
(agree, yes understand what he is saying and agree)
(no effect on my opinion one way or the other)

1:08:04 PM EI2133, identified

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(June 1, 2005 findings from Dr. Boehm)
(not seen but agree, well support and sensible)
(page 11, yes, he wrote that and means if you want monitoring you need proper studies to resolve this issue)
(totally agree with this statement)

1:10:57 PM

Sidebar begins

1:11:19 PM

Sidebar ends

1:11:29 PM

Re-direct by Mr. Fibich

(CDE, can do anytime and FDA did not agree with it, not consistent with what FDA saw)
(several boxes received from the State of Alaska)
(have seen enough to express my conclusions)
(because if on the basis of conclusive and important of evidence, as expert you, can form an opinion, makes no difference)
(FDA request for more information, FDA did not hve all the important information following New York Times Article)
(yes, sometimes at the end of Warning Section, prior to 2007, no, it is not)

1:14:38 PM

Brenner – objection, not clear

(from 1996 to 2006, in the warning section, reading from 2004 warning)

1:15:20 PM

Brenner – objection, beyond knowledge/ there are other witnesses, sustained

(FDA can't remove drug once on the market)
(Dr. Cavazzoni, yes)
(disclosure at the bottom, yes)
(New England Journal of Medicine)
(yes, conclusion in this magazine of weight gain, etc.,)
(no, required there be sufficient evidence to consider a risk)
(yes, I am)
(November 19-21 2003 meeting)
(Presentations made by FDA, Janssen, Bristol-Meyers Squibb, Pfizer, Eli Lilly etc., only fair, manufacture of 2nd generation of antipsychotic drugs)
(8 people on this, yes)
(yes, they had all the studies, appears to be)
(conclusion of consensus panel was weight gain, as listed, Clozapine down to Ziprasidone)

1:24:28 PM

Brenner – objection, leading/it is but allowed

(Policy Committee Meeting, April 12, 002, yes)
(internal Lilly document, yes)
(not as Lilly saw it in their document)
(A retrospective cohort study of diabetes, etc., yes, reading from
(that is right)

1:27:26 PM

Ex. 7971 – referenced

(3.6 for Olanzapine an 1.5 for Placebo)
(no Idea how they got that)
(enough to show the difference to say something is totally wrong here)

(Hyperglycemic Diabetes data on Demand Resource Guide
(60 percent said link with Zyprexa and diabetes)

1:30:37 PM Brenner- objection, expert opinion

1:30:54 PM Brenner – same objection/overrule
(would object to that)
(yes, and FDA did not get this information)
(totally inappropriate not sure if illegal)
(no)
(when there was enough evidence to show maybe there was a public health issue in 1995, 1996
and by 2002)

1:33:30 PM Re-cross by Mr. Brenner
(yes, as to medical officers too)
(not the PDR)
(it is in the warning section but not in the PDR an there is a class effect saying not worse than
other atypical antipsychotic)
(reading, just said that)
(with information they had or didn't from Lilly)
(DDMAC, should be)

1:36:46 PM 149, referenced
(normal because it presents the consensus of all expert scientists)
(normal way to do things)

1:37:26 PM EI 2001, identified
(agree on one issue, to monitor patients treated with second generation drugs but FDA not able to
do more than that)

1:38:58 PM Re-re- direct by Mr. Fibich
(no)

1:39:10 PM Brenner – objection
(internal documents, not part of DDMAC)
(2003 comparing to 2004 warning label, no it Defendant Absent, In Custody)

1:40:07 PM Re-re-cross by Brenner
(of course)
(her it is...)

1:40:31 PM Court - changes to 2003 packet insert depends on publication schedule for 2003
(for 2003 and 2004)
Re-re-cross continue

(2004 PDR publications doesn't show what was in the 2003 publication)

Court -

(ion 2003 but not 2004)
(in the PDR)

1:42:06 PM Court - reading juror (4) question

1:42:19 PM Sidebar on jury questions
1:44:48 PM Sidebar ends

Court - asking questions from Juror number 4

Reference ex. 1111

(do not agree with bullet point number 1, as the issue is not settled)
(bullet point two, weight gain and hyperglycemia, explaining)

1:49:29 PM Witness steps down

Court - end of day

- be back at 9:30, admonish to jury
- leave published document on the corner of half wall

1:51:13 PM

Outside presence of the Jury

Court - question of interaction of off label marketing and warning, letters, responses etc,

Allen - not talk about off label promotion but issue of the actual use of the drug in the population, other uses

- 23 million...
- gave you Eski deposition and this is to e played Wednesday, they need to give you h cuts

Court - I would like that

Lehner - this afternoon

Court - next is Eski

Allen - to be played Wednesday morning
- rulings by tomorrow

Court - get me responses to them and decide tomorrow

Allen - Dr. Beasley to be played tomorrow morning and Robin after Mr. Beasley
- Beasley, Wojcieszek and Lechleiter and maybe Tollefson

Gussack - cut down

Allen - getting something to you, hands deposition to judge, you know have them all
Court - as to Eski and Breier tomorrow

Lehner - tomorrow, if we can

Allen - not revised Eski cut

Court -

1:57:40 PM Fibich - no court on the 17th

Court - because of settlement conference for others but I have moved them today an think for next Monday to

- tomorrow at 8¹⁵ or 8:30
- waiting on defense cut for Eski

1:58:51 PM Of record

In the Superior Court at Anchorage Alaska

Media No: 3AN4308-50

Judge: M. Rindner

Date: Friday, March 07, 2008

Clerk: M. Borneman

Case No: 3AN06-5630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial - day Five

Counsel Present:

Plaintiff: Scott Allen, Esq., David Suggs, Esq., Tommy Fibich, Esq., and Mr. Sniffen, AAG

Defendant: Mr. Brenner, Esq., Mr. George Lehner, Esq., Ms. Gussack, Esq., Mr. Brewster Jamison, Esq., and Mr. Kantra, Esq.

Court Orders: Motion to Preclude Speech is denied
Motion to Limit Testimony of Dr. Gueriguian is denied

Summary of Proceedings: Exhibit 4436 is admitted as are exhibits 988, 1453, limited purpose. Jury questionnaire of Mr. Hinton is made part of file and is filed with exhibit clerk, confidential.

8:24:26 AM

On the record

Outside Presence of Jury

Court - pretrial issues to take up

- disclosure, assigned a case for representation hearing involving a person where it involved commitment to API and forced medication
- Mr. Gottstein filed a lengthy filing and affidavits, but have not read the affidavits but did read pleadings
- I saw topic was about Zyprexa and stopped reading the pleading
- Went on record and arranged to have it assigned to another judge, recused myself from that case
- Noting prevents me from being impartial, application today

8:27:59 AM

Allen - none

Lehner - no

Jamison - case number

Court - set today at 3pm but might be moved

- pleadings from defendant and rules required to get two hole punched, she is getting worn out from punching the documents
- pending motion filed yesterday in the morning to exclude testify of speech from opposition

8:29:51 AM

Allen - do so on record, do not have man power

- speech can be protected and they stated doctors still prescribing the drug and we have done nothing
- but when state has tried to do something Eli Lilly formed groups and hired lobby firms to stop our actions
- they can do this but when you talk you are not entitled to a cloud of privacy, public

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- allowed to show they did

8:31:21 AM Lehner – atoned to issues

Court – Nora Pennington issues

- not determining the relevance of evidence, understand Mr. Allen you want to use this but

Allen – Eski to you on Monday

- Ms. Gussack in her opening said doctors have not complained but Preferred Drug list and Open Access and when the government through legislation tries to get prior authorization for payment, they get involved by way groups, truth squads etc., and they succeed preventing prior authorization from taking place
- Even consider taking action is prevented, unfair representation
- Example, entitled to rebut this evidence on no one doing anything

8:34:37 AM Brenner – proves our point, how are you to link up the letter writing

- disagree with analysis of cases you have
- first amendment rights would be chilled if you do what you are doing
- our reading is contrary to yours

Court – somebody bribing legislature and somebody wants to bring in background, example

Brenner – personal injury suit, no safety standard due to efforts of industry

- not money damage claim for speech

Allen – incorrect, using to refute defense they have

- how to prove causal, direct and indirect evidence
- they used money and lobbyist with purpose in mind and entitled to show purpose

8:37:16 AM Court – rebut and better to see witnesses and will become apparent and a line could then be drawn and rebutting defense requires defense to be put on

Allen – 100 to 200 range, bet you'll find it

- evidence is allowed to come in predicated on subsequent evidence and if you waited a lot of evidence escapes you
- they stood up in opening and then do not put on evidence, its out thee and in front of jury based on openings
- Campana and Eski deposition

Court - will deny for now based on Nora Pennington

- debt filed motion to limit the testimony of John Gueriguian
- will have to hear testimony to determine if he has qualification

8:42:12 AM Brenner – labeling issue, at deposition he said he never saw or read any of the labels

Court – goes to cross and need to hear his testimony

Brenner – will have to voir dire

8:42:55 AM Lehner – Brancati motion is based on demonstrative exhibits

8:43:25 AM Allen - I bet we do not do what they have done

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Court - Mr. Allen has filed a letter this morning saying things on rebuttal or do they come in now

Allen - sure they will reply and we are working on it now

Court - decided to work informally but proper paper

Allen - fine

Court - some on film that Orlansky is gone

Allen - no, but ...

Court - letter has to be docketed and filed in file, two hole

8:45:40 AM Fibich - two additional document to submit and publish to jury
- Jury to see the documents themselves, hand to in-court...

Court - ask and then pass to jury
- move about freely and do your job

8:46:48 AM Fibich - new evidence exhibit 988, 4436

Lehner - 4436 first, psychotropic label, objected to and consistent with Motion in Limine

Court - preserved but overruled and 4436 is admitted

Lehner -

Fibich - notice

Court - 988 is admitted only to show Lilly was on notice, limiting instruction to be given if they wish

8:48:33 AM Lehner - yes, limited purpose
- designation depositions add one into theirs, page given to them, John

Court - one for Torres and six for Lechleiter

Allen - if I agree

Lehner - six

Court - no agreement o the one or six

Allen - two of six given and I agreed to two on Lechleiter and those are agreed to but others I do not
- issues

Court - do so seamlessly

Allen - creeping into the order and will look what he has tonight and the other six or four and certain I will object

Court - give me the four and the one Torres, five cuts in dispute

06-056
8:52:58 AM

- give me page n line if not able to agree and I'll decide the completeness issue or do not like what they are saying and where it belongs

Allen - four or five more cuts today

- question asked and then objected as no-responsive and if they want to play, in my case, a question as being non-responsive and you determine this I should not be required to present a proper question, waste of time to object
- answer with no question, do not allow

Court - give me the four or five cuts and by end of day I will rule on them

- have seven for this week
- do I have Lily specific objections to new stuff

Lehner - can do so now

Court - will take that now

- end of day to what is in dispute
- two cuts from yesterday and the new five and get them by noon tomorrow it would allow me to have the seven and give answers by Monday, no promises
- Torres an Lechleiter are pretty much done but I have 9 depositions to be played

Lehner - give list of what they are going with on depositions, who is with judge now and who is being pulled up

Court - being responsive to what I have done an working hard to get things done in timely fashion

- deposition designation is primary thing for me to do

Allen - meeting this weekend but focus on Torres and Lechleiter

- Jordan and Bandick
- An look at Charles Beasley to be played next week
- Lechleiter next week

Court - as to Torres an Lechleiter, give me today

- As to cuts of the five new Lilly...

Lehner - by noon tomorrow

Court - fine

- an give me order of the seven, noon tomorrow
- will meet in lobby of Captain Cook, no talking

Allen - Rule 104 (b)

Lehner - Beasley,

Allen - Beasley, Kinon, Taurel, and

9:02:51 AM

Lehner - admonish on what they are watching

Court - have several times already and being asked but will give instruction on seeing things inadvertently

- will remind jurors about daylight saving time
- jury questionnaire of Mr. Hinton, part of record but will be confidential

9:05:55 AM
9:14:01 AM

off the record
On the record

Jury is Present

Court - welcome

- reminder about daylight savings time, don't be late
- trial publicity, do not read or listen to the news on this case
- note about brand names

Allen - yes

Lehner - will write it now and

Allen - can do it now

Court - give cheat sheet

9:17:34 AM

Allen - writing names on board for jury to view, demonstrative

9:20:47 AM

Dr. John Gueriguian, sworn

9:21:06 AM

Direct Exam by Mr. Fibich

(reside in Rockville, Maryland)

(grew up in Egypt)

(French system of high school, education given)

(accepted at University of Paris)

(followed six year curriculum, obligation of medical thesis, accepted and to two years of internship)

(1965 I came to the USA)

(returned to France as I had J-VISA)

(By Chemistry Department at University of Paris)

(NIHM, National Institute of Health comprises of a number of institutes, explained)

(did research and published articles)

(published 40 to 50)

(returned to USA of as mentor at Harvard moved to North Carolina and he asked if I come and work for him, I did)

(pharmacology department, duties listed)

(left after four years and went to Minnesota University, same but with better salary)

(tenure, explained)

(work history given)

(bureau of new drugs and started with FDA in 1978)

(stayed 20 years and retired in 1998)

(acting director to medical officer at the FDA)

(medical officer is in charge of IMD and MDA together with other obligation)

(MBA are after IMD, explained)

(IMD sent to FDA by a drug company and in it the drug company has perform drug studies, and asking the FDA for approval)

(industry meets statutory and regulatory for new drug approval)

(medical officer makes recommendation and works it way upwards where it is then approval or not approved or even approvable)

(make first recommendation to do human testing and upon review MDA I approve or not approve or approvability)

(MDA is end of IMD work)

(once all studies done to prove safety of drug it make the MDA file and sent to FDA)
(medical officer yes, in charge of scientific part of IMD and MDA, my position an others in the FDA)
(lot of information brought in)
(FDA doesn't test themselves)
(localities in which drug company chooses and according to protocol)
(scientist working for drug company or outside company)
(100 drugs I approved minus 3)

9:43:39 AM Brenner – drifting from qualifications

Court – some latitude

9:43:53 AM (currently, I'm a drug consultant)
(worked for industry, law firm and mostly for plaintiff and on occasion defendant, etc.)
(anyone who wants my opinion)
(Bristol Meyer's Johnson and Johnson, etc.)
(charging for my time today, yes)
(review of drugs on physical chemical, animal and clinical trials or human testing)
(benefits exceed its risk)
(prescribers need to know everything that is of importance for their drug)
(yes, I did in the MDA they get labeling proposal, written by drug company)
(medical officer looks at all data and says yes or no and with flaws)
(industry interest is important and if you do something at the FDA and not acceptable by statute of regulation, they will cut you down)
(federal regulations as to labeling, yes)
(yes, for 20 years minus couple I was only medical officer in charge of diabetic drugs)
(very good relationship with Eli Lilly for number of years and familiar with what they do and say)

9:50:35 AM Brenner – qualifications/clearly

Fibich – offer Dr. Gueriguian is offer as expert based on trained etc.

- labeling, practices and custom of FDA, pharmacology, Epidemiology and matters in front of FDA

9:51:52 AM Voir dire by Mr. Brenner

Court – explained to jury on voir dire of this expert

(referring to something that happen in deposition of April 2007...)

9:52:59 AM Fibich – objection

(read about the labeling itself and extracted information on labeling as to I read or not, at the end of the day I answer to be interpreted that I did not)
(no, I did not)
(left in 1998, FDA)
(Division o Neurological, did not work in that division)
(did not work on Zyprexa drug)
(division of Drug Marketing and DDMAC)

9:54:42 AM Fibich – objection/overruled

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(that is correct)
(not work in Chief Legal Counsel Division)

9:55:43 AM SA Food and Drug Administration on the screen for jury

Court - outside of qualifications

9:56:13 AM Taken off screen

(no, legal determining on scientific matter are for medical officers)

9:57:10 AM Fibich - objection/allowed

(no, matters that are confidential)
(not licensed in USA an not a psychiatrist or epidemiologist)
(nor board certified endocrinologist)
(schizophrenia, not as expert)

9:58:47 AM Fibich - not offer

Brenner - will stop then

Court - not a topic

Brenner - have application

Court - excuse jury

10:00:01 AM

Outside presence of jury

Court -

10:00:16 AM

Lehner - would give him copy of notes, etc.,

Allen - not needed

Court - not sure Allen has seen what Mr. Lehner is talking about
- the handout, but capable of letting people know these things, have done it

Fibich - not have him lecturer us on anything

Court - I'll do it

10:01:59 AM

Mr. Brenner - just confirmed he did not read labeling on Zyprexa, not allow testimony on Zyprexa labeling, no foundation

- 2nd, regulations and not offer opinion on how to apply
- 3rd, number o internal documents to come up and he will express personal opinion on these
- rule 703, not permit to give testimony

Court - as to how FDA goes about it business, by training and work experience the doctor has sufficient expertise to testify in this area

- internal documents, on notice of this and able to cross him on these

- opening was based as FDA being COP on the beat and what FDA does or doesn't do and think he has training to do this
- opinion on label he never saw and not in the report and never indicated he saw it, goes to notice

Mr. Allen – think he tried to explain this, in the material he had there are portions of label in the material

- their letter from 2007 the label is part of the letter and lot of material he reviewed has the label in it as opposed as the label itself
- has reviewed label, not accurate
- lot of matters are for cross and opposed to disqualify

Brenner – he never read the label

Court – never read the label but did he see and read documents parts of or portions of label, etc.,

Brenner – very small portion

Fibich – attach to his deposition are line a page where he discusses label, etc.,

Court – might have been general sense not Zyprexa label or Zyprexa label itself, not clear

Fibich – what he saw in record

Court – no opinion to say label is inadequate but can say he review this document etc., and opine on that

- nothing about 2007
- but can talk about document that contain portion or section of the label, allowed

Brenner - time to specific document

Allen – let them object, like a trial

Court – can be done and will happen and then admit the document

Fibich – motion filed by them with report but not all of his report attached

Court – to make full record on notice

- expertise and notice questions
- not admit notes as exhibit but should have to make record

Brenner – continuing objections

- overruled application on his perusal opinion that do not need rule 703, internal documents
- standing objection so as not to interrupt

Court – yes

Lehner – have list of dug names, etc

Court – will break

10:30:00 AM On the record

Jury is Present

Court – stipulation on trade names given to jurors, accept as true
Court – will Dr. Gueriguian as expert in area of label, practice and custom of FDA, etc.,

10:30:59 AM Direct Exam by Mr. Fibich

(and applied on numerous occasions as documents sent to FDA on safety etc., and review team looks at these documents and we look at label and ask ourselves if all the important information is in the label so prescribers knows how to administer the drug)
(has to be clear and information on safety has to be communicated to FDA, prescribe to patient)
(if person is diabetic you do not want to prescribe something, drug, that causes or problems for diabetes)
(adverse section more frequently seen)
(infrequent events but can be serious and severe and can kill)
(warning section, highlight something that is so important as to safety of drug that special effort should be made for prescriber, labels are long)
(and reason to have special ways to draw attention of subscribers)
(black box warning is something that appears at top of label)
(and is bolded and with in rectangular box)
(FDA has data base and everybody can send adverse report to company or FDA and the company has obligation to send all what they receive to the FDA)
(Changes being affect is special regulatory concept the allows company to cut through red tape if something important has to be communicated quickly to prescriber)
(can do anything the company thinks it should be doing)

10:39:20 AM Demonstrative exhibit for jury to view

(use this regulation very often, explained to jury)
(serious events and talking about potential safety hazards and public health protection, what it is all about)
(potential risk and causality doesn't have to be proven at this time)
(nobody has time to wait for academia to prove causality and the drug is out there and hard to do studies as it cost money an can't prove causality while people are being harmed)

10:42:24 AM Brenner – objection, leading/it is

[Allen, place back up – demonstrative exhibit]

(talking about warnings)
(they have to defend their position and if disagreement the proper things to do is call in independent parties)

Fibich – will now use Elmore

10:44:35 AM Fibich ex. 1596 being shown on screen, admitted exhibit

(Public Advisory Committee, is to help FDA when FDA is facing a thorny and difficult question, open to public)

10:46:32 AM Brenner – objection/if you know

(I was executive on advisory committee, question being asked of FDA, safe drug or not or does

label need to be changed or not)
(the committee hears both sides and if advisory committee decides the FDA generally follows suit)

10:48:24 AM Brenner - objection/overruled

(they wanted private hearing as you can not control advisory committee)
(when you enter into negotiations with the FDA you can have FDA propose a label change and the company takes time to look at it and comes back with counter-offer, can go on for long time)
(but at some point in time you have important information to get out and better to have something out rather than nothing out - compromise)
(does take six months, yes)

10:50:58 AM Brenner -

Fibich - withdrawn
- publish this to the jury

Allen -78.2

Brenner - objection

Court - admitted, allowed to be publish to jury
- one attorney for one witness from now on

10:52:12 AM Mr. Fibich continues with Direct of witness

(psychiatry division, yes, rules is to listen to legal counsel and they listen to scientific argument and try to come up with something to satisfy both sides)
(DDMAC, Promotions...)
(I speak five languages)
(when division has preview of drug but not expertise in all areas that division ask for complimentary review)
(both experts in the field)
(not able to talk with the FDA, not able to ask confidential questions)
(well aware that you have to obtain permission of FDA if you are asked to appear as a witness)
(Dr. Brancati's opinion, I share)
(and as to weight gain)
(FDA as cop on the beat, frankly, its insulting to police and to FDA)
(agency in protection of public and deserve respect)

10:58:13 AM Ex. 1586 on screen

(that is right, Zyprexa approved in 1996)
(San Juan, Puerto Rico meeting of 12/10/95)
(information on weight gain, yes)
(Olanzapine gained average 24 pounds end of 12 months, significant weight gain)
(weight gain is risk factor and consistent with cholesterol, good and bad and triglycerides and all measurement are independent risk factors of cardiovascular risk and deaths)
(HGHG trial, yes, Olanzapine v Hal.)
(look at lowest yellow line)
(P value of .031 and if less than .05 is statistical significant and studies should be perform to find out if clinically significant, does it produce disease)

(P value is .023 an more statistically significant)
(potential for adverse events)
(signal means, sufficient worry and concern to mandate addressing the question with additional studies)
Ex. 1169

11:05:07 AM (letter from FDA on 1/96 an sent to Charles Perry, Eli Lilly and Company)

Court – ex

Fibich – Ex. 1169

(false and misleading, and in violation of FDA Act, yes, I see that)
(its after promotion has been done does DDMAC decide it was false due to comments they make)
(can only correct fact the fact)
11:08:22 AM (I do see that)
(fair balance goes to heart of 1962 Act, mandating FDA to do their job and it goes to benefit and risk of drug)
(obligation to inform on dangers of the drug an lack of balance is maximizing benefits while minimizing the risk)
(number of ways to communicate context of promotion material to prescribers, all drug company's do this)
(going back to advocacy side of equation and talking about lack of balance in saying advantage and disadvantages with approved labeling)
(if you over state the 2nd generation antipsychotic were less able to give dyskinesia, not balanced)
(that is what it says)
(in the adverse section, yes)
(that is what it says)
(contradicts approved label and not allowed)
(reading from ex. at paragraph number 6)
(on the honor system)
(FDA doesn't catch everybody, I think not)
(Dr. Tollefson, comments, has to be factual correct)

11:17:58 AM Fibich will publish ex. 1169 – previously admitted

11:18:26 AM Ex. 088 - referenced

(this is piece of good work because adverse events, post marketing, are usually more instructive following market)
(it is a Census of Spontaneous reports for Olanzapine for first two years of marketing)
(by Dr. Hornbuckle and Dr. Fung, correct)

Court - number

11:19:54 AM Fibich – 988

11:20:04 AM (diabetic acidosis, change in the PH level of internal body of blood)
(blood in body has to be 7.4 o PH)
(Diabetic Coma is when patient loses consciousness)
(end of 1998, two year period, there were 194 reports of adverse events dealing with blood sugar levels, that is correct)
(not all are reported, no)

(unreported is about 1 to 10 percent of actual events are report to FDA)
(and drug companies, yes)
(actual adverse events would be 1994 or 10 percent)
(1 percent would be 10 times more or 19400)
(between 1994 and 19400 events, to be fair)
(I do have opinion and it is yes, they should have been on warning)
(change in submission, yes, they could of)

11:25:21 AM On screen dealing with hyperglycemia and eight gain, November 1995

(registration trials, 2500 receiving Olanzapine)
(Non-fasting is blood glucose, or glycemia)
(Dr. Casey changed with 136 patient who took Zyprexa for four months or more, average was 17 months and 50 percent had weight gain of 7 pounds or more after start of treatment)
(7 of these who had normal blood glucose develop treatment effective hyperglycemia, blood levels went up, abnormal)
(hyperglycemia is sign of diabetes)
(Animal studies done with Clozapine not Olanzapine)
(only animals studies I found were using Clozapine not Olanzapine but two rhesus monkeys had fasting hyperglycemia, which is better measure as non-fasting and average weight gain was 26 percent)
(blood level measurement better than what humans had)
(HBA1C, above normal, have to find normal first and anything about that is above upper limit of normal)
(no, what I know is WHO and American Diabetes Association has place upper limit at 126mg for fasting)
(non-fasting is less accurate than fasting)
(more fluctuation in non-fasting and this reduces ability to observe significance)
(should of known as they are the expert in diabetes)
(no idea why they did this but not correct way to do this)
(that would be 66 pounds over a period of one year of treatment)
(weight gain evident in animal studies and all monkeys had high levels)
(insulin levels in blood of monkeys increase, diabetic state)
(insulin resistance)
(Clozapine in these measures appear to be worse effects)
(antipsychotic and same class as Olanzapine)

Fibich - more to publish ex 4176 to jury

Court - documents admitted will be with jury during deliberations

11:41:14 AM Reference ex. 4176, on screen

(yes)

11:42:58 AM Ex. 390

(Eli document from 1999...2000 and there is on the table a proposal to change the label with respect to hyperglycemia)
(to state random glucose greater than 160mg has been occasionally seen in clinical trials, read from exhibit)
(calling it common or frequent as far as it being greater than 1 percent but smaller than 10 percent)

(not appropriate change, no)
(facts given under how has this proposal arisen, reading)
(four fold increase)

11:46:30 AM Ex. 4858 – ID

(Letter to FDA from Eli to propose a label change)
(section 2, frequency of hyperglycemic events in comparable study of Olanzapine and sugar or placebo group)
(four times higher than placebo, totally different and incorrect)
(misrepresentation to material fact as to this drug, yes)
(reading from FYI portion of meeting with endocrinologist consultants)
(Warner-Lambert, another drug company)

11:51:49 AM Brenner – objection/sustained

11:52:11 AM Email from 10/9/2000 to Mr. Baker from Tom

(reading from email)
(Lilly put on notice that they have problem with Olanzapine and analysis from Lilly is not convincing them of no problem, need to come clean on this situation)

11:54:14 AM Brenner – objection/overrule

(yes, honored bound to tell)

11:54:30 AM Email from baker to Beasley, 10/9/2000 at 3:42

(yes)
(yes, Lilly data based but FDA is usually richer)
(adverse event can be reported by anyone and sent to company and or FDA but the company has to sent to FDA what they get)

11:56:42 AM Brenner – objection, no question

11:56:58 AM Sidebar begins

11:58:13 AM Sidebar ends

Continue with Direct by Mr. Fibich

(no, because it is very difficult to stop smoking or be on diet long enough)
(drugs to reduce weight, long run they do not and in the end you end up with higher weight than when you began, it doesn't work)
(cut points is way to perform categorical analysis and find subcategories who gain 20, 40 or more pounds)
(need all data to make categorical analysis reflects the truth)
(torturing the data means torture people or data to say something that is not true)
(denial can be discreet or aggressive and pointing fingers at other causes of Zyprexa can be discreet or aggressive an saying this rug is no worse than other antipsychotic drugs)
(class effect while your drug is more toxic than other members of its class, not telling the truth)

Fibich more to publish 1453 may be published

Court - will beak, admonishment to juror's
- jury is leaving

12:07:34 PM

Outside presence of jury

Court - time wise

Fibich - another 30 minutes

Lehner - last exhibit admitted over an objection

Court - 1453 is admitted but with instruction to jury on notice not for truth of matter asserted

12:08:42 PM

Allen - have cuts for you judge
- Beasley Taurel, Torres, the five

Court - and objection from Lilly to morrow

Lehner - 988

Court - admitted

12:09:43 PM

Of record

12:22:43 PM

On the record

outside presence of jury

Court - Alaska Supreme Court has decide a case today dealing with preemption, supporting my view,

- jury note from juror number one, Mr. Jump, reading note
- will bring him back

Fibich - will take longer than the hour remaining

Court - fine

12:24:27 PM

Lehner - informed them of our witness Thursday morning

Fibich - as we do, issue

Lehner - gave notice

Fibich - not arguing

Court - everybody on notice

12:26:17 PM

Mr. Jump is present, juror number 1

Court - what exactly did you hear and how

Jump - presented internal stuff from company saying they new, way it was said was negative
- not in courtroom at this time

Court - counsel
- still be fair and impartial

Jump- absolutely
Court - New Time Reporter, addressing reporter, juror overheard you
New York Times - will be careful
Lehner - speaks to juror number 1
Jump - no have not
Court - thank you
12:29:09 PM Mr. Jump departs
12:29:17 PM Court - outside presence of jury
Fibich - nothing from us
Lehner - nothing from us
Court - no action to be taken at this time
- addressing reporters, be aware
12:30:27 PM Off record
12:35:36 PM On the record Jury is Present
Court - two documents, state's 1453 and 988 are admitted for limited purpose
- Lilly on notice of these events
12:36:50 PM Mr. Fibich continues with Direct of Dr. Gueriquian
(Dr. Casey, right)
(same Dr. Casey involved in the Rhesus monkeys, yes)
(all monkeys had about the upper limit of normal)
(126 MG which is cut of point from normal to high hyperglycemia, normal fasting glucose levels)
(do not understand but person wrote this had reason to doubt these were no-fasting)
(in 1999 he was invited to present seminar, Dr. Casey)
12:42:03 PM Ex. 195 - ID
(from 2000 and this letter from FDA to Eli Letter)
(stating a number of things that needed to be taken care of and the adverse reactions, reading,
talking about changes proposed for the label)
(FDA has reviewed the application)
(2955 patient years of exposure)
(reading from exhibit)
12:45:59 PM Fibich publish ex. 195 to jury
Ex. 1111 - referenced
(dealing with diabetes as related to Zyprexa, yes, reading)
(comparable rates means simply a class effect, all atypical antipsychotic have comparable rates)

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of adverse events)
(weight gain and hyperglycemia)
(manage the information)

12:48:57 PM Brenner – outside of qualification

12:49:06 PM Brenner – same objection

Court – outside scope of report, sustained
(no it doesn't)
(statement not supported by facts that Eli is aware of and the opposite is supported)
(a misrepresentation)
(reading from exhibit)
(no, its putting profit over concern of the consumer)

12:51:13 PM Reference ex. 1111
(atypical antipsychotic are all alike, close to the truth)
(diabetes desired evolution, not appropriate)
(looks like supplement an a study done with glycemic clamp)
(do not know anything on this study but for they use a machine that maintains over time of giving glucose in the view to maintain constant level of glucose in the blood)
(11/28/2001)

12:55:04 PM Fibich – publish ex. 195 to jury/ may publish to jury at this time...

12:55:22 PM Lehner – 1111

Court -1111 maybe published not 195, at this time

12:55:59 PM Ex. 1962 – referenced
(sales sheet)
(document that tells you how to sell the drug)
(reference to DONNA, crated by company, and means this is a lady who has mood, stress, mood changes and depression and has to do with direct primary care physicians)
(talking about problems with Zyprexa and diabetes and how representative should address that problem)
(AOC is area of concern)
(yes, don't open up the diabetes issues but wait and see if physician asks the question)
(verbatim is document given to quote)
(yes, the rep. is to go to physician the good side of any drug and the bad side of the drug and if you do not talk about problems proactively you are hoping they will not raise the issue)
(but if raise you have been given exactly what to say to reassure them)
(if you convince the physician not to worry about Zyprexa and diabetes, now is the time to talk about Donna)

1:01:26 PM Sidebar begins

1:02:09 PM Sidebar ends

Court - off label use is not one for you to consider in this trial unless it relates to questions of warnings, which you are being asked to consider

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- not issue before you

1:02:51 PM Ex. 1962- referenced
(totally if it is addressing the Donna example)
Court – may publish 1962 to the jury at this time

1:04:34 PM (Zyprexa sold world wide, yes)
(other countries have similar agency as to FDA, yes, European Union, Japan, Canada)
(yes, change label in Japan, aware of this)

1:05:23 PM Ex. 320 referenced
(dear doctor letter is a letter written by company because there are important safety concerns generated and seem to have worsen to sent letters to doctors in that country)
(now called Dear Health Practitioner letter)
1:06:42 PM (320 is a document from Japan and telling Eli to tell prescribers if patient is diabetic or history of do not give Zyprexa to patient)
(and I you do you have to monitor the glucose level in the blood and compliance of telling family members of this so they understand the importance of this warning)
(very good document)

1:09:13 PM Letter on screen for jury to view
(June 2001 for product on Japanese market)
(April 2002 date of safety information)
(means during this year they had reports where nine serious cases of diabetes occurred and two died from this)
(diabetic ketoacidosis, goes into coma next stage, can't deny the relationship with Zyprexa, causal can't be denied, it says that)
(within ten months of marketing Japan)
(statue and regulation is safe and effective in USA for which it has been tested)
(but psychiatric patient are not diabetes patients)
(yes, obvious since you have not tested in the MDA a diabetic group of patients and since Diabetic coma occurred in USA you have to monitor a given patient who have been given Zyprexa so you can do something if an when values of blood sugars shot up)
(some in excess of 600)
(hyperglycemia, and four fold increase and when they observed the weight gain, when they knew about other problems etc.,)
(knew this in 1995 but in 1995 the only, what they should of done after this was to do proper studies or error on safety side)

1:15:22 PM Court – ex. 320 maybe published at this time
Ex. 4436 - referenced

1:15:52 PM (comparison of countries, listed, to how those countries treated this product in their area)
(contraindicated in some cases)
(Japan is number one on this race and European Union is number two, and USA comes last)

1:18:31 PM Brenner – objection/sustained

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1:18:43 PM Brenner - objection/sustained

1:19:15 PM Court - ex. 4436 maybe published at this time

1:20:15 PM Ex. 10094 - referenced

Court - agree

Lehner - agree its 10094

(not sure of date of this document)
(letter from FDA to person in regulatory affairs at Eli...)

1:21:39 PM Sidebar begins

1:22:54 PM Sidebar ends

(this letter represents a communication from with FDA and Eli on new product and approval of)
(MDA, response)
(2007, March 28)
(FDA realized they did not hve all the information on that subject, weight gain an hyperglycemia)
(implication is they do not hve information to characterize the risks)

1:26:46 PM Brenner - objection/allowed

(yes, I do understand)

1:27:00 PM Brenner - approach

1:27:05 PM Sidebar begins

1:28:19 PM Sidebar ends

(investigative reporter obtained certain document and the yare of a nature to allow New Times to conclude)

1:29:31 PM Lehner - objection, approach

Court - will let jury go home as it is 1:30

- admonishment to jury
- not to read or watch TV on subject matter or internet searches

Juror number 5 - on question

Court - when attorneys finish their questioning, explained

Witness steps down

1:32:31 PM Outside the Presence of Jury

Court - thank Eli for way of their objections, not speaking objections

1:33:21 PM Lehner - Motion in Limine with respect to New York Times, denied in part

- beyond scope

Court - overruled the objection, context of Lilly writing to FDA on sequences of events

Lehner - by investigative reporter and came to conclusions, not proper subject of questioning and reason for Motion in Limine

Fibich - will rephrase the question Monday

Court - thank you

- temporal sequence

1:35:32 PM

Allen - agreement on deposition of Ms. Torres to put in what Mr. Lehner has asked for

- two of them agreed to leaving four for you to look at
- noon

Court - noon- tomorrow on where we stand and disagreement on Lechleiter, give me the cuts
- and response from Lily on five new cuts Beasley, Taurel, Kinon, Collins, Tollefson,

Lehner - and save our for our case

Court - correct

1:37:49 PM

Brenner - witness on stand, rule to allow someone to talk with him

Court - do not think so

Allen - would like to take to dinner

Court - can take to dinner, no problem

- Monday at 8:15
- Get started on time
- Daylight saving times reminder

1:38:54 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3AN4308-49

Judge: M. Rindner

Date: Thursday, March 06, 2008

Clerk: M. Borneman

Case No: 3AN-06-05630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial, day Four

Counsel Present:

Plaintiff: Scott Allen, Esq., Tommy Fibich, Esq., David Suggs, Esq. and Mr. Sniffen

Defendant: Mr. Lehner, Esq., Ms. Gussack, Esq., Mr. Brenner, Esq., and Mr. Jamison, Esq. and Andy Kantra, Esq.

Court Orders:

Summary of Proceedings: Trial continue to March 7, 2008.

8:28:37 AM On the record Outside Presence of Jury

Court – list case and parties

- Lilly has file Motion to Exclude Testimony of Frederick Brancati, M.D., denied, goes to side affects of diabetes and the affects on the sales
- Assumption that was writing on the objection as roman numeral 2, is actually to Denise Torres
- Every questions was objected to and some of them border on rule 11 violations
- Ms. Torres objections, some sustained, as some of them related to off promotion labels but questions pointed and related to off label, reason for sustaining the a good portion of objection on her deposition

8:32:42 AM Allen – 23 million users, saving people from electric shock therapy, misperception to jury plus the fact you sustained an objection on this product, used for schizophrenia and bi-polar disorder

Court – think overruled on that

- lot on childhood disorders and Alzheimer's

8:34:04 AM Allen - need to look at this and they open the door on risk and analysis

- use on children, 35 percent
- not saving people from lobotomies

Court – can ask me to reconsider but not where we are at this point in this case

8:35:36 AM Allen – will take this up

8:35:49 AM Fibich – need to do so today as Dr. Gueriguian is testifying tomorrow

- they open door on risk analysis

Court – if door is open, not readily apparent at this point, will take it up

- risk and analysis is in the general sense
- may after today's testimony

- door maybe open as to bi-polar but that is all I see
Fibich - end of day

8:38:09 AM Lehner - Dr. Brancati, he is making comments on 2007 label and his report, never supplemented his report to include 2007, not able to question on this, exclude

Court - is he to testify on 2007 label

Suggs - goes to comparable rates and abased on scientist literature
- deposed in January 2007

Court - before 2007 label

Suggs - yes, and no additional disclosure

Court - can testify to 2003 but 2007 is not to be brought up

Suggs - if they cross on comparable rates, door open

Court - depends on what they ask, but not preclude

8:40:41 AM Suggs - will do sidebar, if door opens

Lehner - can cross on comparable rates

Court - fashion questions carefully
- will say on notice he is to testify on comparable rates and all he is to say this is one more piece, new piece as he did not have it at time of report but there was no supplementation

Lehner - no time to depose him on this

Court - test is fair notice, close call

Fibich - its their label

Court - issue is was this witness to offer opinion on 2007 label
- other issues

8:42:59 AM Lehner - tried to put deposition pieces together and happy to show video on this

Court - motion for clarification on presentation

Court - normally, video is different, but if snippets that real do not give clear context or presentation of other side is misleading, I will consider application of snippets to be included in plaintiff's portion
- rule is if they present deposition testimony, when its your turn, you can

8:45:36 AM Lehner - designate somebody, as they do, and sit down and reconcile this and bring to you those parts that are in disagreement

Court - implication of my ruling, but yes
- make it understandable to jury and need to be fair to both of you

Allen - have ruling and will abide
Court - acceptable with you to get with them

Lehner- need people on this

Court - who's is next

Allen - will get you more this afternoon

Court - let me know when to play, gives me deadline

Lehner - and our objections

Court - bring in jury and do introductions

8:48:22 AM

Off record

8:55:39 AM

On the record

Jury is Present

Court - introductions to jury, good morning

- instruction read for jury:
- witnesses
- expert witnesses
- exhibits to be consider
- objections
- direct evidence and circumstantial evidence
- jury notes
- jury questions
- do not investigate
- four week case
- do not reads articles or watch news report on the TV or internet
- delays and interruptions of trial

9:10:22 AM

Mr. Fibich - call doctor Brancati as expert witness

9:11:02 AM

Frederick Brancati, sworn

9:11:18 AM

Direct Exam

(Newfoundville outside Baltimore, Maryland)
(John Hopkins University)
(to testify on diabetes, report prepared)

9:12:43 AM

Fibich - ex 10127, not admitted but will be using this report

Court - will follow the rule

(48 and wife is doctor)
(two children)
(Harvard University, 1981, Magna Cum Latta)
(Education listed)
(internal medicine, diagnosis and treatment of adults)
(yes, post doctoral decree, three years, epidemiology)
(master, Epidemiology is the study of pattern in disease in population)

06-05630CI

(1992 John Hopkins University, biggest and oldest department)
(full profession at Jon Hopkins and Director of internal medicine)
(job history, given)
(I mentor 7 faculty and same number of students)
(focus of research is diabetes and identify risk factors and consequences of diabetes and do clinical studies to prevent diabetes)
(being paid here for this case, yes)
(donated to university)
(personal satisfaction)
(peer review, other researchers who review our work in impartial way and give candid honest opinion)
(anonymous reviews, reason given)
(150 published articles and out of this 120 were on diabetes)
(I peer review for about 15 journals)
(National Advisory Committees, defined)
(yes, Pfizer and Norvaris)
(type one and type two diabetes are the two big ones)
(type one, less common type, 5 percent of USA cases, kids and young adults get this)
(inflammation of pancreas)
(type two, is elevation of blood glucose and account for about 90 percent of USA cases, middle age, overweight and sedentary)
(and they become insulin resistant)
(pancreas unable to compensate)
(believe there is, Zyprexa and type two relationship)

Allen - trouble hearing witness

9:24:31 AM

Reference screen

(Type 2 Diabetes Mellitus)

Court - offer doctor as expert in field of diabetes

9:25:11 AM

Lehner - voir dire of Dr. begins

9:25:21 AM

(no)
(not a physiologist, correct)
(not a psychiatrist)

Suggs - beyond scope

Court - it is

Lehner - on type two only

Court - objections

Suggs - no

Court - expert on type 2 diabetes

Suggs - offered on two but expert on both types

9:26:59 AM

Court - recognized
Direct Exam continues by Mr. Suggs

(sweet urine, tested in old days by tasting)
(20 million in USA with diabetes and 80 percent of those are of type two diabetes)
(middle age and overweight inactive people, type two diabetics)
(insulin, pancreas secretes insulin, as people gain weight they develop resistance)
(still secretes but not enough for the person)
(blood sugar rises and cells become less efficient and diabetes develops)

9:29:51 AM

Slide reference

(Symptoms: increase urine production, increased thirst, increased hunger, unexplained weight loss, fatigue, light headaches, blurred vision)

9:32:10 AM

Slide on Diagnosis of Type 2 Diabetes

(three ways, fasting plasma glucose, first thing in morning an needs to be less than 126 mg)
(plasma glucose, oral glucose test, give patient a sweet drink and measure blood sugar before n then wait two hours and measure again, needs to be 200 mg or less)

9:35:03 AM

Slide reference, Food Carbohydrates

(Food Carbohydrate slide, determines long range weight loss)

Court - using term trial, not us today

(right, in scientific jargon its group of people who are at risk and do studies on them and look for difference in those people)

9:36:23 AM

Continue with Direct by Mr. Suggs

(carbohydrates is most used but liver is clearing house to convert foods)
(side being explained to jury)
(liver, muscle and fat insulin sensitive organs)

9:38:58 AM

Slide on sugars

(side explained)
(in training thought was fat was storage area, energy but today we know fat cells secrete hormones, explained)
(weight gain is related to insulin resistance)
(100 to 125 blood sugar level range, not diabetic range but on the way to get diabetes)
(hyperglycemia refers to increases in blood sugar, normal is 80 to 90 and if they go to 105, they are showing signs of hyperglycemia)
(might be 300 to 400, if a child, depends on age and or setting)
(sign is from examination)
(symptom is a complaint)
(hyperglycemia is sign of diabetes, yes)
(no, unless in hospital and having glucose running in to them)
(126 or greater, diabetic range, the drug is provoking episodes of diabetes)
(if in non-diabetic range is pushing on way to diabetes, but not there yet)
(long term vascular damage)

06-0563001

- 9:46:50 AM Slide of diabetes leads to long term health problems and Death, etc
(macro is prefix that means big and micro is small)
(vascular means arteries)
- 9:49:17 AM Atherosclerosis slide
(cross section of coronary artery.)
(damage to line an inflammation to area)
(cholesterol develops and down stream is at risk)
(narrowed artery becomes blocked and leads to heart attack)
(can occur anywhere in the body but we are concerned with it leads to key organs)
(brain, heart and legs)
- 9:52:50 AM Slide on atherosclerosis of vessels leading to the heart
(explained, plaque in artery wall, blood clot)
(sure once a clot there is a heart attack but if just blockage, close to start of artery and downstream things are clean)
(can bypass the vein, coronary bypass surgery)
(or use of balloon, angioplasty)
(and today there are stents)
- 9:55:43 AM Slide on brain
(cross section of brain, carotid artery, one each side of neck, explained)
(this can develop atherosclerosis)
(and can affect limbs, legs, yes)
- 9:57:20 AM Slide on leg being shown
(leg and arteries being shown, explained)
(atherosclerosis, pain and limping with exercise but ok at rest, explained to jury)
(less and less blood and oxygen and death of tissue down stream and called gangrene)
(wet gangrene and dry)
- 9:59:12 AM Slide of dry gangrene being shown
(turns black due to lack of oxygen)
- 9:59:57 AM Slide of diabetes leads to long term health problems, etc,
(narrowing of small arterioles in retinal, kidney and nerves, micro)
(high blood sugar damage)
(Retinopathy, blindness)
(Nephropathy is kidney failure)
(Neuropathy is disease of leg and sensation loss)
- 10:02:56 AM Slide of diabetic Retinopathy
(hyperglycemia damage small vessels in retina, retina lacks oxygen)
(diabetes also leads to glaucoma)

10:04:41 AM	<p>Diabetic Retinopathy</p> <p>(eyeball shot, explained)</p> <p>(retina, vitreous, vessel affected by diabetes, develops microaneurysms)</p> <p>(yes, substance of retina, explained, exudates, hemorrhages, etc..)</p> <p>(might just be blocking light)</p> <p>(abnormal blood vessels, at risk and laser therapy is started)</p>
10:09:13 AM	<p>Diabetic Nephropathy 1</p> <p>(damage the filtering function of the kidney)</p> <p>(blood supply comes into contact with structure that leads to urine)</p> <p>(vital protein is lost, leaky)</p> <p>(50 liters of blood a day and very little protein should leak)</p> <p>(we detect diabetes in kidney this way)</p> <p>(body needs the protein)</p> <p>(less filtering or not leaky enough, and over amount of filtering is decrease and waste products accumulate in the blood)</p> <p>(frequent blood and urine testing is done to detect diabetes)</p>
10:13:49 AM	<p>Diabetic Nephropathy II</p> <p>(later problems are more serious)</p> <p>(fluid accumulation I legs and chest)</p> <p>(reason for two kidneys)</p> <p>(waste products accumulate in blood, like acids)</p> <p>(leading cause of kidney failure and need dialysis)</p>
10:15:49 AM	<p>Diabetic Neuropathy slide</p> <p>(damage to nerves)</p> <p>(most common in feet and legs)</p> <p>(Paraesthesia, chronic pain)</p> <p>(numbness, loss of sensation and undetected injury)</p> <p>(increased risk of infection)</p> <p>(gangrene)</p> <p>(amputation of toe, foot or even leg)</p> <p>(diabetes is leading cause of leg amputation)</p>
10:18:15 AM	<p>Slide showing foot</p> <p>(person lost sensation and not able to sense the foot, injuries)</p> <p>(penetrating to bones, serious problems)</p> <p>Court - will break, admonishment to jury</p>
10:19:16 AM	Off record
10:38:07 AM	<p>On the record</p> <p style="text-align: right;"><u>Jury is Present</u></p> <p>Court -</p>
10:38:19 AM	Direct Exam continues by Mr. Suggs

(association means A is associated with B when they go together in pattern of disease in populations, example)
(causation leads directly to)
(gray hair is non-causal but are growing old)
(risk factors, explained)
(yes, risk factor is used when relationship is probably causal)
(smoking and lung cancer is causal)
(coffee drinking study, and relationship to heart attack, could do this ethically)
(implies we are thinking causal, gray hair is sign of increased risk for heart attack, causal but not direct)
(cigarette smoking, no definitive test to prove but epidemiologist doing a lot of studies on this, 1960's)
(Bradford-Hill, two epidemiologist, Criteria for Causality)
(can be sued to sift through evidence and helps us to see the holes for next research)

10:47:24 AM Bradford-Hill Causality 1

(strength of association, how many more times more likely with A get more specific complication, smokers used)
(smoking and lung cancer, very strong for risk but many people who do not smoke get lung cancer)
(but odds are stacked against you if you smoke)
(smokers are 1.5 times more likely to get lung cancer)
(consistency has to do with how well we are able to replicate the results in different studies)
(specificity has to do with the idea of A leading to B, explained)
(element of specificity, affects organs direct smoke is hitting)
(Temporality is extreme important, time sequence)
(A equals B then A comes before B, donut consumption and diabetes, people who had diabetes actually ate less donuts, example)

10:54:17 AM Bradford-Hill Criteria for Causality 11

(dose response)
(strong relationship with smoking and duration, biologic gradient)
(Plausibility has to do with how biologically the relationship seems)
(Coherence has to do with well all research fits together)

10:57:38 AM Bradford-Hill Criteria for Causality 111

(analogy, A leads to B, cigarette example)
(experiment, long term randomized trials, not available for cigarette smoking)
(risk factors for diabetes, yes, here are)

11:01:43 AM Risk Factors for Type II Diabetes

(modifiable and non-modifiable)
(Non-modifiable is age, race and ethnicity, and family history)
(Modifiable, obesity and weight gain for risk of diabetes is exponential, and mental illness have higher risk, yes)
(substantial risk and the weight gain increases diabetes)
(or asking someone to lose weight, 5 percent, that has big effect the lowering diabetes risk)
(small weight loss has big benefits but weight gain in same range can multiplying effect for risk)
(yes)

056
(3 fold is 300 percent and 4 fold is 400 percent)
(Zyprexa, familiar with this drug, second generation anti-psychotic drug treats seer people with delusions etc.)
(schizophrenia and bi-polar)
(over 100 articles, I read and got them National Library of Medicine on the internet)
(and reviewed articles plus took notes at conferences, etc.)
(part of my approach to draft a report is to ask junior colleges to help, as it allows me to deliver product ht is more complete an more on time, I allow people to pull articles and then I look at it and makes sure it reflects my views)
(right, at Hopkins we do systematic review, explained)
(peer review, yes)
(we did restrict ourselves to this, higher value an subject to most scrutiny)
(Gold standard in the business, peer review)
(from mid to late 90's and end of 2006 when I wrote the report)
(studies conducted)

- 11:14:06 AM Types of Scientific Evidence Available to Determine Whether Zyprexa Cause Diabetes, reference
(case report is just that, case that sparked the curiosity of a physician on patient)
(case series, first case not wrote on but when 2nd and 3rd came in they suspect something, motivated to write it up)
(no, can't prove causation)
(no one study itself can but important part of scientific studies)
(de-challenged and re-challenged, explained)
(Cross sectional studies, yes, is like donuts and diabetes, take group of people and interview, not optimal, explained)
(Cohort studies comes from Roman times)
(experimental studies, explained)
- 11:21:37 AM Zyprexa and Diabetes Case Report and Case Series, slide
(we found many case report on diabetes occurring in people using Zyprexa)
(de-challenge done and improvement made and one FDA report ten cases where de-challenge and re-challenge Waives attorney don, Hyperglycemia got better and worse when taken)
(causal relationship to me)
(Clozapine, Zyprexa, Risperidone and Quetiapine)
- 11:23:56 AM Zyprexa and Diabetes Cross Sectional Studies, slide
(did not find much on this)
(chicken or egg)
- 11:24:38 AM Zyprexa and Diabetes Case control Studies, slide
(finding people with diabetes and those who do not and go through records and see who is taking Zyprexa and no Zyprexa use)
(one study showed anti-psychotic show relationship)
- 11:26:12 AM Cohort studies, slide
(17 cohort studies done an found relationship with the drugs and diabetes)
(Zyprexa most likely to hve subsequent diabetes)
(two studies found higher than Risperidone)

11:27:31 AM Experimental studies, slide

(Clozapine and Zyprexa had higher blood sugar)
(Zyprexa had weight gain an increase of blood glucose)
(Hemoglobin A1C, widely used to measure long-term glucose level, relative to Risperidone, Perphenazine, and Ziprasidone, and blood sugar binds to hemoglobin)
(hemoglobin and diabetes, nothing, but so much of it, accidental an absorbs blood sugar)
(as blood sugar rises A1C rises, and each percentage rate is 35mg of glucose)
(red blood circulate for three months)
(draw in morning or in the afternoon, useful in studies)
(anti-psychotic drugs might provoke hyperglycemia)
(Zyprexa raised hemoglobin)
(CATIE, Clinical Antipsychotic Effectiveness Trial)
(yes, smart idea as blood sugar levels vary depending on time of day)
(takes high levels of hemoglobin to raise A1C)
(trade names given for the drugs, listed)

Court – when was the CATIE study done and published

(2004 study and did not get reference section

Suggs – did not copy

11:38:36 AM Allen -in hotel

Suggs – will get information to you

11:38:45 AM Bradford-Hill Criteria, slide

(good evidence for all but for Biologic Gradient)
(Strength is moderate range)
(Consistency, lot of it in my opinion)
(Specificity, not a lot of reports on Zyprexa and adverse affects, we focus on diabetes and obesity)
(Temporality, comes from case control an experimental studies)
(Biologic Gradient, not great evidence on this one)
(Plausibility, is factor and strong association with Zyprexa and weight gain)

11:42:37 AM Weight Change After 10 Weeks, hart referenced

(chart explained to jury)
(10 weeks study)
(first generation drug haloperidol)
(range of weight gain over ten weeks given, lot of weight over a year)
(Olanzapine and Clozapine were higher on the scale than other drugs on scale)

11:46:25 AM Bradford-Hill Criteria, side

(Coherence, yes, animal studies done with disorders)
(Analogy, goes to cigarette smoking an passive smoking, second hand, Clozapine on market before Zyprexa but had substantial weight gain and risk factor for diabetes)
(chemically related to Zyprexa)

11:48:28 AM Mr. Kantra – objection

3AN5630ci-03-06-08

06

	Court – expert witness, latitude
11:48:53 AM	Continue with Direct by Mr. Suggs (two drugs that are bio-chemical similar) (satisfied or experiment, yes, CATIE study, very compelling) (no long term randomize human experiment, the gold standard) (my opinion on Zyprexa and Type Two Diabetes, it increases the risk for) (yes, I do) (do think it is, causes diabetes and for weight gain) (greater than other atypical anti-psychotic, other than Clozapine an Zyprexa) (no, many other experts share this opinion)
11:53:47 AM	Plaintiff ex. 2368 – reference, (admitted) Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes (right 2003 conference)
11:55:33 AM	Table being shown on screen – SGA and metabolic abnormalities (this table summarized the deliberation of the panel in all the fields on whether and which antipsychotic causes diabetes, did not urge FDA to revoke but address to patients and physicians to give them a heads up) (Clozapine, Olanzapine, listed the drugs on chart) (Risperidone and Quetiapine are in the middle) (and risk for diabetes, second column, Clozapine and Olanzapine are at risk for diabetes) (Aripiprazole an Ziprasidone, more aggressive screen for diabetes concluded) (included data from previous years) (William Wirshing, yes, he did present and will testify in this trial) (yes, and they came up with these findings)
12:00:57 PM	Reading from exhibit..... (FGA , first generation of antipsychotic) (yes, consistent with my opinion)
12:02:02 PM	Summary of article, on screen (yes, mention increase obesity, diabetes and dyslipidemia) (high cholesterol, dyslipidemia) Court – if close to finish I'd prefer to finish and then break
12:04:33 PM	Continue with Direct by Mr. Suggs (required to inform FDA of adverse affects, many go un-reported) Court – will take break at this time - admonishment to jury
12:05:47 PM	Off record
12:25:03 PM	On the record
3AN5630ci-03-06-08	<u>Jury is Present</u>

06-0563001

Court – 1:30 departure time, might need a little extra time, if needed

12:26:17 PM Suggs – give report to witness
- date found on CATIE

(9/05)

Court - published

12:26:38 PM Cross Exam by MR .Kantra

(Look Ahead Study is randomize control trial to determine long term health benefits of people who have diabetes)
(weight loss might reduce risk of heart attack in people with Diabetes)
(not consulted for FDA)
(blood made of up many cells, red, white, etc., and variety of flavors of white, some are called agranulocytosis)
(July 2000 submission not relied on, that is right)
(or May 2001 submission by Eli Lilly, that is right)
(March 2003 submission of Lilly, correct)
(June 2003 FDA submission, did not review)
(May 2001, I know Dr. Allison, yes, he is witness in this case, respected)
(consulted with him on this report, one occasion)
(diabetes prevalent, yes)
(5 million to 16 million)
(roughly 7 percent of Americans, 20 million people, 1 out of 14)
(and lot of un-diagnosis people with diabetes, correct)
(sounds right, 20 million people taken Zyprexa)
(would develop diabetes during course of Zyprexa, yes)
(risk factors for diabetes, yes, asked this)
(number of different factors)
(being over 45 is risk factor, yes)
(obesity and over weight, risk factor, correct)
(basis medical school stuff)
(chart published nine years ago)
(two out of three people in America are over weight, yes)
(can be as high as 50 to 60 percent for diabetes over life time)
(insulin resistance, need to produce more to be in normal range)
(25 percent of public has this insulin resistance)
(right , pre-diabetes)
(blood sugar problems but have not develop diabetes)
(correct)

12:38:39 PM (yes, observation studies as opposed to experimental studies, those factors are distributed equally)
(some are prospective and then we look forward)
(case reports an case series are real time, small groups and experimental are real time as well)
(but case and control are generally done with data base)
(noting beyond 2006 in report)

12:43:14 PM Ex. 156 Body Weight patterns from 20 to 49 etc., on screen

(yes, peer review and very proud of this)
(weight gain, we had 30 to 40 years of knowledge)

06-05630CI

(not looked at weight gain in short tie frame, no, did do inverse)
(member of America Diabetes Association, yes)
(consensus statement, yes)
(not official position of American Diabetes Association)

12:49:27 PM 2001 referenced, Page four

(Gerard Boehm, MD, Judith Racoosin, MD., Thomas Laughren, MD and Dr. Katz, MD)
(correct, FDA position of 2004)
(I also teach, yes)
(work is done with animals, at times, yes, and then the need to be confirm in humans, yes)
(re-challenge case, yes, adverse conditions returns)
(de-challenge, yes, symptoms go away)
(right, not sure number of people put back on drug and then reoccurrence of event, right)
(could be, yes)
(spontaneous is rare but happens, not seen it, but report in literature)
(yes)
(mid 90's, case reports)
(alert physicians, in general, yes, with diabetes its common enough)

12:58:59 PM Suggs - objection as to form/overruled

(did not structure report in time sequence but too and through end of 2002 and by 2002 there was one paper that had hundreds of case reports, referenced earlier)

12:59:56 PM Suggs- objection, allow to finish/

(do not remember any sitting here today, published literature)
(observation epidemiological studies)
(actually)
(randomization is patients assigned to groups)
(Correct can't be sure we are playing with level playing field)
(yes, not limit yourself to one bucket of evidence but experimental can be hard to come by)
(number of ways to evaluate diabetes outcome, yes)
(cut off points of glucose, yes)
(126 or higher is basis for diagnosis of diabetes)
(and pre-diabetes as category of diabetes)
(hyperglycemia medication, yes, another way to look if somebody has diabetes)
(and continuous levels, yes)
(in general yes, but human experiments top of studies an evidence is limited in time, weeks or months)
(when you go into studies with this time frame it is not reasonable to hypothesis on)
(in shorter studies, yes, six month studies)
(Ability, yes, increase in average blood glucose, correct but problem with is they use non-fasting glucose as compared to fasting glucose)
(clamp study, yes)
(yes, hyperglycemia clamp study, yes)
(un-glycemic clamp study)
(those studies convince me to make it more probable, weight gain from Zyprexa that lead to insulin resistance)
(correct)
(and would not expect it)

1:15:49 PM Sidebar begins
1:16:48 PM Sidebar ends

Court -

1:16:57 PM Pause Mr. Suggs confers with co-counsel

1:17:16 PM Re-direct by Mr. Suggs

(clamp studies, purpose were to look at the question of direct and immediate affect by Zyprexa on the pancreas and if negative, no direct affect)
(limited by people in it an the duration of study, effects of Zyprexa might take long, then not detected)
(but rule out toxics effect)
(weight gain as mediating factor)
(24 pounds in year is fairly short time frame)
(Zyprexa causes diabetes, nothing on cross changed my mind)

Court -

Kantra - no re-cross

Court - jury have questions

1:21:26 PM Sidebar begins on jury questions
1:23:02 PM Sidebar ends

Court - will ask three of four questions asked by jury

(generic names, need to research to make sure)

Court - stipulation tomorrow

Allen - can do it now

Kantra - tomorrow

Court - form of stipulation

(eight gain and mental illness, could be exercises less or in environment that they just eat more)
(clamp studies, no, designed to be short terms studies of Zyprexa)

Court - follow up question from attorneys

Suggs - no

Kantra - none

1:26:09 PM Witness steps down

Court - end of day, tomorrow at 8:30
- admonishment to jury

1:27:14 PM

Outside of presence of jury at his time

Court – anything to take up

1:27:28 PM

- Allen – agree to generic names, listed
- surprise it takes them 24 hours to agree to something like that

Court —

1:28:38 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3An4308-48

Judge: M. Rindner

Date: Wednesday, March 05, 2008

Clerk: M. Borneman

Case No: 3An06-05630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury Trial – Day Three

Counsel Present:

Plaintiff: Scott Allen, Esq. David Suggs, Esq. Tommy Fibich, Esq., and Mr. Sniffen
Defendant: Mr. Jamison, Esq., Ms. Gussack, Esq. Mr. Brenner, Esq. and Mr. Lehner, Esq.

Court Orders:

Summary of Proceedings: Two designation deposition and Clarification of Video Testimony to be ruled on 3/6/08. Trial continues to March 6, 2008 at 8:30.

8:27:23 AM

On the record

Outside the Presence of the Jury Panel

Court – on the record

- pre trial motions to take up
- pre-admissions issues, overrule objections and admit Eski 12 exhibit
- overrule the 2000 annual report
- deny Motion to Preclude Use of Eski Deposition, will allow portions that were requested, few to be used at opening, but not ruling entire depositions can be admitted

8:29:13 AM

Allen – Eski call note

Court – need more information on this one, not clear from what was attached what those really are, says Eski 8, but portions that were attached...

8:29:45 AM

Allen – not using all of Eski 8, will show both at this time, October 24, 2001, reading

- comparable rates is one of the unfair trade practices; misrepresentation of Zyprexa
- additional risk of hyperglycemia, diabetes, etc.,
- one message of the warning was comparable as to other anti-psychotic, have admitted documents

8:31:23 AM

Brenner – cover with exemption of UTPA, sales representative

- federal regulatory scheme, UTPA invoked and that statement is not relevant

Court – understand, dismissed claim about UTPA claim, to be used for more than one purpose, and might be relevant to call notes and is relevant to warnings, common law claims

- calls notes to come in for that purpose, need tie up to reflect Alaska
- will allow Eski Exhibit

8:32:55 AM

Suggs – rely on Seneca case, reading form

- 21CFR212.11, no reference to sale representative

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8:33:55 AM

Brenner – discovery taken on activities of Lilly for drug lists in State of Alaska and talking to legislators, classic petition under constitution, can't use this and we object
Court – portions not used

Allen – not use those but will argue State has not taken action, they have and when they do they form Alaska State Action Committee to fight

Court – no one made Nora Pennington motion, not rule

8:35:54 AM

Jamison – Virginia Peterson, juror, relationship with person at Eli Lilly, this is Alex Azar, first cousin

Court – and doesn't talk about business

Jamison – Senior Vice President, top five or six in the company, direct involvement in state government, senior member of Eli
- rule 47©(9)

Court – parties or attorneys

Jamison – right, he is a party

Court - not named in complaint

Jamison – no

Court – says parties or attorney

Jamison – it's a corporation an they act through employees, rule 47© is absolute basis and want this jury to be fair and impartial, she needs to be stricken for cause

Court - not strike for cause at this time
- question extensively on this relationship,
- denied to strike for cause

8:39:24 AM

Lehner – playing Lichleiter or Torres's deposition, and looking at this last night, doesn't seem to make sense, confusing
- we have motion on this

Court – will look at deposition designation booklet, tonight

Allen – maintain the ruling

Court – will see what they file and wait and then rule on the motion

8:41:38 AM

Allen – they were at the deposition and could of done direct then

Court –

Lehner – motion goes to completeness, and look at it with this in mind

Court – on completeness or order of completeness on these people, wait your turn, they say and Lilly says they shouldn't have to wait to allow jury to understand

Lehner – they play their portions and then we play ours

Court – comprehensively, context so as not to mislead jury

Allen – that would be my problem

Court – right but context might give false sense to jury, want to avoid this

Allen – classic cross examination, they can cross

Court – perpetuation deposition

Allen – yes

Lehner – discovery

Allen – no difference, only had one day to take this deposition

8:44:57 AM Lehner – can show case management order
- no application to take for trial

Allen – one day to do this for all the country

Court – and precluded from doing follow up

Allen – yes

8:45:39 AM Lehner – time limited negotiated early on, Judge Weinstein never preclude, no one asked

Court – will read deposition and then rule
- article in the paper, question panel

Fibich – no need, only serves to further this

Court – make sure nobody read something, bets to do now

Fibich

8:47:06 AM Gussack – yes

Court – will ask the general question of jury

8:47:32 AM Off record

8:53:26 AM On the record Jury Panel is present

Court – three seats to fill
- article in today's paper, anybody seen this, nobody raises the hand

8:56:21 AM Lynn Soiseth(9), general questions, financial hardship

8:57:52 AM Dan Seiser(10), general questions

8:58:45 AM Tom Wofford(12), general questions, privacy issue, and leaving Alaska, out processing issues

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3300050-00

Court – Approach

9:00:11 AM Sidebar begins
9:02:45 AM Sidebar ends
9:02:52 AM Ms. Gussack voir dire of panel members
Mr. Soiseth (9), answers
Court - do that in chambers
9:04:04 AM Mr. Seiser(10), answers, privacy
9:04:21 AM Mr. Wofford(12), answers
9:05:04 AM Court – will excuse Mr. Wofford, military services
9:06:18 AM Loren Nilles(12), general questions, private issues
Court – take Mr. Soiseth, Seiser and then Nilles
9:08:10 AM In-chambers interview with Mr. Soiseth(9) begins
9:10:36 AM In-chambers interview ends, excused
9:11:37 AM In-chambers interview with Mr. Seiser(10), begins
9:24:31 AM In-chambers interview ends, stays
9:25:23 AM In-chambers interview with Mr. Nilles(12), beings
9:35:22 AM In-chambers interview ends, excused
Court – will keep Mr. Seiser and deny the application for cause
- parties arriving in back in the courtroom
Ms. Peterson – obtained two jobs, tight on income
- excuse, please
Court – will speak later on this issue
9:42:13 AM Ms. Misty Steed(9), general questions
9:42:59 AM Ms. Jennifer Mitchell(12), general questions
Ms. Gussack question new members
9:44:00 AM Ms. Steed(9), answers

10:07:31 AM - You are the jury and will be re-seated in a moment, no response

10:09:45 AM - Jury has been sworn

10:11:15 AM - Remaining jurors are dismissed and jury is being re-seated at this time

- will do openings, day explained to juror's

10:24:48 AM off record

10:49:31 AM On the record Jury is Present

Court – five parts to trial, explained

- day explained
- openings

10:57:03 AM Opening Argument by Mr. Scott Allen

- Eli Lilly violated Alaska Consumer Protection Act, unfair and deceptive trade practices
- In the sale of Zyprexa
- Representation of Zyprexa that had characteristics it did not have
- Diabetes, hyperglycemia, increase cholesterol and severe weight gain
- Fraud, deception, false misrepresentations and concealed and omitted a material fact to the people who purchase this drug relied on
- Failed to give adequate warning on this drug, Zyprexa
- Medicaid pays for this drug and medical care and costs
- Do not have to prove any individual has been misled or damaged, Consumer Protection Act
- Do not have to prove any damages or what damages are
- Trial has been bifurcated, first look at Eli Lilly's conduct and the other phase other people will worry about damages
- Nor do we have to prove causation
- Problems associated with taking this drug, but do not have to prove this
- Just have to prove they had evidence but did not provide to parties/doctors
- And FDA which governs this specifically say that Eli Lilly has to prepare a warning, packet insert, under the heading that label shall address hazards and limits imposed on them, to include a warning
- If they suspect a problem with the drug, they have duty to advise consumer by way of label
- We say they did not do this
- Was Lilly fair and disclose what they knew, did they give the warning once they had evidence of problems, no
- "Informed choice"

11:16:16 AM

- case is about anti-psychotic, Zyprexa, its for schizophrenia and bi-polar
- first generation drug, listed
- second generation drug, listed
- motivated the defendant's was money
- reference exhibit on screen for jury
- worst safety profile of them
- Geodon an Abilify did not have
- Olanzapine is the generic name for Zyprexa
- PDR, Physician Desk Reference
- OWC, Olanzapine weight change
- Sales representatives, sales force going to hospital, nurse, doctors and detail the drugs
- Over 2,000 in this country
- beta, gamma, long term etc.,
- and failed to give warnings to them
- glucose is high blood sugar, diabetes
- AES, Safety data base
- 100,000 people at 90 pounds of weight gain or more
- they will say the FDA had this, but facts are they did not do independent testing on these medications, do not do research, etc.,
- not about what they gave but about what they did not give to FDA, internal, private conversation and discussions and they thought nobody would see, but you will
- FDA found out and they changed the warning
- FDA is on this side of the case, your attorney general side
- This medication is serious for schizophrenia an bi-polar mania
- Financial problem on different front and they exceed in their performance on this drug
- Bet company farm on this drug
- Not a cure but treats as done of these drugs cure the problem
- witnesses to be called: Dr. Brancati, Epidemiology, and he agrees that Zyprexa causes diabetes; Dr. Gueriguian, M.D.; Dr. Allison, Ph.D., and Dr. Wirshing, M.D.

11:35:05 AM

11:38:26 AM

- reference exhibit from FDA to Eli, reading
- Reference exhibit, March 28, 2007, letter reading
- We are no confused and FDA has said he company has not warned properly, best interest of public health for Eli to change warning labels and warn on Zyprexa
- new information to be advised, reading from exhibit being referenced
- only one way to monitor, must draw blood
- hid information and they used to try and sell product telling doctor's not to even monitor

11:42:30 AM

11:45:23 AM - blood
 - reference exhibit on new warning, numerous pages, five new pages of warnings to be placed on product
 - 2007 attorney general filed this lawsuit and if I lose I will hang up my hat and find something better to do

11:48:06 AM Gussack – instruction

Court – not relevant to this trial, going back to Texas, disregard

Opening statement by Allen continues – apologize

11:49:05 AM - Reference exhibit, 1995
 11:52:24 AM - Reference exhibit, meeting from Puerto Rico
 - Dr. Charles Beasley Jr., MD, duties listed
 - Other doctor listed and job/duties listed
 11:55:53 AM - Reference on Schizophrenia Advisory Meeting, Type II diabetes and increase cholesterol
 - Told this in 1995 of this problem

Court - one hour

11:57:31 AM Opening Statement by Mr. Allen continues

12:01:08 PM - Preclinical Pharmacology
 12:02:33 PM - Joey Eski deposition, Executive Sale Representative in Alaska, reading from
 - Denise Torres, deposition referenced, reading from
 - Big board placed in front of jury on warnings, reading from
 - 1995 to 2003 there were no warnings
 - Diabetes sell sheet, referencing
 - Adverse conditions section, read
 - Hypoglycemia, low blood sugar and weight loss, opposite of weight gain
 - Will use full time

Court – and they start up tomorrow

12:13:37 PM Mr. Allen continues Opening Statement

12:16:49 PM - Not only continue not to inform FDA but have done it or years
 - reference exhibit and lost patent on Prozac, and use of Viva Zyprexa song and other advertising
 - in 1996 FFDA told them to say weight gain is benefit
 - Dr. Alan Breier, says, reading from exhibit
 - Weight gain is side effect of Zyprexa and a benefit for elderly, trained sales representatives
 - Internal documents from the company that they knew but did not warn of
 12:22:34 PM - Here's one from 1998, by Peter Clark, marketing guy,
 12:23:40 PM - Dr. Bruce Kinon, letter up on screen, exhibit
 12:24:35 PM - 1999 memo referenced, screen exhibit, to Dr. Beasley, reading from
 12:25:34 PM - November 17, 1999, internal memo, referenced
 12:26:53 PM - Attachment E, Global Product Labeling Committee, internal and private document, referenced, reading from
 - Warning change to this
 12:29:08 PM - reference warning on screen, exhibit
 12:30:01 PM - 2001 PDR referenced, on screen
 12:31:56 PM - October 9 and 10 emails on this topic, starting with Dr. Baker and he reports on diabetes
 - Marketing and scientific approach at issue, but should only be one, scientific

12:37:41 PM

- Blaming the victim, patients, not the drug
- Referencing weight gain, on screen
- And March 15, 2001, reading memo from Andrea K. Smith on Olanzapine and cardiovascular risk

12:40:37 PM

- Reference sales note in Alaska, October 24, 2001, reading

12:41:19 PM

- Reference June 22, 2002 note, reading

12:42:07 PM

- Japanese FDA make them change the label, causation can not be denied, summer 2002, reading

12:43:56 PM

- 2003 FDA tells them to change warning
- reference Consensus Development Conference, on screen
- thank you

Court – short break to rearrange courtroom, will go a little bit late today and get to evidence tomorrow

- admonishment

12:46:18 PM
1:06:28 PM

off record
On the record

Jury is Present

1:06:36 PM

Opening Statement by Ms. Gussack

- Zyprexa for serious mental illness schizophrenia and bi-polar mania
- Approved in 1996, break through medicine
- Other before 1996 but with side effects and patients were unwilling to stay on them
- Played video, closest thing to magic
- 23 million people have been prescribe with this drug
- used everyday in this country and in other countries
- no cure for schizophrenia or bi-polar but search everyday to keep people with loves ones functional
- company is very proud of this drug, Zyprexa
- Dr. Kahn to testify on treatment of schizophrenia
- Bi-polar is another devastating condition, highest risk of suicide and hard to diagnosis

1:19:47 PM

Allen – may we approach

1:19:53 PM

sidebar beings

1:20:12 PM

Sidebar ends

1:20:15 PM

Ms. Gussack continues with Direct

- make sure physician an nurse practionners have the information
- not simple to say you hve this problem an therefore you take this medication
- misleading or mislabel and they have you believe they, Lilly, failed
- FDA submission on Zyprexa and use of other medication, approved 2003
- January 2004, approved again
- Safe and effective medication
- Not label on bottle you get at the pharmacy but the length requirement by FDA
- Unraveling paper, loud and noisy
- Regulated by FDA down to the size of the print
- market began in 1996
- state wants you to believe Eli Lilly have fooled doctor's in Alaska
- no Alaskan doctors coming to court to say they were mislead, etc.,
- Lilly will bring in Alaskan doctors, Dr. Hopson, M.D.
- They don't but we will
- Two years with no restriction or restraints on doctors, two years after receiving complaints

1:28:04 PM Allen - objective

Court - state of counsel, not evidence

Opening statement by Ms. Gussack continues

- 1:28:45 PM
- best choice at considering all the risks of this medicine
 - not advertise on radio or TV, its for physicians
 - a judge has to rule if a patient doesn't take this drug, that is how powerful this medicine is
 - after two years the State of Alaska continues to prescribe this medication
 - studies done in laboratory and in clinical trials
 - when FDA gives the green light we produce and when they say stop we stop
 - what FDA says is final, the way the cops on the street
 - weight gain to be placed on the label and in the adverse section
- 1:33:09 PM
- reference label on screen, 1996 Zyprexa label on weight gain information
 - doctor's new and doctors know the risk of weight gain, risk factor for diabetes, etc.,
 - hyperglycemia and Diabetes information on the screen, 1996 Zyprexa label
 - 1998 to 2002 1 different medical letters, defined
- 1:38:40 PM
- reference Hyperglycemia/Diabetes data on Demand Resource Center, on screen
 - October 2000, 60 percent of physicians survey thought connection of diabetes and hyperglycemia with use of Zyprexa
 - And increase to 100 percent of physicians by April 2001
 - My partner Mr. Lehner will now speak with you

1:41:29 PM Opening statement by Mr. Lehner

- more and more information is gathered as the medicine is prescribed and information comes in
- 1:43:08 PM
- May 2000 FDA ask Eli Lilly to provide information
 - Letter on the screen
 - to evaluate anti-psychotic
 - July 2000 comprehensive report to FDA on Zyprexa
- 1:44:59 PM
- October 2000 FDA ask Lilly to remove information on label
 - letter placed on screen for jury to see
 - annual periodic report to FDA
 - report on screen
 - October 2002 Lilly provided briefing documents, placed on screen, nine million people taking this drug
 - March 2003 and June 2003, new submissions
 - After three years of reviewing and analysis of all data the FDA told Lilly its time to add new information to the label, placed on screen for jury to view, 2003 Label Class Warning
 - At same time FDA sent letter to all companies, September 2003, reading from, on screen
 - 2003 what information on groups who are at risk and what kind of research has been completed
 - and Lilly did this for the next three years, same time FDA was gathering from other companies
 - pancreas issues with diabetes
 - major change in how Lilly described blood glucose and Zyprexa, reading 2007 label, on screen
 - this label is just another step in evolution of the label
 - likely to be more label changes in the future as more information comes in to the manufacturer, nature of prescription medicine
 - doesn't say Zyprexa causes diabetes, very complicated disease
 - family history, age, background
 - and schizophrenia and bio-polar more likely to get diabetes

1:58:05 PM

- nobody knows what cause diabetes
- weight gains doesn't cause diabetes, either
- several label changes which added information for doctors and doesn't mean deceiving but responding to customers and FDA
- Japan label, did not agree but made the changes and once done Lilly told the FDA on this Japanese label change, letter on screen
- no secret and Lilly disagree with this on the label change, as data did not support the label change
- 22 million people using this drug and approved in 80 countries and each country has it own standard for labels
- FDA Response to Consensus Statement, on screen
- Why are we here, State of Alaska v Eli Lilly, lead you to believe doctors will be hear to say how they were deceived, but they are not
- Dr. Hopson did not even know about this

2:02:47 PM

Allen – objection, outside of/argument of counsel, not evidence in this case

2:03:33 PM

Continue with Opening statement by Mr. Lehner

- Dr. Hopson did not learn until after two months after being filed
- Nor Dr. Curtis
- Dr. Campana, reading from his deposition, on screen
- This case should of never been brought, Lilly always given information and no evidence to support allegations
- No doctor or state official asked for this lawsuit to be filed
- Will speak with you again on closings but will fine Lilly did nothing wrong an the positive attributes of this medicine
- Verdict for Eli Lilly
- Thank you

2:06:26 PM

Court – concludes openings statement for today and are dismissed

- back at 8:20
- admonishment to jury
- more instructions tomorrow
- thank you, see you tomorrow

2:07:51 PM

Outside presence of the jury

Court – matters

Allen – no

Lehner – will get transcripts to your chambers on depositions

Gussack - and demonstrative exhibits to be used by doctor

Court - clarification on video testimony

Allen – not read but you know position

Court – this and two deposition designation to be ruled on tonight

- be her early
- shorten up delay in getting jury in and out

In the Superior Court at Anchorage Alaska

Media No: 3A4308-46

Judge: M. Rindner

Date: Tuesday, March 04, 2008

Clerk: M. Borneman

Case No: 3An4308-46

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Jury trial - Day Two

Counsel Present:

Plaintiff: Eric Sanders, Esq., Scott Allen, Esq., Mr. Suggs, Esq., Mr. Sniffen and Mr.

Fibich, Esq.

Defendant: Mr. Brenner, Esq., Brewster Jamison, Esq. Mr. Lehner, Esq. Mr. Brenner, Ms.

Gussack, Esq. and Andy Kantra, Esq.,

Court Orders:

Summary of Proceedings: Jury trial continues to March 5, 2008 at 8:30. Exhibits admitted today are 2119, 2109, 2122, 2133, 2120, 2121, 2131, 2132, 2731, 3068, 3795, 2113, 1064, 1092, 1093, 10147, 10156, 10157, 10158, 10159. Judge Rindner to review 2000 Annual Report, call notes and Ms. Eski deposition tonight and rule tomorrow.

8:29:32 AM

On the record

Jury not Present

Court - no panel members are present

8:29:47 AM

Allen - do have for you the deposition issue to work on first Lechleiter and Torres

Court - thank you

Allen - and the Eli Lilly Annual report, not to be used in the opening

- plus call notes we intend to use and highlight for other side
- exhibits 9 and 10
- have 38 seconds to show and see

Court - reviewed Eli Lilly documents that they wish to pre-admit, all are admitted: 2119, 2109, 2112, 2133, 2120, 2121, 2130, 2131, 2132, 2731, 3068, 2732, 2737, 3795, 2113,

- state's documents no response until this morning and I have it
- want to look at except for annual report
- 1014, admitted not seen and Lilly did not get copy
- 1037 and 1039, showing stock exchange are not admitted, goes to profit and income, not motive
- 1092, 1093, admitted
- 1098, not admitted
- 10147, admitted
- 10156, admitted
- 10157, 10158, admitted
- 10159, admitted
- New England of Medicine article that was agreed on

Allen – agreed to admit last night
- admission and reading, if used with expert they can be admitted for discussion but if issue on pharmaceutical issue, example given, not treatise rule but also substantive evidence, publish and given notice

Lehner – do not agree because of file they come in

Court – purpose for saying is to put Lilly on notice in this area

Lehner - exactly,

Court – and for that it may be used, will admit for now

8:38:03 AM Allen – we had agreement last night and they are going change I want it on record

8:38:10 AM Lehner – use these in opening and able to describe title, but not agree to admit into evidence for truth of the matter

Court – pre-admitted what I have but later used in different way than suggested
- dealing with profit and motive, if line cross and talking more about rich company I will do something about it

Allen – 10098, handed to you this morning, call notes, highlighted sections

Court – will get something to you

8:39:58 AM Allen – deposition testimony agreed to and now have 38 seconds of video, from their file

8:41:08 AM Video starts

8:41:45 AM Video stops

Allen – that is it, will explain later

Court - not apparent

Allen –

Court – this is not to be viewed, jurors not to be view
- will protect pictures of perspective jurors, etc.,
- administrative rules

8:43:32 AM Lehner – deposition designation we agreed to, my over sight, did not pay attention closely that Eski deposition was there, others can be played by not Eski, we object

Court – go to Eski

Allen – I thought so

Lehner – my fault

8:44:27 AM Court – everything but Eski is agreed to
- will take a look at Eski

06-0563001

Allen – page 210, line 20
- 270 line 3 to 16
- page 272, line 15 to line 24

Court – helpful to me but trying to keep up an there are more of you than me and there are nights I want to keep to myself, Tuesday and Thursday, specifically

8:46:22 AM Jamison – one issue regarding perspective juror Ms. Schmidt, who blurting out things on Zyprexa, prejudicial

Court – will give instruction if needed

Jamison – address her separately

Court – used to identify

Jamison –

Fibich – jury questions

Court – can take areas first on those area in chambers or ask general questions first
- approach bench and identify, do so in chambers

8:50:30 AM Gussack – thank you

Court – will bring in panel

8:50:47 AM Off record

8:57:24 AM On the record Jury Panel is Present

Court – will now draw names
- can be private, if needed, in chambers

9:07:47 AM Clerk – has drawn 22 names

Court – introductions for members
- will answer questions on the card

9:08:55 AM Mr. John Borgan, answers general questions

9:10:02 AM Ms. Julianne Hernandez, general questions

9:10:29 AM Mr. Roger Maggard, general questions

9:11:11 AM Ms. Cheryl Feuge, general questions

9:11:53 AM Mr. Kerry Hinton, general questions

9:12:28 AM Mr. Dennis Jump, general questions

9:13:23 AM Mr. Isac Arellano, general questions

9:14:18 AM Mr. Ross Bennett, general questions

9:15:00 AM Mr. Orlando Chinena, general questions

9:15:42 AM Ms. Carol Woody, general questions – wants to talk in private

9:16:28 AM Ms. Denise Schmidt, general questions

9:17:30 AM Mr. Rodney Marsh, general questions

9:18:19 AM Mr. Kenneth Morris, general questions

9:19:14 AM Ms. Gretchen Ilutsik, general questions

9:20:19 AM Mr. James Cloud, general questions – knows Mr. Jamison, worked with him on other matters

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9:21:40 AM Mr. Gary Wells, general questions
9:23:07 AM Mr. Theodore Meyers, general questions
9:24:05 AM Mr. Charles Ramirez, general questions

Court - will break, may stand when needed, be comfortable

9:25:46 AM Ms. Virginia Peterson, general questions - family member works for Eli Lilly
9:26:38 AM Mr. Clarence Venhuizen, general questions
9:27:24 AM Mr. David Reineke, general questions
9:28:26 AM Ms. Pamela Shepherd-Bronyaur, general questions

Court - attorneys will now ask questions of you, plaintiff first

9:29:44 AM Mr. Fibich - introductions, general question of panel

9:35:36 AM Ms. Woody (10), incident that I did have problem, Department of Natural Resources, is resolved
Fibich - continues

9:36:29 AM Mr. Reineke - as Public Defender I have them every day
Court - thank you, question Mr. Reineke
Mr. Reineke (21), do not think I favor one side or the other
- I do not know I can be fair and impartial
- know people who have taken Zyprexa: clients, mother-in-law, nephew
- gives me concern

9:39:37 AM Mr. Charles Ramirez (18), read about lawsuit, work for BP

9:42:14 AM Mr. James Cloud (15)
Court - microphone

9:42:46 AM Ms. Schmidt (11), in private

9:43:06 AM Mr. Borgan (1), in private
Fibich - general questions of panel
11, 4 and 18 - primarily education

9:45:13 AM Ms. Virginia Peterson (19), family works for Eli Lilly, not sure of division and just started this summer, last saw this member at Christmas

9:47:30 AM Mr. James Cloud (15), no, not directly
Fibich - burden of proof, preponderance of evidence, explained
- diabetes questions

9:50:47 AM Ms. Schmidt, stages of diabetes, it's a killer
- controlling diabetes, explained
- hyperglycemia, high blood sugar
- hyperlipidemia

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- weight gain and diabetes

9:56:55 AM Mr. Theodore Meyer(17) – turned himself in

9:58:15 AM Ms. Schmidt (11), familiar with Zyprexa

9:58:40 AM Ms. Shepherd (22), list drugs

9:59:38 AM Ms. Ilutsik(14) family members on drugs
- son on risperdal and Ritalin
- see positive results

10:05:38 AM Ms. Woody(10), research

10:06:29 AM Ms. Hernandez(2), special ed teacher, 3 to7 kids in class

10:07:45 AM Ms. Feuge(4), pronunciation of name

10:08:22 AM Mr. Hinton(5), home daycare

10:08:52 AM Mr. Dennis Jump(6), song writer

10:09:26 AM Mr. Bennett(8), pilot, friend with diabetes

10:10:23 AM Mr. Rodney Marsh(12), insurance adjuster, manager

10:12:56 AM Mr. Gary Wells(16), work for MS society, may have had funding from Eli in the past, not sure, but most likely

10:18:11 AM Mr. Ramirez(18), can educate yourself on drugs, internet

Fibich – Ms. Eski issue yesterday, anybody know this person

10:19:29 AM Mr. Gary Wells(16) – know her husband if its Wayne, but not seen in 7 years

Fibich – completed for this, but have private talks with people

Court – have Reineke, Cloud, Wood, Schmidt and Mr. Borgan

10:21:05 AM Fibich – Mr. Ramirez

10:21:14 AM Jamison - repeat

Court – repeated

Fibich – Mr. Morris

Court – and Mr. Morris, order of

Fibich – Borgan, Woody, Schmidt, Morris, Cloud , Ramirez, Reineke

Court – order given, will start questioning in chambers in that order
- break for the rest

06-0563001

- can have coffee and juice but no food

10:24:35 AM Jamison – approach

10:24:40 AM Sidebar begins

10:25:57 AM Sidebar ends

Court – be back in ½ hour, unless you are one of the seven

- admonishment to panel, do not speak with parties or among yourself on this case
- Mr. Borgan first

10:28:21 AM In chambers interview with Mr. Borgan(1), starts

10:33:40 AM End in chambers interview with Borgan, excused

10:34:10 AM In chambers interview with Ms. Woody (10), starts

10:38:29 AM End in chambers interview with Ms. Woody, excused

10:39:37 AM In chambers interview with Ms. Schmid(11), starts

10:41:54 AM In chambers interview ends, excused

10:43:06 AM In chambers interview with Mr. Morris(13), starts

10:48:39 AM In chambers interview ends, will stay, fair and impartial, overruled challenge

10:49:53 AM In Chambers interview with Mr. Cloud(15), starts

10:58:13 AM In chambers interview ends, excused

10:59:11 AM In chambers interview with Mr. Ramirez(18), starts

11:05:28 AM In chambers interview ends, stays

11:06:01 AM In Chambers interview with Mr. Reineke(21), starts

11:07:41 AM In chambers interview ends, excused

Court – Mr. Reineke, Mr. Cloud, Ms. Woody , Ms. Schmidt and Mr. Borgan are all excused for cause

- alternates and more questioning to be done

11:11:29 AM Off record

11:15:43 AM On the record Jury Panel is Present

Court – five new members to be called

- general questions, please

11:18:09 AM Ms. Joann Wallace(1), general questions

11:18:58 AM Mr. Bruce Newby(10), general questions

11:19:41 AM Mr. Randall Twenhafel(11), general questions – owns Eli stock, have had lunch with representatives

11:21:58 AM Donald Glatter(15), general questions

11:22:45 AM Mr. Timothy Mattoon(21), general questions

Court – five new members

11:23:51 AM Mr. Fibich questions new members to jury box and of Mr. Maggard

11:24:29 AM Mr. Roger Maggard(3), able to be fair but have conference out of state
 11:25:52 AM Ms. Joann Wallace(1), answers

11:32:14 AM Mr. Randall Twenhafel(11), answers questions from Mr. Fibich, own stock and may have conflict
 - 377 shares

Fibich - will pass other members at this time, do have matter to take up with you

Court - Mr. Mattoon from question on the board, general questions, take up and in private

11:48:46 AM In chambers interview with Mr. Mattoon(21), starts
 11:51:08 AM In chambers interview ends, excused

Court - Fibich

Fibich - raises concern on juror

Jamison -

Court - conversation no juror will grant cause on Twenhafel

11:55:01 AM In chambers interview ends

11:55:14 AM Court - on the record and Mr. Twenhafel, stock ownership

11:55:58 AM Shepherd - dental problems

Court - think so, afternoon

11:57:36 AM Mr. David Noland(11) - general questions, hardship, work on commission
 11:59:41 AM Mr. Angel Guillen(21), general questions

12:00:39 PM Fibich question Mr. Noland

Noland - answers questions from Mr. Fibich

Court - questions Mr. Noland

12:02:47 PM Noland - answers question from judge and hour commute

12:04:48 PM Sidebar beings
 12:05:25 PM Sidebar end

12:06:20 PM Matthew Steele(11), general questions

12:07:02 PM Mr. Fitch - questions Mr. Steele

Steele - all commission, different store but same boss

Court - will excuse for cause at

12:08:54 PM Peter Cervelli(11), general questions

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12:10:46 PM In chambers interview with Mr. Peter Cervelli(11) starts – internal Eli memo's read, intern
not catch all of in-chambers interview
12:14:41 PM In chambers interview ends, excused
12:14:55 PM Court – parties arrive back in courtroom
12:16:09 PM Natalia Soto(11), general questions, privacy
12:17:31 PM In chambers interview with Ms. Soto, starts
12:19:04 PM In chambers interview end, excused
12:19:39 PM Court – new number 11, please
12:20:21 PM James Sabrowski(11), general questions
Court – state pass
Fibich – we are but have challenges
Jamison – break or pile on
Court – keep going
12:23:29 PM Ms. Peterson – job interview at 2pm
Court – lets go to 1:30, stay for now
12:24:42 PM Off record
12:31:20 PM On the record Jury Panel is present
Ms. Peterson – have worked it out
12:31:30 PM Mr. Jamison questions panel
12:37:41 PM Gary Wells(16), answers questions on weight and diabetes
12:40:24 PM Mr. Rodney Marsh(12), medication side effects, yes
12:41:57 PM Mr. Gary Wells (16), FDA oversees pharmaceutical industry, etc.,
12:43:56 PM Fibich – objection...
Sidebar begins
12:44:21 PM Sidebar ends
Mr. Jamison continues with voir dire of panel
12:45:24 PM Mr. Charles Ramirez(18) – answers questions
12:48:00 PM Mr. Hinton(5) – answers questions, think

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12:51:15 PM Allen – in juror in this case
Court – Mr. Hinton is excused at this time

12:52:28 PM John Sudderth(5), general questions, stock owner in company
Court - excused at this time

12:54:18 PM Court excused
- other jurors who may own this stock - none

12:55:11 PM Sidebar begins
12:56:09 PM Sidebar ends

12:56:13 PM Lisa Sand(5), general questions

12:57:30 PM Mr. Jamison questions panel
Ms. Lisa Sand – can be fair and impartial
- over utilized advertising and use of Zyprexa

1:00:16 PM Mr. Gary Newby(10), answers, personal experience, not sure I can be impartial, privacy

1:02:08 PM Mr. Orlando Chinena(9), personal and privacy
Mr. Jamison continue with voir dire

1:03:28 PM Ms. Joann Wallace(1), answer questions

1:05:20 PM Mr. Gary Wells (16), answer questions

1:05:46 PM Ms. Joann Wallace(1), answering question
Court - not hold it against them
Ms. Joann Wallace(1) – will not

1:06:14 PM Ms. Julianne Hernandez(2), answer questions, able to be fair

1:08:22 PM Mr. Roger Maggard(3), answer questions

1:10:10 PM Ms. Cheryl Feuge(4), answer questions

1:12:28 PM Mr. James Sabrowski(11), answer questions, privacy

1:14:19 PM Mr. Ross Bennett(8), answer questions

1:15:27 PM Mr. Isac Arellano(7), answers, privacy

1:17:12 PM Mr. Dennis Jump(6), answer

1:19:52 PM Mr. Rodney Marsh(12), to be done in privacy

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1:20:11 PM Mr. Kenneth Morris(13), in privacy

1:20:23 PM Ms. Gretchen Ilutsik(14), answers, privacy

1:22:44 PM Mr. Donald Glatter(1), answer

1:27:26 PM Ms. Pamela Shepherd, answers

1:36:03 PM Mr. Angel Guillen(21), answers, privacy

1:37:31 PM Mr. Clarence Venhuizen, answers

1:39:49 PM Ms. Virginia Peterson,(19), privacy

1:41:00 PM Theodore Meyers,(17), answer

Rodney Marsh(12, answers

1:45:20 PM Jamison – take up private people
- I have seven and Mr. Newby
- Eight
- same instruction as before, short break

1:49:11 PM In-chambers interview with Mr. Rodney Marsh(12), starts

1:56:00 PM In-chambers interview ends, excused

Court - Hinton remarks and objection, and his questionnaire, open the door on this, find the questions invited this response

Jamison – did not ask what his thought were but any reason, etc.,

Court – but asked any reason, and it was on his questionnaire

1:59:02 PM In-chamber interview with Mr. Chinena(9), starts

2:04:06 PM In-chambers interview ends, excused

2:04:52 PM In-chambers interview with Mr. Sabrowski(11), starts

2:10:36 PM In-chambers interview ends, stays

2:11:38 PM In-chambers interview with Mr. Arellano(7), starts

2:15:29 PM In-chambers interview ends, stays

Jamison – length of voir dire, equal time

Court – time concern

2:17:13 PM In-chambers interview of Ms. Ilutsik(14), starts

2:19:56 PM In-chambers interview ends, stays

2:20:22 PM In-chambers interview with Mr. Guillen(21), starts

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2:22:39 PM In-chambers interview ends, stays

2:23:27 PM In-chambers interview with Ms. Peterson(19), starts

2:26:03 PM In-chambers interview ends, stays

2:28:09 PM In-chambers interview with Mr. Bruce Newby(10), starts

2:34:58 PM In-chambers interview ends, excused

Allen - Mr. Ramirez has a burr in his saddle

Court - the deposition designation

[Parties speaking in chambers out of clerks sight, not able to say who is speaking]

2:40:20 PM Allen - 201.57, demonstrative, will show to jury

Court - no take up at this time

Gussack - broader motion

2:41:18 PM All parties arrive back in courtroom

2:41:46 PM Court - on record

- three panel members hve been excused
- will be bringing you back tomorrow and have 3pm hearing and 4pm hearing
- back at 8:30
- another hour or so for this process will conclude this tomorrow and do openings tomorrow and evidence on Thursday
- no panel members in the court room
- excused for the night
- one ruling deals with the Eski deposition and portions to be used

Allen - yes, and 2000 annual report and the call notes, ex. 12

- June 27, 2002, call notes, bottom of page one

Court - formal objections to this

2:48:49 PM Lehner - this morning

Gussack - not probative

Court - Eski 12, 2000 annual report

Allen - and call notes used in Eski deposition and video

2:49:52 PM Court - having view the portion you showed, do not understand relevance

Allen - saying they do not advertise, but they did, the video

- dangers of Zyprexa and primary care market
- heard today on voir dire, company of science, etc.,
- educational video

- Court – not let it come in on opening or direct, not relevant
- excluded under 403
- if the door is open, may do so on rebuttal

2:51:27 PM

Gussack – is educational point to the video

Court - not allow it for opening or in the Case-in-Chief of state

Allen – accepted

Court – Eski 12

2:52:14 PM

Allen - Eski 12, not sure of ex. number, that is it

Court - I have it and will look at this, the 2000 annual report, call notes and the Eski deposition

2:53:19 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3AN4308-45

Judge: M. Rindner

Date: Monday, March 03, 2008

Clerk: M. Borneman

Case No: 3AN06-05630CI

Case Title: State of Alaska

Vs.

Eli Lilly & Co.,

Type of Proceeding: Jury trial, Day One

Counsel Present:

Plaintiff: Scott, Allen, Esq., Mr. Suggs, Esq., Mr. Sniffen and Mr. Fibich, Esq.

Defendant: Brewster Jamison, Esq. Mr. Lehner, Esq., Mr. Brenner, Ms. Nina Gussack, Esq.,
Any Kantra, Esq.

Court Orders:

State of Alaska's Motion in Limine to Preclude Testimony or Argument, etc., is denied
State of Alaska's Request for Clarification of Court's Orders Excluding Evidence of O
Drugs, etc., granted
Eli Lilly's Motion Requesting Confidential Protection of Regulatory Communication No
Subject to Public Disclosure is Denied

Summary of Proceedings: Continue with Voir Dire on March 4, 2008 at 8:30.

8:54:56 AM

On the record

Jury Panel Not Present

Court - list case and parties present

8:55:33 AM

Kantra - Andy

Court - thank you

- issue pending before panel comes up
- jury panel is assemble and filling out the questionnaire and then they will be brought to the courtroom and take the hardship issue
- will introduce you to them and them to you

Suggs - Mr. Sniffen to do introduction

Court - fine

- will start talking with jury panel about the case and explain to them why they are here and what is going to happen for next four weeks
- will give the oath to the panel and send them home for the day
- have 75 jurors coming in this morning and will have the jurors in the bench seats, back of room
- other counsel may have to move to accommodate
- orders on remaining issue of Limine, no pending motions done
- gone over the documents the state has filed on opening statement
- six or seven new documents submitted by state, have objections and will get them done tonight

9:00:28 AM

Allen - have some more, five or six, hands to the court

- do not know, not using all of them but judgment call at this point

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Court – understand and assume objections to come in

9:01:14 AM

Lehner – list of 120 you initially submitted, if so, we already objected...will check
Allen – same for Ms. Joey Eski deposition and the FDA letter from January 2007

Allen – objection to evidence itself and the Motions in Limine already granted

Court – clarified by ruling today

- Lilly has file preadmission on some exhibits
- FDA internal documents

Lehner – packet in the hour

Court – will read new ones and objection from Lilly to old ones

- authenticity objections made at times, hard to rule in the abstract, not sure of basis as to certain documents
- number 19, 284, 320, 995, 1110, 1111, 1169, pre-admitted

Suggs - 1145

Court – 1145, admitted

- 1215 but not ruling on completeness of document
- 1605, completeness argument on this and will admit
- 1962, 3109, admitted
- 3924, admitted but with foundation issue
- 4007, 4051, 4176, 4968, 5073, 5565, 5846, admitted

9:06:36 AM

Lehner – last one

Court – 6128 but objection is sustained on this one, not use during opening, admitted

- 6215, need more discussion on, not admitted at this time
- 7802, completeness argument and foundation
- 7822, foundation argument but admitted
- 8479, 8584 admitted
- 8911 sustained
- 9281, 9731, admitted
- 10017 foundation issues, 10061 objection sustained to this one, 10064 subject to foundation
- 10066, 10068, 10094, admitted
- 10095 objection to this one

9:10:13 AM

Allen – will pull these ones

Court – original ones

- attachment C, new exhibits just filed by Lilly, and exhibits on Lilly's response, 10153, 1003 agree to admit notice, object or agree

9:11:26 AM

Lehner – hearsay but can be admitted with notice

Court – agree it can be used during openings

Lehner – provided instruction given

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Court – will give instruction on openings

Lehner – not for truth of matter asserted

Allen – 1926 skipped over

Court – I did and will go back and review

- will review attachment C exhibits and 1926
- and the ones submitted today will wait for Lilly to respond
- Lilly needs to get documents to me for their openings, helps to be in binders along with state's objections, the way they did, same packet, its useful

9:13:55 AM

Lehner – will provide but same kind of document with different dates and sequence, will be able to look at all but ruling one is the same as to all

Allen – prepared to address

Court – jury coming up at about 10:30

- Judge Christen asked me for a copy on the ruling on the preemption matters, orally done and I gave her copy of the transcript, I misspoke or not transcribed right like when I talked about the product labels have been superseded by other product labels and that this wasn't a consideration of product label currently being discussed and I mentioned that wasn't a case where I felt FDA, being fully informed, told Lily don't put warning label on this subject but it reads the opposite, it reads FDA did consider all this stuff and then reject Lily to add additional warnings, if that is what I said not what I intended to say
- If Petition for Review, just wanted to make a record
- Statement of the case, state filed objection but no statement from them, this is not what I expected to get, far to advocate piece to start this piece of the trial
- living hell, and some of those things, Lily will have to tone this down
- helpful to have something from the state

9:18:21 AM

Fibich – no objection to ours with exception, added provision on bifurcation and he has had issue on how I said that

Lehner – no objection but for last paragraph on damages "if any" were added we'd be happy

9:19:09 AM

Jamison – based on idea of parity we thought the same tone

- state says withheld information, loss of sales, etc.,
- living hell language, this came from state's own witness

Court – will not preclude in openings statement but not for introduction to the jury, just let them know what this is about

- reading from introductions
- Zyprexa number one treatment for which it is approved for
- Do not like last sentence in first paragraph
- State paying for medication should be stated as a positive, take out "although"
- Why not say, Lilly denies these allegations

Jamison – wanted to include element on what has to be done, approved

Court – is that what you are doing, and have the warning but not much said, state talks about UTPA claims but you do not

- first sentence of last paragraph is fine but, reading, take that out

Jamison – fine in favor of Lilly

Court – save that for openings

- tell them about the case not what they should do
- make it more neutral

9:25:17 AM

Jamison – objection to portion that talks about the state seeks to forcibly medicate patients with Zyprexa

Court – not necessary to explain the case to jury

- will learn the state continues to pay for medication in facilities

Jamison – understand

Court – will read objection on exhibit C and would like guidance from you as to what do you want me to focus on, pre openings, state asking for pre-admission, not sure about Lilly

- Designations depositions objections and will take up when they come in, prioritize this for me so I can make rulings on designations that might come up

9:28:23 AM

Lehner – will resolve fairly quickly

- not that many outstanding
- deposition designation to be resolved by the rulings you just made as you dealt with objections we made
- will get with them to talk about this
- they intend to call live witnesses Thursday and Friday

9:29:23 AM

Allen – right

Lehner – will get to that later in the week

Allen – agree on issue on exhibits, making copies as we speak and will sit now down and see if we agree

Court – if my rulings take care of a bunch of designation depositions, fine, but need to make record, standing objections allowed so nobody waives something that is objected to

9:30:52 AM

Allen – opening statements exhibits are of concern, will prioritize

Court – will do so in evenings or on weekends and want to take them in order you need them

Allen – will provide deposition excerpts this afternoon

Court – give me written list letting me know which ones to work on

Allen – doctors to be called and will play deposition and will have one video for you this week

- will cut down to one, if I can

Court – will them concentrate on designation depositions, see I this can be reduced

Lehner - will

Allen – as soon as the four are together I can met with Mr. Lehner and agree, if possible

Court - do not hesitate to let me know what is coming up and what needs to be ruled on, do not hesitate to tell me I over looked someone

Allen - thank you

9:34:25 AM

Court - foundation and authenticity objections, appropriate but this but I prefer to allow, if we

- one or two other rulings less clear about
- exhibit less clear than objection

Allen - Lilly documents, ones I identified and they can not deny

Court - will check jury

Allen - if produced by defendant, takes away authenticity

Lehner - need to look at documents before I agree

Court - disagree

Lehner - doesn't self-authenticate just because we produced them in discovery

Court -

Allen - redaction on regulatory, will live with that

Court - redactions for all sorts of things, like jury's to decide on what is going on, not to guess

- take a look at some of the documents, other issues

Fibich - start at 9

Court - need time to make record

- FCC court at 1:45
- Lot of hardship and other issue to take up, takes time

Fibich - voir dire and panel tomorrow

Court - goal is for openings on Wednesday

- can go long on some days
- if short on jurors after today, will take more time

9:42:31 AM

Fibich - four hours go fast and if it pushes voir dire to Wednesday, we then do not have four hours for openings, issues

Court - understand

Fibich - openings statement that you approved, we do it or you do it

Court - bring them in and give introductions to the panel, by doing so by lawyers, might make jurors more willing to stay but do it today

- needs something from Lilly

9:44:17 AM

Jamison - moment

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30C

Court – will go off record and once resolved will bring panel up and start

9:44:49 AM Jamison - working it now and just need to make certain all agree to it

Court – fine

9:45:06 AM Fibich – voir dire, we have member to challenge for cause at the time

Court – ask to approach, correct, and we'll take up the challenge

- will rule and excuse the person, if needed

Fibich – and in the hall

Court – will go to chambers and will be recorded by Mr. Borneman, will make record

- they come back will parties and I meet and greet and go to my office
- one person from each side, not the entire party of lawyers
- once qualified I will place 24 into the box...ask them the questions
- pass all 2 for cause and when do we have 22 passed for cause and then we do preempts

9:48:57 AM Fibich – 12 that will deliberate will be unknown

Court – right, 2 blind alternates

9:49:26 AM Lehner – we indicated this morning on sales representative depositions, do not believe testimony is relevant, she is heading to Hawaii with children and back March 24

Court – file motion and I'll rule

- state did not intend to call her live, Hawaii

Allen – will speak legal issue later but understand, we do not intend to call her first two days and understand the fact of her being on vacation, we do not want to interfere but she is critical witness

- they chose her out of all the sales representative in Alaska
- state to pay for her ticket to come and go back to Hawaii
- will be through before the 24th
- but may need hr to come back but will pay for it

9:52:29 AM Fibich -two experts coming in and one of them has a marriage to attend in India, no room to modify

Court – will bring her back and forth to be live, obvious problems

Lehner – very young children

- not on witness list until...

Court – we do telephonic witnesses all the time and other ways to do this, video perpetuation deposition and show her this way

9:54:08 AM Allen – I have family and this is reasonable but they knew when this started, long time ago, they knew their witness and no they are out of town

Court -live or do what you can with video

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Allen – just wanted it on the record

Lehner – not on witness...

Allen – incorrect..

Court – unless appeal point, not make record, very willing to make records to appeal points, etc., but rather not to go on things that aren't...

Allen – not appeal, can we take her deposition to do so in court this weekend

Gussack - leaves on the 10th

Court – why

Allen – will drop the request to do deposition in court, not cause problems

Court – inclined to say no

Allen – request is withdrawn

Court – do revisions and if not will bring up panel

Allen - foundation objections

Court – yes, next thing is at 2:30, settlement conference

9:57:50 AM Jamison – revised statement of case, can go over now, took out the language
- third sentence, taken out and added, reading

9:58:33 AM Allen – haven't had chance to look at it

Court – will go off record and do

9:59:04 AM Off record

10:54:35 AM On the record

Jury Panel is Present

Court – good morning

- everybody in a seat a perspective juror, only please
- introduction to panel, introduction of defense attorneys

10:55:26 AM Jamison – list attorneys present

Court – State of Alaska

10:56:07 AM Mr. Sniffen – list attorneys

10:56:58 AM Court – thank you for coming in this morning, juror services is greatest civil duty a citizen can do
- will proceed to selection of jury in a moment, twelve and two alternates
- voir dire process explained
- confidential area of questions, can be in private

10:59:56 AM Jury qualifications given

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Court – four week trial, into March
- trial day is 8:30 to 1:30

11:01:25 AM Mr. Fibich – brief statement of the case given to perspective panel members

Court – Mr. Gussack

11:04:07 AM Ms. Gussack – brief statement to the perspective panel members

Court – statement of attorney is to give overview of case and to help you later on in the case, nothing said is to be considered by you as fact in this case

- questionnaire filled out, will qualify you as juror's or not
- any one of you who is not a citizens of the US of A, all are residents
- resident of Alaska, all are
- at least 18, appear to be 18
- of sound mind, all of sound mind
- natural faculty her see, smell and touch

11:08:58 AM Ms. Woody – not able to smell

Court – thank you

- read or speak english
- felony, none
- related to any parties or witnesses in this case,
- identify witnesses

11:10:12 AM Allen – list witnesses to be called

11:11:09 AM Randy Twenhafel

Gary Wells, may know husband

Court - fair and impartial

11:11:53 AM Gussack – list witnesses to be called

Court – know any listed

Jim Cloud – I know Dr. Jackson, can be fair and impartial

11:13:40 AM Ms. Schoellhorn – I work for DHFS

Court – jury service in past year, none
- employment

11:15:08 AM Ms. Cain – Assistant Attorney General

Court – excused

Allen – fine with us your honor

Court – next

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11:16:11 AM Amanda Boswell – National Guard
Court - your fine

11:16:36 AM Ms. Ms. McGinnis – Department of Mental Health Land
Court – will stay at this time

11:17:02 AM Ted Meyer , DOT
Court – stay

11:17:18 AM Mr. Maggard - doctor

11:17:40 AM Ms. Rivas DHSS
Court – excuse

11:18:27 AM Schoelhorn – Department of Health
Court – excuse

11:19:04 AM Ms. Soto
Court - will stay
Reineke – Public Defender
Court - will stay

11:19:21 AM Joanne Wallace, Department of Corrections
Court – will stay

11:19:37 AM Mr. Mattoon

11:19:49 AM Court – will stay
Cervelli – work
Court - will stay
Twenhafel – know of Eli
Court –

11:21:16 AM Mr. Seiser - defendant in your courtroom
Court - read or seen anything on this case

11:22:28 AM Ms. Schmidt – nurse and did read...
Court – enough

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11:23:19 AM Mr. Barnett – read article, made mental notes and placed on from

11:23:49 AM Mr. Wells - saw the article

11:24:00 AM Reineke – read article

Court – fine, not evidence
- length of trial questions and issues

11:26:05 AM Ms. Woody – just got back from Belize, personal hardship and bad bites from critters I need to go to doctors for, 4:30 today
- and I own and operate two business, I get paid when I finish the job, lectures coming up, etc.,

Court –in different parts of the state

Woody – contractual issues

Court – will ask you to come back tomorrow, not excused yet

11:28:46 AM Ms. Lahey – financial as I work in Peters Creek, have one other person and she is off doing other things

Court – talk with her tonight an explain the situation, come back

11:30:37 AM Sidebar begins

11:30:44 AM Sidebar ends

11:30:46 AM Court – excuse, Ms. Lahey

11:31:25 AM Ms. Boswell – two training engagement in the lower forty eight

Court – excused

11:32:34 AM Mr. Cervelli – article due, deadline

Court - not excused

11:33:39 AM Ms. White – own business and manger quit on me and bookkeeper
- tanning salon

Court – excused

11:34:47 AM Ms. Peterson – looking for job, interviews up and coming

Court – not excuse

11:35:39 AM Ms. Ramsey – personal daycare attendant

Court - excused

11:37:00 AM Ms. Sharrar – work, baker, etc.,

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Court - excused

11:38:06 AM Mr. Sowl - wife having back surgery

Court - excused

11:38:51 AM Ms. Shepherd-Bronyaur - hardship
Court - stay at this time

11:39:57 AM Stehr - surgery on the 26th

Court - parties

11:40:31 AM Sidebar begin
11:41:06 AM Sidebar ends

Court - excused

11:41:34 AM Mr. Soiseth - financial advisor

Court - stay for now

11:42:14 AM Mr. Sudderth - work hardship

Court - will ask you to stay at this time

11:43:36 AM Ms. Stroud - just started new job

Court - excused
- anybody else

11:45:07 AM Mr. Wofford - active duty

Court - will stay for now

11:45:58 AM Mr. Withers - ER doctor

Court - parties

11:46:30 AM Sidebar begins
11:47:34 AM Sidebar ends

Court - excused

11:48:07 AM Mr. Chang - leave Wednesday night for business, real estate development

Court - excused

11:49:03 AM Mr. Olson - construction worker, very big hardship

Court - excused at this time
- parties, may I see you

11:51:09 AM Sidebar begins
11:51:31 AM Sidebar ends

Court - will excuse you for the day but back tomorrow at 8:30
- will place 22 of you in the box tomorrow and continue with voir dire
- confidential matters and privacy explain to panel
- preempts explained to jury panel
- alternates explained to panel

11:55:47 AM

Panel is excused at this time

Court - come back to the courtroom

Jamison - lot of folks in the hallway

Court - not being rude, will not to speak with you nor you with them
- will be and have been publicity on this case, do not read or view such reports or articles
- do not do research on the facts of this case, will get in court, only

11:59:00 AM

Panel is leaving the room

11:59:26 AM

Off record

11:59:52 AM

On the record

Outside Presence of jury Panel

Court - no panel members left in court room at this time
- doing good on time, should have jury tomorrow
- anything anybody wants to place on record

12:00:32 PM

Fibich - need list of people excused

Court - will get to you

12:01:37 PM

Allen - James Cloud, employed as expert witness for Lily, independent

Court - question him while in box

Jamison - have worked with Mr. Cloud and is retained by client but not by me, paid by Lilly
- banking practices

Court - do it tomorrow

Allen - expert for defense

Court - tomorrow
- exhibits
- will break at this time

12:03:18 PM

Jamison
- one of the panel members made statement and would like to think of response but also avoid eliciting comments like this

Court - can ask about and what the panel members know about this case, do not want to lose this panel

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- anything else at this time
- will break for 15 minutes
- filed in court for Motion to Preclude Joey Eski testimony

Allen – just got copy

Court – opposition by Friday

Allen – will get something to you

Court – need at least a night to do this before I rule

Allen – have her testimony and court ruling, will not require anybody to come back from vacation, will listen to deposition and play what I have

Court – not just dealing with her ability, but not testify period

Allen – will report tomorrow

Court –

Jamison - hand to clerk deposition transcript at this time to clerk

12:08:14 PM

Off record

12:42:56 PM

On the record

Outside Presence of the Jury Panel

12:42:59 PM

Court – copy of jury attendance

- pre admitted

Lehner – first list, objection to 1215, withdrawn by Lilly

Court - ok

Lehner – 1605, admitted

3924, objection

Court – foundation,

Lehner – not contested

Court – overrule objection and it is admitted, 3924

6215, Motion in Limine Objection, not contested

Court - 6215, overrule

Lehner - 7802 – withdrawn/admitted

- 7822, objection/ admitted
- 10017, objection/admitted
- 10064, withdrawn objection/admitted
- 10068, open for time being/left open
- 10095, Motion in Limine objection

Allen - letter notify the label change and with new label, once it went out it was received and in possession and admitted

Lehner - relevancy go to Motion in Limine, redundant

Allen - only evidence of the warning

Lehner - the warning itself

Court - will admit 10095

Lehner - attachment C...

Allen - will not use 3238 of C

12:49:24 PM

Lehner - seven documents to C
- object to 1941, not admit this document, irrelevant

Court - will admit this exhibit

12:50:50 PM

Lehner - 2133...
- 3238, not to be used in open
- 3278, no objection to/admitted
- 10003/admitted
- 10035/admitted
- 10153, subject to Motion in Limine, hearsay objection

Court - 10153, again

Lehner - subject to Motion in Limine we filed on Regulatory document from 2007/ why hearsay in light of FDA

Lehner - would withdrawn hearsay

Allen - took Ms. Gussack to get back and may well agree with that

Court - inclined to find these to be public records
- 10153 - deferred at this time but will overrule if objection is Motion in Limine

Lehner - 2133, doesn't relate to hyperglycemia and not to be used in the filed

Allen - but not what it is offered for

Court - understand objection

Allen - failure to warn and false and deceptive trade practices
- 2nd generation anti-psychotic
- they received this email
- black box and red box warning on diabetes, etc.,

Court - black box warning is just that

Allen - yes, literal statement

- Canada is black box
- When warning issued in Japan they did not send sales representation into the filed the information that came from Japan
- they have capability and responsibly to inform Alaska doctor of this black and or red box
- warning, they say no
- clearly indicates they had ability to inform if it benefited them

Court - if required to black box something like Zyprexa but if competitor product they did
 Allen - yes, that is exactly right

Court - not for use in the filed

- Allen - 2133, reading, Brand Manager and Market Place Manager, reading
- will tell about black box warning on other's product, they have ability to do this
 - segment specific an to share with key customer
 - reading, exactly what they did not do in Japan
 - can do it unless they do not want to

1:01:30 PM Lehner - need to look at this document on its face

- black box warning in Canada and not to regulatory obligation of Lilly
- introduces mini - trial we seem to be embarked on, high prejudicial

1:02:35 PM Allen - goes to state of mind and abilities

- not dealing with hyperglycemia, 2nd generation and they have ability to tell doctors

Court - will admit 2133, find it relevant

Allen - two more matters

- CD, handed to judge, about three minutes long...

Court - not if they have not looked at it

Allen - copy of Jordan exhibits 9 an 10, Jack Jordan, Lilly's Marketing Director

- October 200 launch and I want to play 30 seconds of that
- I did not make CD, can view it tomorrow

Court - no ruling until I hear a position from Lily

- what is it

Allen - case decided to Warner v Kent, US Supreme Court, decision

- decided and I our favor

Court - dealt with Michigan statute and pre-approval, fraud on the FDA

- thank you
- affirmed by equally divided court

1:07:20 PM Lehner - will file objection to this

Court - dealt with all attachment A, preadmission an attachment C pre-admissions stuff

- still have Lilly list of tabs, and the state has objected to
- if I adhere to my decision on public records, any other

1:08:46 PM Suggs - relevance
 3AN06-5630CI-03-03-08

Court - do see relevance, lot of allegations on what Lily should of and did not do, and what they concealed

- entitled to put on defense to this
- if relevance that would be overruled
- understand objections but will probably admit the 16 documents

Lehner - will file objections

Court - get me something to night an I'll read tonight and place on record tomorrow

Allen - will be speaking tonight and think we agree on most

Court - and then what we're working on next

Allen - yes

Court - and order on who should be looked at first

Allen - cut down to seven hours from 40

Court - be here at 8:15

- want to get jury picked and then will bring back at 4:15 or so

1:12:31 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3An4308-44

Judge: M. Rindner

Date: Friday, February 29, 2008

Clerk: M. Borneman

Case No: 3AN-06-5630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Status hearing – Jury Questionnaire

Counsel Present:

Plaintiff: Eric Sanders, Esq., telephonic

Defendant: Brewster Jamison, Esq., telephonic

Court Orders:

Summary of Proceedings: Changes to jury questionnaire completed and Mr. Jamison will drop copies by 5pm tonight.

4:06:08 PM

On the record

Court – list case and parties present

- last minute issues on jury questionnaire
- first, each question are number an Sanders wants bullet points

Sanders – form has number off to the side, example, assume some code, not necessary

Court – overruled

Sanders – questions 41, reading

Jamison – my language

Court – change to four weeks

4:08:00 PM

Jamison – about four weeks

Court - changes to be made, copies by 4:30 or get to jury clerk Monday by 7:30

- will meet you and get copies, by when

Jamison – just hit print and it will take to 5pm

Court – will meet you at 5pm, call

Sanders – plan for Monday

Court – settlement conference cleared and we will bring in the panel and give them the questionnaire to fill out and when done we will bring them up stairs and do preliminary questions and then take up hardships exemptions

Jamison - and introduce trial teams

- exchange

Court - by noon 3/1/08

Sanders - give understanding on hardship to lawyers form out-of-state

Court - spring break vacation people who have tickets are off panel

Jamison - you will question jurors

Court - not all but initial

- may have to call in more people on Tuesday, will slow thing down

4:15:28 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3AN4308-40

Judge: M. Rindner

Date: Tuesday, February 26, 2008

Clerk: M. Borneman

Case No: 3AN06-05630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Oral Argument

Counsel Present:

Plaintiff: Mr. Scott Allen, Mr. Suggs, Mr. Fibich, Esq. and Mr. Sanders and Mr. Sniffen,
AAG

Defendant: Mr. Jamison, Esq. Mr. Lehner, Mr. Brenner, Esq.

Court Orders: Motion in Limine filed by Lilly not opposed and is granted.

Summary of Proceedings: Decision to be made, orally, tomorrow on the record for the Motion on Federal Preemption, at 11am.

11:32:49 AM On the record

Court – list case and parties present

- Oral Argument on supplemental motion dealing with federal preemption filed by Eli
- State has filed two, under seal, request for clarification of orders dealing with testimony of drugs being produce and of profit and net worth
- Preclude the state from motive in this case
- Not arguing mini trial on other drugs and or profits, etc.,
- Due to what was happening in other drugs and profitability

11:35:43 AM Suggs - right, motion speak for themselves

Court – want to give Lilly an opportunity to respond but not get into issue of profit and net worth, the numbers

11:36:43 AM Lehner – understand intent the motion and goes to intent, will file brief tomorrow

11:37:05 AM Allen not net worth of company but numbers in annual report, lost patent of Prozac, need to produce another multi million dollar drug, those numbers come in

- Relevant to motive

11:37:51 AM Court – both motion go to introduce, preclude from dealing with this at all and...

Lehner - argument on this

Court – if needed will allow

- two late filed Motions in Limine, one by plaintiff to preclude Zyprexa warning and one by Lilly filed yesterday, motion to accept late, granted, reading about adverse event
- response from Lilly to first motion and one from state as to one filed yesterday

06-0563001

Brenner – tomorrow

Fibich – not object to their Motion in Limine

Court - to exclude adverse events, order to be issued

- proposed Jury questionnaire filed today, do tomorrow

Jamison – filed

Court – right, wand wait for objections

11:41:18 AM

Fibich – want argument non this as we oppose this questionnaire or we have one of equal length

Court – helpful to se yours and needs to be done quickly

Fibich – will file today, will address tomorrow

Court – alternate questionnaire, want to know why

Fibich – by close of business today

Court – instruct to jury as to what the case is about but I prefer you each describe the case to the panel and generally do not give instruction on case

- issue of opening jury instruction pre-evidence, tomorrow

Lehner – did prepare something for them and with idea if you wanted something

Court – summary judgment motions for today

Lehner – large number of pages added to designation, will consult with them, but if done will file something, but we are checking

Allen – cut down and he says added pages but cut 75 percent to designations

- no 80 pages added

Court – argument on pending motion federal preemption, asking me to decide this motion because of disclosure by state to request being asked that the state let them know of communication that violate the UTPA, two types of evidence states says, product label and sales representative communication as reference by call notes, off label notes of Zyprexa

- product warning labels, if basis the yare preempted by federal law
- now saying the whole warning claims is also preempted as a matter of federal law
- taken up next term in federal court and w have case law that goes both ways
- dealt with in Judge Weinstein case
- can label be used to proved UTPA claim as opposed to warning claim
- and nobody talking about sales representative call notes, preemption argument hve anything to do with that par of UTPA claim

11:52:24 AM

Brenner – its exemption under State of Alaska's UTPA

Court – thank you, as to both types of claims but certainly to labels, now state has clarified and Lily saying clear exemption

11:53:27 AM

Brenner – yes, we submit both claims, labeling and call note claims, are exempted by this provision

- not disputed the regulation of labeling is extensively by the FDA
- they pointed out Friday, reading from state's brief
- true and undisputed if contravened the statute or regulations it is liable for sanction for misbranding
- conduct, labeling, regulating else where an prohibited by FDA exemption applies, that is the labeling part
- call notes are also regulated by FDA, in the brief, its criminal
- off label promotion is violation of criminal law, they are right

Court – New York Time's off Label is being looked at for this very purpose

Brenner – so says the New York Times

- call note conduct, prohibited and straight forward reading of UTPA exemption
- exemption applies, its straightforward
- federal preemption, is not preclusion of evidence but summary judgment for failure to warn an preempted by federal law

Court -first part, not preemption issue, its in the statute, satisfied test but UTPA takes it out

Brenner – right

- cases going both ways
- this is the hot topic in pharmaceuticals circles
- end of year we will have answer from Supreme Court
- Regal case
- Ken v Warner

Court - read the case as the FDA changed the label, what does this do here

Brenner - Levine will decide if we have jobs, product liability

Court –

12:01:03 PM

Brenner- Judge Weinstein came down against us

- many case not filed on preemption 21CFR317.340

Court – FDA, some say change and others clarification, is this minimum and determines how courts rule on preemption issue

- solicitor an FDA positions in 2009
- Judge Weinstein have analysis on deference to be given to this pronouncement
- Case law find preemption but different for labeling

Brenner -

- Telling us FDA has deference, Skidmore doctrine

Court – I it makes sense

Brenner – contrast is substantial deference to be given to agency on its own rules, why important, solicitor general brief says its an over reading

- Levine, FDA overtime was in communication on risk, not to trigger CV
- CV trumps preemptions, and we're told it doesn't
- Section 202, 1960 amendments

12:05:35 PM

3AN-06-05630ci-02-26-08

- Solicitor general brief is instructive

Court – if I get to preemption issue...argument of dismissing the UTPA claim as both types of proof falls within exemption as they are regulated by FDA and if I decide against FDA claims preempted as are common law claims

- why call note claims preempted if I find they are not sufficiently regulated to fall under state law

Brenner – 3rd circuit decision, call notes issue, that case they looked at Delaware UTPA for false advertising, false representation by reps., FDA domain

- those claims must be preempted
- conduct of sales people off labeling is criminal, prohibited by FDA and enforceable by them
- state not seeking compensation but acts to enforce quasi law

Court - enforcing their own laws, why if state can enforce UTPA as to labeling and calls, how does it interfere for fed's to go after people

Brenner - 3rd circuit decision

Court – rules I against preemption, life maybe changing, but it is today and historically the drug trade was regulated by states

- no express preemption in the statute applicable here

Brenner – yes

Court – so drug industry being highly regulated, maybe true maybe not

- FDA process of approving a drug, some question state have regulated this and federal regulations as to oversight is less pervasive

Brenner – presumption is against it but it goes on all the time

- Buckman the claim was FDA no aggressive enough

Court – and ultimate finding was state had no a lot of interest in fraud against the FDA, is it true

- drugs were regulated by states an now FDA more active in this

Brenner – 1962 and even the 1938 Act, regulation by federals more than state

Court – case that find preemption are fairly recent and older cases general did not find preemption

Brenner – correct observation but doesn't change analysis

- why has FDA taken this position, do no want 50 different standard in the USA
- FDA is expert agency designed to make careful balances on warnings, very heart of preemption

12:18:35 PM

Court - depending how I rule on labels and preemption will it follow I make same ruling on common law claims

- if I find no preemption on UPTA claim, do I find none on warning claims

Brenner - no, could see a way to rational the two

- suppose you could say regulation of labeling is more pervasive and extensive and more consistent with underlying purposes of preemption

Court – cigarettes company's had warning labels, approved by government, claim preempted and still lawsuits were filed saying it's a defective product

12:21:31 PM

Brenner – expressed warranty and fraud, would not survive preemption.

- CV provision has nothing to do with sale calls and labeling
- If you rule in favor of defendant never have to reach preemption but for common law claim

12:22:40 PM

Mr. Suggs

- Under Alaska UTPA said must be interpreted broadly
- Not to be false or misleading
- AS17.20...

Court – evaluation and determination on labeling be to strict that it would deter people from using the drugs or to lose as to not now the risks, balancing act

- call notes highly regulated by FDA

Suggs – yes, but because drugs are regulated it doesn't take out of scope of Alaska

Court –

Suggs – pretense, they knew all along

Court – I did not

Suggs – Alaska law says that Smallwood v Central Peninsula Hospital, some other agency regulated doesn't take it out of the scope of UTPA, but for care and on going regulation and have to be able to show conduct regulated by agency specifically prohibits what is governed by UTPA

- but AS17.20.300, hands copy to judge, this says, reading
- nothing compares with this and takes 17.20 out of exemption. Whole different set of criteria
- if any difference between Alaska UTPA and some other regulatory scheme that is not applicable, reason no exemption to the statute
- section AS45.50.471(a), reading, where is FDA is the counter part to this
- (b)(4), reading
- AS45.50.471(b)(12), reading

Court - understand argument but why preemption

- you're saying under Smallwood, careful and ongoing conduct, conduct to be prohibited
- some one could of said labeling on cigarettes would of been preempted under Cipollone

Suggs – dictated by FDA but that was expressed preemption case, different than this

Court – we have specific labels

Suggs- yes, but

Court – insert product label approved by FDA is violation of Alaska law

Suggs – yes, under Cipollone different than drug case, long standing policy regulations are minimum standards

Court –

12:34:50 PM

- Suggs – no, up to 2000 there is no case that held preemption in prescription drug context
- in 2002 FDA began review of its labeling
 - reading, can give cite
 - only minimum standards
 - can strengthen warnings
 - common law says FDA must be exceeding

Court - changing regulations at any time seem to be not in vogue with government these days

Suggs – in 2006, different administration had new preamble said minimum standard and maximum ceiling

- not all cases go along with that, their brief
- Judge Weinstein rejected that a year after preempt
- Judge Fallon also rejected this
- Reject federal preemption

Court - contrast claim and how it violates state law

Suggs – in both cases saying label defective as it did not adequately warn

Court – you say violation of UTPA in Alaska and FDA has balance what goes in a warning
And implication in your argument as to UTPA claim, maybe warning claim, that label subjects you to violation of state law and then a different label would be used throughout the states

Suggs – no, look at label and if in fact it lacked warning, violation of common law and UTPA

- application of both of common law and finding they violated the law, it doesn't place them in violation of FDA regulations
- Alaska is saying, in the past they did not warn us of risk, not in conflict with FDA, 2003 and 2007

Court – suppose FDA hadn't require Lilly to change the label and we still had the original label

Suggs – '96 or 2003

Court – but current label is ok

Suggs – as of 2007

Court -

Suggs – change in fall of 2003 but not to doctors until 2004 and PDR until 2005, but it did change

- now we discover they had information dating back to 2002 or a stronger label and not until after New Time article did FDA come after Lilly, label changed in 2007
- Judge Weinstein said might be poster child for having private citizens as it brought out the problems in the is label
- Changed label to protect public health
- No actual conflict that would put them in bind

Court - because label has been changed

Suggs – context of this case, and this case places them in a conflict and to proceed with these claims

- future or this case

Court – not sure when you decide a preemption you do so as matter of law or whether you're looking at it in its entire case

Suggs – look a particular of the case since preamble, there is preemption, in four of the case, bizarre circumstances, warning about suicide

- Dexter and Glaxco Smith Kline case

Court – no conflict for state to enforce

Suggs – yes, four reason not to find preemption, majority of cases after preamble found none

- 2nd, even in the case where preemption were found had bizarre facts, told drug company not to warn
- 3rd no conflict in state or federal law
- 4th, not find based on FDA preamble as its not pervasive
- preemption in this case means any company could come into this state and make false warnings and nothing the state could do

Court – case with the cigarettes

Suggs – expresses and implied

- Act of congress saying this is in the label

Court – yes, and address under Smallwood that specific conduct prohibited under federal law is not sufficient, not met the test

- and warning violates state law, feds told you the labels used to demonstrate violation of UTPA had to be changed and they were changed, product of the market
- requirement of what would have been done had they provided better information
- where's preemption here, use of label fed's said to change

Brenner – changing labels is common event, but doesn't negate but strengthen, labels change all the time

- what does manufacture do in this situation, science evolves
- will be decided later this year

Court – and I decide tomorrow

Brenner – conduct regulated else where and is it prohibited

- 21CFR201, has to be accurate and informative, subject to sanctions
- Lilly warning changed and how many times did FDA go back to it
- FDA are not minimum standards, but to give substantial deference
- Laws change all the time
- Seneca case from third circuit, reading

Court –

12:58:19 PM

Mr. Suggs

- mere label change basis for liable claim, no, but if label change and we find out the drug company new of risk but did not convene it, negligence
- law is, read all the cases, Judge Weinstein and Fallon opinion the law is FDA regulations are minimum standards
- our claims deal with adequacy of label and sale reps.

06-05630CI

Court - the calls by representative of Lilly to doctors is a form of advertising
Suggs - gets us back to Smallwood

1:00:37 PM	Brenner - and physician directed pitches by sales reps. , 499 F3rd 245
1:00:50 PM	Court - oral decision tomorrow, 11 am
1:01:21 PM	Off record



In the Superior Court at Anchorage Alaska

Media No: 3AN4308-38

Judge: M. Rindner

Date: Friday, February 22, 2008

Clerk: M. Borneman

Case No: 3AN-06-05630CI

Case Title: State of Alaska

Vs.

Eli Lilly & Co.,

Type of Proceeding: Pretrial Conference

Counsel Present:

Plaintiff: Mr. Sanders, Esq., Scott Allen, Esq., Joe Steele, Esq., telephonic, Tommy Fibich and Daniel Suggs, Esq.

Defendant: Mr. Jamison, Esq., Mr. Lehner, Esq., Mr. Gussack, Esq., Ms. Brenner, Esq.,

Court Orders:

Summary of Proceedings: Oral Argument set for 2/26/08 at 11:30 and February 27, 2008 from 11 to 12 pm.

3:11:43 PM

On the record

Court – list case and parties present

- set to go to trial the week of the 3rd
- orders issued on all the preliminary motions and orders on the Motion for Reconsideration to bifurcate the trial
- oral argument set for the 27th on the supplemental motion on federal preemption
- do oral argument on the 26th at 11:30

3:13:06 PM

Sanders – yes

Court - will move to the 26th at 11:30

- Summary judgment motions are left to decide
- Terms of schedule we discussed Settlement conference on Monday and having jury panel coming in the 3rd to fill out jury questionnaire, objection

3:14:26 PM

Sanders – not seen it and not sure its needed

Court – matters to discuss

Sanders – did not get

- office problems, might of got it

[Jamison hands letter to Sanders]

Sanders – Mr. Fibich

- Mr. Allen and Mr. Suggs

Jamison – Brenner and Lehner and Ms. Gussack from Pepper Hamilton firm

Sanders – Tuesday at 11:30

- not seen the orders, might what clarification, need time on Tuesday for this, deposition

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Page 1 of 7

designation

- Court – two hours set aside and another Oral Argument on that day
- can use time at 11, Wednesday, until about noon at which time I have Child in Need of Aid
 - will set 11:30 to 1:30 on the 26th
 - and 11 to noon on the 27th
 - and then at 4:30, after hours
 - only day we have problems is on Tuesday

3:19:32 PM

Sanders start with list

Court – how long of trial

Sanders – since last time here we worked and now less than ten hours of deposition and our case is about 6 trial days, after openings

Court – six days of evidence

Lehner – 6 or 7 days for testimony

Court – each side has six days worth, 12 days of testimony and then we have Tuesday and Wednesday pick jury and arguments

Lehner – correct

Court – three weeks

Lehner – not sitting on the 17th

- Court – I have Child in Need of Aid on the 13 and 14th but may hand off to another judge
- 17th I have settlement conference in the morning and will try to move to have the full day of the 17th for this
 - will try to get relief on my conflicts

Lehner – sitting on the Friday, the 21st

Court – yes

3:22:26 PM

Sanders – not problem to hve two hours for openings

Court – works

Lehner – fine

Court – each side gets two hours for opening statements

- voir dire, normally it works the panel is brought in and statutory questions to be asked and then ask them for any emergency juror may have – three week trial
- at sometime the jurors have to hve case described to them, one or two minutes worth
- engages the jurors a little more, not argue but tell them this is the case about the drug an claims
- prepare something short and neutral on the case for me to see and then tell the juror's about

3:25:26 PM

Jamison – submit to you

Court – yes, and I'll read or you can, looking to keep it neutral and excite the jury for preparation of three weeks of trial

- time limits for voir dire
- challenges for cause to be done at the bench
- will do preempts in chambers, must use all eight; 22 in box and 14 left is the jury, process explained

3:29:35 PM

Fibich – will do voir dire an need t here or four hours total, might be less depending on questionnaire, would oppose this

- two hours on behalf of my client

Court – two days for voir dire and openings

- opening going to take four hours
- voir dire should be done on day one and day two for openings
- two hour each side for voir dire

3:31:12 PM

Lehner – will work and not a long questionnaire, submit something next week to opposing counsel

Court – need to let jury clerk know what size of pool to bring in

3:32:02 PM

Sanders – state employees to sit on jury involving State of Alaska, position

Court – do not know off top of my head but, um, is there a division of law that handles this

3:32:46 PM

Sniffen – Health Care Services, Medicaid issues and the Department of Law who monitor them

Court – those divisions will be more concern than say DOT and Assistant Attorney General office

- other questions on voir dire
- jury questionnaire when we have one
- number of lawyers to open and close for each party, multiple

Allen – yes, I'll do opening

3:34:30 PM

Lehner – same

Court - fine

- demonstrative

3:35:02 PM

Lehner – will want to see what they want to use but guidelines

Court – show to other side before using them

Allen – if they do, but will excerpts of documents

Court – if using power point do not hve to show slides but if using exhibits that are documents, show them that

Lehner – or document

Court – trial schedule, best we can, is 8:30 to 1:30 with two breaks 10 and 12:30

- but also tell juror's if they need break to raise the hand, if needed
- two 15 minute breaks in the day

witnesses, general allow latitude in taking witnesses out of order
prefer to get experts in and back to work

06-0563001

3:39:17 PM Court – address Mr. Houston, back of room, well be awhile
Court – list of witness prior to days event, gives time to prepare

3:39:57 PM Jamison – flying in form all over, order of witness so we can do what to prepare for cross or
direct, we'll do the same

3:40:18 PM Allen – not prepare to do this at this point but will do the 24 hour notice as you just stated
Court – by next Friday give list of witnesses and in order subject to changes, but still 24 hour
notice
Allen -yes
Court – noon week form today for list of witnesses
- deposition designation
Allen – toss those and I took their video, nine hours, and cut 66 percent and I will have hour out
- they objected to every questions I wanted top play back
- will meet and confer
- new designation filed
- not a problem, before next Tuesday
Lehner – just got their second round and see what remains
Allen – by Monday
Court - parties to meet Monday and deposition designation

3:43:11 PM Allen - object
Court – preference is to put on and counter-designation get played, unless concerns
Allen – if inaccurate they can play what they want
Court – if misleading the year entitled to say that, extra stuff that will not disrupt the order
- guidelines to recall
- suggesting not play cross of witness by deposition but save it for later
Lehner – correct and goes to Allen's point of view
Court - asking the same thing
Allen – wasn't sure I play an they do their cut and back and fort hand then again on their case-in-
chief
Court – might not be fair, want cross played as cross examination just as live case
- call what they prefer
Allen – do I have designation of recall

Lehner – yes
Court – exhibits, issue

3:46:50 PM Lehner – not listed demonstrative, will give notice
Allen – trial by ambush
Court – 24 hour notice for this demonstrative exhibits

3:47:41 PM Fibich – witness who fly in might bring things with them, not be tossed out
Court – will give latitude but try and avoid as things can be FedEx
- courtroom technology concerns me, setting up and tearing down of, not sure when set up can happen
- Court View Room Network to record the trial
- Pepper Hamilton called a couple of times but bad communication, Wednesday not free to set up, what and when to do this
- Exactly what is set up and what amount of space for monitors
- Room needs to be put way and safe for others to do work after you

Lehner – been talking between us on this
Court – but when is this to be done, I have hearings
- 4:30

Lehner – work at court schedule and staff, couple of hours needed
Court - in place so as not to interfere to other people and hearings
Suggs – on the 3rd
Court - have settlement hearing that day, the 3rd would work fine
Lehner – will work
Court – talk to Mr. Borneman, in-court
- addressing people in back of room, running late
Lehner – our people he look this over in the courtroom
Court – Court View TV
Allen – not opposed

3:53:31 PM Lehner – we oppose this, will file opposition
Court – file something quickly
- lot of stuff filed under seal
- if objection to being open, get me something by Monday

3:54:37 PM - things filed under seal, this is open court and not a case that I statutorily confidential, have case law

3:55:20 PM Lehner – will file something by Monday

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Court – be very clear on what the objection is a others will be here, newspaper etc.,

Sanders – New York times, Wall street News, etc., serve on them as we hve not discussed this but they have interest

Lehner – understand

Court – if asking to exclude others will want to give the other agency a chance to have a say on it

Lehner – but Monday

Court – jury instructions jury verdict form, etc., will do so by Tuesday

Sanders – we both have proposed jury instructions

Court – normal practice and before we instruct the jury I will put together the jury instruction and give parties time to make heir records, after trial

- this gets us through the list, other matters
- Judge Christen is wiling to reconvene if needed

Fibich – familiar with other side still open to settle this case but do not think settlement is fruitful with Judge Christen

- better to prepare for trial

4:00:01 PM

Lehner – we know how to reach each other, best to spend time on trial

Allen – exhibits, session on Tuesday to prepare them, mostly form their file

Lehner – think number objections to exhibits and need for court to address, some can be pre-admitted

Court – can make record on what is admitted and not go through the process, do so in advance and we'll know what is objected to and I can rule on them, do so by this week

Allen – need ruling before

Court – issues o opening, let me know what it is, not gone through all the objections to exhibits

4:02:30 PM

Jamison – we have a full set of exhibits for you 65 note books

- CD or DVD as your like

Court – prefer paper, 65 binders is a lot, will have another table brought in

- do want copies in binders and tabbed, easy for me to read along

Jamison – real time transcript and where they will sit

Court – we worked together and helpful for all

Jamison – trial by ambush

Court - took it as a joke

Jamison – will laugh along

Allen - no more humor

Jamison – evidence they seek to admit and theory of

4:05:31 PM

Court – not make them change trial brief at this time

- argument on Tuesday, preemption question, do have Medtronic case, decide yesterday, not read but will before argument, do not submit

4:06:41 PM

Lehner – coffee in courtroom

Court – free to approach witness without asking but may want to do so the first time, free to approach, act appropriately

- do allow coffee, no food
- water is available etc.,

4:08:50 PM

Lehner – question behind lecture

Court – do not care but if you move about, have to be make sure microphones are close to make good record

4:10:02 PM

Allen – happy to have podium

Court – see you Tuesday

4:10:41 PM

Off record

06-05630CI

In the Superior Court at Anchorage, Alaska

Media No: 3An4308-23

Judge: M. Rindner

Date: Tuesday, January 29, 2008

Clerk: M. Borneman

Case No: 3AN06-05630CI

Case Title: State of Alaska

Vs.

Eli Lilly and Company

Type of Proceeding: Oral Argument

Counsel Present:

Plaintiff: Eric Sanders, Esq., and Ed Sniffen, Assistant Attorney General and Joe Steele, Esq.

Defendant: Brewster Jamison, Esq., and Mr. John Brenner, Esq.

Court Orders:

Summary of Proceedings: Summary Judgment is under advisement.

9:02:22 AM

On the record

Court - list case and parties present

- oral argument on Eli Lilly's Motion for Summary Judgment, Mr. Brenner
- yesterday received expedited motion from Eli Lilly' asking leave to file supplemental brief, state filed supplemental exhibits in opposition
- did not receive these exhibits, did not come in yesterday but they came in this morning and have read those exhibits
- state's position on supplemental brief

Steele - not necessary, somehow they did not know until Friday that we'd claim every prescription given was accompanied by packet insert, as they all

Court - do you want to file something

Steele - factually incorrect

- 9/20 we file supplemental responses telling them every prescription was of violation of UTPA, packaging was incorrect

Court - why not file with brief, if so clear and obvious

Steele - ordered by Judge Hensley to provide further answer and when we did we thought it wise to attach this, shows violation and exhibits that document the violations

Court - will allow supplemental brief, when to file

Brenner -Thursday, if useful

Court - will be gone

Brenner - one week from today

Court – they file by the 5th of February and response due on the 12th of February

Brenner – design defect claim, Zyprexa outweigh by risk

- no proof in support of this claim

Court – that claim is gone leaving warning claim and the UTPA claim

Brenner – UTPA is two parts, compensatory and civil penalties

- section 551, every prescription is in violation but of UTPA, additional briefing allowed on this and left for another day

Court – do them now, not for another day

Brenner – under 551 they seek to penalize Eli for using this label, used pursuant to federal law

- state wishes to penalize a company, constitutional proportion
- no enforcement of UTPA
- submitted records between contact of doctor and sale representative
- offered without affidavit's
- they can give interpretation and I can give mine but not enough in record to tell us what it means
- left to draw inference and not enough to defeat SJ
- entitle to judgment on this claim
- under either action the state has to prove approximate causation and show a different warning would have had different results
- improperly labeled, no proof under UTPA
- they say they do not have to provide this proof
- July 2007, decline to rule until discovery unfolded

9:13:01 AM

Court - Louisiana, they say its an overpricing case and doesn't apply and if it is its, its wrongly decided

- not talking about overpricing

Brenner – they sought reimbursement of medical expenses due to another drug, Rezulin, and prescription that should not of been written

Court – entitled recover as they mislead, reading form order

Brenner – just more authority for you to consider

- causation, state doesn't deny but they want to show when adequate warnings produce Zyprexa use declined

- Japan, warning label change there and report of their expert,
- anti-psychotic, first drug usually doesn't work
- reliance of physician's
- they can not have it both ways, no proof
- off label use is not illegal or improper
- no linkage between statements from Lilly and actual prescription in Alaska

9:18:20 AM

Court – you talk about physicians reading the warning and still used the drug, but claim is the labels were inadequate and that Lilly was aware of things they did not warn the physicians

Brenner – must show warning is inadequate but separate from causation

- some do not look at labels, or weight gain but many doctor's thought this cause weight gain and they took this into account in their prescribing practice

Court – assuming their facts are true, things known to Lilly but not disclosed, that the medical community by seminar, etc., was aware of the problem and had everything been known some physicians would of said they new this already

Brenner - yes, Dr. Hopkins at API knew this and he is using Zyprexa at API
- not able to be done

Court – if material facts in dispute SJ's are denied
- but if expert testimony doesn't deal with subject your talking about they are more easily granted, why not adhere to his approach

23:24 AM

Brenner – nothing from any prescribing doctor in Alaska, no anything
- the expert cited doesn't address approximate cause, would not use as first line medicine and then he recanted this; it is first line drug for some patients
- testimony from prescribing physician, none
- we are entitled to SJ

9:24:54 AM

Mr. Steele
- any questions

Court – first, talk about the Rezulin case
- and talk about Judge Weinstein decision, lot of discussion about individual doctor's or patient's and suggests what they would of done or not
- the way Zyprexa is used, first line drug for conditions and what are risks and benefits
- and then people you used a different drug but for same conditions and the risk of Zyprexa was to risky and then turned out not to be and moving on to second and third drugs of choice, despite risk, as the first drug not being used
- then off market usage, what are risk a doctor would consider and then warn about, did Lilly advise people on this
- what would of the doctor's do if fully advised
- how many kinds of usages are we talking about
- even with perfect disclosures this might be a good drug; how do we know its this case or that case
- if Zyprexa was used and caused other conditions, is there a damages case

9:30:34 AM

Steele –
- Rezulin is not related to our theory

Court – Judge Kaplan decision, reading
- exact same thing you are claiming

Steele - yes, and why he dismissed the other claims, he doesn't say
- not binding on this court
- goes to damages, fraud on the market
- we do not have fraud theory as to liability or as to cause
- no fraud theory as to damages
- what is fraud on the market, element skipping case, have to prove they made fraudulent representation and I they relied on it and acted on this and damaged but fraud on market allows you to not use the second element, relied on fraudulent representations

Court – why

Steele – when buying pharmaceutical

- they have monopoly and not price sensitive case

Court – need to consider the risk worth taking and did they use other drugs with less risk and would they work

Steele - not cause requirement in Alaska

- third, to prove cause do you have to prove reliance by a specific physician
- 45.50.551(b), not require, period
- 45.50.551(b) is like traffic ticket liability, pay a fine

Court – has to be an ascertainable loss

Steele - 531(a) not 551(b)

Court – as individual

Steele – not the deal here, under 551(b) no causation requirement, but under 531(a)

- and under strict liability and failure to warn, conduct of defendant has to be substantial factor in bringing about the injury
- Shank's is case on point

Court – and ascertainable loss under

Steele – yes

- Rezulin has nothing to do with this as its not our theory
- This is bifurcate and the courts order is the trial on liability is March 3 and trial for causation is set for later, reading from order
- Unrelated issue to liability and discovery is proceeding
- We would of filed a 56(f) but we are not there yet, discovery ongoing
- Causation issues are being developed and if they tee up this issue...when they get evidence you'll decide if its good enough, but here in Alaska they have to do their description of undisputed facts and then we can bring in evidence for trial
- They violated Alaska UTPA under 45.54.471 and if you violate 45.50.471 you are subject to penalties under 45.50.551(b) and 531(a) its ascertainable loss
- 531(a), they are plainly wrong on what this requires
- they are wrong as a matter of law
- Alaska pattern jury instruction 10.4, ascertainable loss defined, reading
- State of Alaska received something else than what was bargained for
- Under 531

Court – run it by me again

- Alaska bargained for the payment of prescription under Medicaid that doctor's prescribed and had they still prescribed this drug, knowing the truth, did the state not get what they bargained for

Steele – no, they want a product that is...

Court – how can you say they did not get the bargain they bargained for after this scheme is undiscovered

9:47:16 AM

Steele – for warned is for armed and when they do ads they say ask you doctor

- If giving a powerful psychotropic drug must weight risk and if appropriate you need to give them informed consent on medication and let them decide if they want to take it and

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- monitor them closely and tell them to look out for diabetes
- Should be given with warnings
- They lie about, under sell the risk and over sell the use of this drug, need to sell this product, more money
- 70 percent of Zyprexa is bought by the State of Alaska and about 37.5 percent are off label and outside compendia
- to get reimbursement from Medicaid you must fit within the approved indication from FDA or one of three recognized compendia
- 37.5 fit with neither
- Alaska thought they paid for reimbursement treatment of the drug
- We thought we were getting reimbursement of this drug, we paid for it and we want our money back, different bargain

Court – if only paying for recognized uses, how is it they paid for outside this

Steele - that is the way it works in Alaska
 - to have Medicaid program you must comply with federal regulations

Court – if non-compendia should have to pay, damages in this case

Steele - ascertainable loss
 - assuming its effective

Court – that is my hypothetical and then how do we know if these non-compendia loses that you want compensation for gave the patient a benefit or not

Steele - Dalbert question

9:55:32 AM

Court – under this theory does Lily have ability to bring in the doctor's and patients for subra of some sort

Steele – they can claim...depends, under UTPA under 531(a), not comparable fault problem

- Under strict liability to warn.....
- They lie about the risk of life threaten disease and they do it a lot
- Under selling risk and lie about what its good for and they know its not good
- But pass it out like candy
- They have to depose every doctor in the state to get out of this as we can do that

9:58:30 AM

Court – so many ways for the use of this drug

- FDA approved things, first line drug, send or third line drug, etc.,
- Off use labels
- Now hearing no-compendia usage; how without knowing what the doctor used the drug for can we separate
- Have to talk with doctor

Steele – yes, you do
 - Medicaid data is voluminous IDC 9 code

Court – not produced

Steele – they have this Medicaid data

- Not produced is what an expert wants to look at and decide if helpful
- Donna the drab housewife, she shows up in the office and a single mother who is not

- sleeping, you need to talk to her about Zyprexa and this may cause her to have diabetes
- Only so many bi-polar's in the world and they have to sell Zyprexa to primary care physician and they implement a strategy to do this
- Are drug representative required to say this to the doctor, yes
- Its their job and they have a script on what to say

Court - let Lilly depose the doctor and ask what they were told and if it impacted their decision

- violations of UTPA and should I not do more than letting an expert define the script but let the people who received this communication on what they received

Steele - might produce some admissible evidence

- but don't burden us to much to pursue a remedy for this obnoxious conduct
- they have not done this and we had depositions set of Alaska physicians and on this issue but they called Mr. Sanders and said cancel and do them later, you told them to do this but they haven't

Court - thought I changed that

Steele - no, but never got that far and would get to it later, discovery ongoing

- not sure a doctor would remember this or not but bring it on and find out

Court - not get into the version of evidence I've not seen and sure Mr. Brenner is wanting to Telephonic me his side

- SJ and implication for discovery

Steele -

Court - asking what is the other side of my hypothetical without speaking to the doctor's

Steele - they are spending million of dollars and send an army out to send this message to the doctor's and the doctor will then behave in a particular way, substantial cause

- Lilly is a marketer and they know marketing works
- 551(a) no cause requirement
- once showing a ascertainable loss, not every prescription, but an ascertainable loss
- \$1000 to \$25,000 for prohibited act, lot of money
- they violated the UTPA here in Alaska, it will be very clear to everybody
- blood glucose or random blood glucose or test for tippets and a scale to weight people
- Rezulin has nothing to do with us
- And the yare wrong on causation under Alaska law

10:17:06 AM

Court - Mr. Brenner, two things, the trial is bifurcate to place causation issue down the road along with discovery doesn't your motion go to this issue and 2nd, would you say Alaska law is different and talk about Upjohn, talk about the effects of this on the motion

Brenner - consumer is the doctor and Alaska law is not contrary to other laws, effects of warning must be measure on the doctors

- warning has effect on user and user here is the doctor
- not able to get records and now the target is changing and not ale to extract causation, failure to warn must show it cause problem

Court - taken under submission...

10:21:41 AM

Steele - page five of your ruling, reading, doctor deposition section
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Court – under advisement and waiting on supplemental briefing, end of February for decision

Sanders – lot of money here, pro hac

- people coming from all over the USA for this case
- have Pretrial Conference
- could we presume the first day is jury

Court – mediation

- two days to pick a jury

Sanders - no, could have one in day but assume one day for jury selection, one day for administrative issues, and one day for opening statements

- no witnesses until third day

10:26:08 AM

Jamison – sounds reasonable and might use jury questionnaire, if you agree, we then would have panel come in on Monday and start with jury selection on Tuesday

Court – no idea how many jury panel we will need but we do have jury parking problems if we have three or four criminal jury trial at the same time

Jamison – fill out questionnaire an then go home and come back next day

Court – jury in on the 3rd doing questionnaire and do selection on then 4th and then do opening and other issue to be taken up

Jamison – state's deposition designations..

Court - big stacks from both, not seen

Jamison – if to be played, that alone is 15 trial days

Court – was set for 20 days total, the state would he to get me indication on length of trial

Jamison – over designate and do so sooner rather than later

- are you going to conduct trials on Friday

Court – yes, but for Mondays

Jamison – 8:30 to 1:30

- Meyers v API, 138 P2nd 238

Court - familiar with case

- Pretrial Conference set for the 22nd might be too late, but I'm not back until the 19th
- 20 days just for liability without causation

Sanders – probably

Court – at Pretrial Conference I want each side length of their case and I will keep time, known to do this

10:33:20 AM

Sanders – we understand not getting 20 days for our case

Court – would surprise me if it went like that

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- but what deposition are being used, entitled to know what ones you are using

Sanders – what to take up at Pretrial Conference of the 22nd

Court – inform you on how I pick a jury, allow them to ask questions, technology questions, etc.,

Sanders – this is very technological orientation

Court – speak with Borneman first and if we need to install something, we will...

Sanders – set date

Court – not now but if you come for trial and I ask about settlement and everyone says no, I will send everybody home until this happens

- will not bring in jury until this happens, formal efforts

Sanders – thank you

10:40:27 AM

Jamison – jury selection method, how

Court – explained, 22 juror's in the box with 8 preempts leaving 14

- I allow juror's to ask questions
- Motion for SJ is taken under advisement and will wait for supplemental briefing

10:47:09 AM

Off record

06-0

In the Superior Court at Anchorage Alaska

Media No: 3AN4307-208

Judge: M. Rindner

Date: Wednesday, October 24, 2007

Clerk: M. Borneman

Case No: 3AN06-05630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Status Hearing

Counsel Present:

Plaintiff: Eric Sanders, Esq. and Mr. Sniffen, AAG

Defendant: Brewster Jamison, Esq. Eric Rothschild, Esq. and Mr. Brenner, Esq., telephonic

Court Orders: Motion to Allow MR. Brenner to participate is granted.

Summary of Proceedings: Rebuttal reports by December 3, 2007. Report or stipulation in a week.

2:03:49 PM

On the record

Court – list case and parties present

- Motion for Mr .Brenner to participate in this case, granted
- Trial issue

Rothschild

- made by them after we made Motion to Continue all deadlines
- neither party has data needed for our experts to review
- Medicaid claims data, none and not sure when we will get it

Court – delay?

Sanders – additional information to be produced

Court – time lines for getting this information and effect on this on deadlines and trial date

Sanders – they asked for extension of deadlines but not for the trial so I called it a Motion to Vacate the Trial date

- need to know this due to deadlines approaching

Court – if granted is this to set the trial off

Rothschild – yes, in proposed order

- needed data and need a period to analyze

Court – best estimate on when this information is to be gather and what is the effect on dates

Sanders

- all goes to damages not liability
- we got their expert witness list, 19 of them, most on liability
- 10 days for trial, no, but probably just on liability
- do liability trial in March and we can do it in ten days and give them ten days

- I few are correct liability and causation is done and then address damages at later time
- And if they are right we are done
- Keep liability trial and vacate the trial date as it applies to damages
- Deadline for data, stagger reports
- We are prepared to give them damage reports, no secrets on liability, only question in this case is on damages
- We give damage expert report before their are due and give them time to review and they then can produce reports

Court – liability trial, stagger expert report and you'll give reports

- other information to be given
- missing information on damages, bifurcation

Rothschild

- issue of causation and reliance and they will displace with this statistical information
- Zyprexa...

Court – phase one was product defective and...

Sanders -

- Is product defective and does this defect cause harm

Sniffen – that is one aspect of the case but another to consumer protection, was the product misleading in anyway and would this cause a consumer to rely on this

Court – causation issues being put off to phase two

- does it cause diabetes and if it does did it cause to any Alaskan or increase Medicaid costs to Alaskans

2:17:14 PM

Sanders – can back out of first phase

- liability and does it cause certain types of harm

Court - liability determined in the MDL

Rothschild – not gone to trial

Court – liability and then causation and damages

- what harm does it cause and what information do you need from state that is not already determined in the MDL case

Rothschild – not sure how we advantage the court system by slicing this up

Court – to extend we are missing discovery that would make causation and damages not doable are there reasons not to do first phase on trial date we have and then why would I want to do this

- why is this saving anything, two trial and two juries

Sanders – if they are right its over

Rothschild – Unfair Trade Practices Act. message truthful or not

- issue is if improper things said to Alaska prescribers
- why would you have jury hear half a case and then bring them back

06-05630C1

Court – if he is right all other information is not needed as there is no liability

Rothschild – no need to rush to trial with half a case only to do more work later

- need Medicaid data and once we have this data we propose six months for analyze of this data and to have reports prepared, six month extension of deadlines

Court – argues to try this in two phases

- if you win not needed but if you lose on this you can settle or take chance on damages part of case

Rothschild

Court – if the drug is defective and the defect causes increase in generic conditions

- and Mr. Sniffin would argue violations in the Consumer Act, causing damages or not

Rothschild – not just causation but did the misbehavior even happen in Alaska and if so did it happen once or fifteen times

- we seek discovery of the allege violations to prescribers and will depose those prescribers
- first time I've heard about this proposal
- should have been attorney to attorney

Court – will not vacate trial dates and could bifurcate this case and what is to be bifurcated

- not clear on the Consumer Protection Act
- is discovery available at this time to be fairly litigated by both sides
- plaintiff to give me proposal on what is to be bifurcated and defense to respond
- and what is being proposed, two different juries, address procedural issue
- and then I can decide if I bifurcate this trial or not, does have advantages
- when

Sanders – can get something to you a week or so

Court – Sanders has until Wednesday and the n when for response

Rothschild - week to ten day

Court – one week

Rothschild – expert report of November 12, first deadline we run up against and not seen production of data and while this issue of the ...

Court – some reports form MDL that could be used, keep this moving

Rothschild – have reports form MDL but lot of elements to this case

- not sure how they are to prove their elements of the case
- claims part is large issue and the appeal stuff

Court – expert deadlines to be met

Sanders – as to liability, yes

- he produced expert report and there's nothing new

Rothschild – same subject matter but cases are not identical

- MDL had evidence form medical prescribers and medical records

- Putting state on notice about the experts
- Do stager report protocol

Court – he offer this

Sanders – how much time do they need, reports form MDL case, nothing knew coming form Alaska, generic drug

Court –

Rothschild – his MDL reports to be recycled without changes, not heard this but if changes in their reports the new need to respond to that

- if bifurcation approach to happen and they produce reports we need month to file response to expert reports

Court – Alaska specific reports

Sanders – no, same pill in every state

- not marketed here any different than anywhere else
- what is it they want
- reports on liability done
- how much more time do they need

Rothschild – depends if he is representing the yare identical to MDL reports

- if reports are identical we can say nothing new to say but if different we have to respond
- products liability case, failure to warn is heart of their case/allegations

2:40:30 PM

Sander – no mystery on their defense as they spent million in the MDL case, they know theory of liability

- what is the proposed date

Court – can product reports on liability by 11/12

Sanders – yes

Court – for non MDL reference, how much time

Rothschild – MDL type experts then a month to file response

Court – why, same reports, will lose dates

Rothschild – not heard the filing on the 12th are to be the same as the MDL and in that case we got to respond

Court – deadlines to be kept on liability reports an dif supplementation is need come back and explain why you need more time

- file reports on liability by November 12, 2007

Rothschild – two different liability reports we are talking about

- obligated to file what...expert opinion on issue that have no relations to facts of Alaska

Court – discovery to allow report...do so by the 12th but if information is missing file something

2:45:02 PM

Rothschild – why the rush

Court – if not hurdled to trial date we'd be back in months with same issue
- can try on some aspects of case and may help to settle the issues that are causing more problems in this case

Rothschild –

Court – will stagger

Rothschild dispositive motions precede Dalbert/Coon and we think

Court - get motions in and decide them now

Rothschild – as set 12/10 for dispositive motions, schedule given

Court – if they have no expert you should be able to file SJ, after Dalbert hearing

Sanders – not allow to go ahead on liability claim

Rothschild – SJ after Dalbert hearings

Court – if late SJ come in and if someone what's oral argument we will be up against the trial date, makes our jobs difficult
- motions as soon as possible

2:50:51 PM

Sanders – like case against Ford no different defect in states than in Alaska
- page limit on this briefing

Court – ten page limit can respond be about the same

Rothschild – bifurcation is difficult and not commit to ten pages

Court – will allow the civil rules to apply here, has page limits, must follow them, no overruled length briefs

Rothschild –

Sanders – they may add new information

Court – but guts is what has been filed before

Sanders – 11/2 we will provide liability expert reports and they will probably adopt ed the reports form MDL
- and you agreed to allow us to supplement

Court – no, if needed to be supplemented tell me and give time

Sanders - MDL reports are our expert reports on liability
- will produce by the 12 our expert report and probably the same ones form MDL

Rothschild – that is what I wanted to know

Court – subject to new information

Rothschild – rebuttal opportunity to respond

Court – no problem with rebuttal supplementation and get on with depositions

Rothschild –

Sanders – wait to see if there is an issue, he's looking to change rules

- talking about liability and reports produced
- what is to rebut if I produced the MDL report

Court – December 3 for rebuttal reports

Rothschild – deadlines coming up to complete discovery and deadlines for phase two should shift

- we need to take deposition of Alaskan prescribers

Court – will assume parties can work out discovery schedule if phase two is necessary

- part of this case is going to be moved back
- reach agreements on bifurcation

3:01:38 PM

Rothschild

- sounds like data aspect of this case to be moved back
- want data by certain date and I want to reserve...

Court – depends on first phase

- one appeal of Judge Hensley decision, briefing done

Rothschild – yes

Court – will wait for briefing or stipulation and proceed o that

3:05:09 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3An4307-154

Judge: M. Rindner

Date: Friday, August 03, 2007

Clerk: M. Borneman

Case No: 3An06-00432CI 5630CI

Case Title: State of Alaska

Vs.

Eli Lilly & Co.

Type of Proceeding: Status Hearing

Counsel Present:

Plaintiff: Eric Sanders, Esq. and David Suggs, Esq. telephonic.

Defendant: Mr. Jamison, Esq. and Mr. Rothchild, Esq. telephonic and Mr. Rogoff, telephonic

Court Orders:

Summary of Proceedings: Eli Lilly to produce expert witness list by Friday, August 10, 2007.

1:42:03 PM

On the record

Court – list case and parties present

- Motion by Eli for extensive of time for retain Expert, not for a week but for no defined date and is a request to blow up pretrial order for new trial dates?

Rothchild – need to adjust schedule

Court – how is it different than the January motion

Rothchild – not occurred as parties were waiting for ruling on defining the case

- state not produce evidence for experts to do expert reports on

Court – naming of expert, why can't they be named at this time

- state had no problem in naming experts

Rothchild – some experts in some categories could be named but they want us to name experts not bound to

- Medicaid data based provided but strip down important fields that need to be analyze
- Useless and state is contesting discovery of medical records and prescriber deposition
- Looking for definition in this case and evidence not produced

Court – hard to produce expert report in timely fashion and might change that date but we are talking about naming experts and why can't it be done at this time

Rothchild – waiting on information and up till now and in the future, we do not have body of evidence to give to an expert

- state is refusing to produce or produced material that is not useable

1:48:14 PM

Sanders

- curious this is being done on expedited basis
- in January we told you how we'd present our case as they did
- if we did it the way they want and the way right we are done

- set trial date and we go forward with you case and if wrong would be dismissed by matter of law or SJ and we are then done
- in April we had a hearing as Lilly wanted to blow up pretrial deadlines
- deadlines given and you told them to file motion if deadlines needed to be moved
- their design in defense of case is to vacate the trial date
- reading form document
- wanting to vacate the trial date
- we identified our experts and Lilly on deadline says they are unable to identify their expert, why

1:51:32 PM

Rothchild - agree would of been better to file earlier, my fault

- but if they intend to proceed with their theory they would of produce the evidence to move forward and they did not do this
- need to revisit as we need to do discovery the way we want
- medical records doesn't fit in this current schedule
- did not have all the information to push this forward as they refuse to give enough information

Court - Lilly to file preliminary expert witness list one week from today

- pretrial deadlines to be honored and the trial date is not being moved based on this record
- if state doesn't provide information for people to do their job
- will rule on things not decided on
- if down the road I decide the deadlines need to be moved I will but not at this time
- one week from today for expert list from Eli
- granting extra week but not per request
- status with orders on Judge Hensley as mediator

sanders - signed

Court -discovery related motions to him

Sanders

- they wanted to opt out for first motion

Court - do recall that

Rothchild - discovery preceded your ruling of August 1

- we do not object to discovery dispute in front of Hensley

Sanders - fine, will do that

- our position is if they do not like what the state is doing, they file Motion to Compel, we all need to comply and meet deadlines

Court - will move if not fair trial date

Sanders - not ignore deadlines

Court - next week for expert witness list - Lilly

1:59:40 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3An4307-134

Judge: M. Rindner

Date: Thursday, July 12, 2007

Clerk: M. Borneman

Case No: 3AN06-05630CI

Case Title: State of Alaska

Vs.

Eli Lilly & Co.,

Type of Proceeding: Oral Argument

Counsel Present:

Plaintiff: Eric Sanders, Esq., Joe Steel, Esq., and Mr. Snippen, AAG
Defendant: Brewster Jamison, Esq. and Andrew Rogoff, Esq.

Court Orders:

Summary of Proceedings: Motion is taken under advisement.

3:32:00 PM

On the record

Court - list case parties present

- time for argument on the Claim of Proof; way the state intends to prove their case

Sanders - Mr. Steel to do argument today

- Mat Garrison is also here today

Court - state wishes to, set aside consumer protection claims, provide epidemiological proof

- defective product, no warnings, misused, etc.,
- want to demonstrate to me there is an increase in diabetes and would not occur but for the lack of warnings

Steel - fair summary

Court - if the defect is lack of warnings and Zyprexa has its uses but with side effects

- but side effects not known and even if they knew they were hidden and given condition of parties and disclosures they would still use Zyprexa and maybe they would get diabetes and how would you prove this

Steel - problem is not if they use or not use it irrespective of warning but how you use Zyprexa with the warning

- anti-psychotic including Zyprexa can cause, weight gain, diabetes, etc.,
- one way to do this is to monitor people for complication and not give to people who are diabetic or becoming diabetic

Court - extra monies the state paid out due to alleged acts by Lilly, assume all these things would have been done and costs incurred were incurred as cost to treat diabetes; how do we know what is to be done by the doctor's

- How is the proof to come in

Steel - best to observe their behavior

- other ways to do this
- warnings in Japan about Zyprexa and Zyprexa was cut in half, can look at what happens once the warning took place
- all information about these people can be learned...

Court- based on Japanese experience there is adequate information to show cost were before the disclosure and have enough information to translate to Alaska

Steel - and European experience and USA experience

- warnings in 2003 and warnings to the doctor's in 2004 and this influence the behavior of the physician who prescribe Zyprexa
- warning has to alert a reasonably prudent physician and ordinary physician

Court - causation or hole in damages claim

- not able to prove what people would of done had they had the warning but you say class set and history to enable you to prove this
- damages hole is...telling me people would do other things that would cost the state are you able to show amount
- how do you prove what this is going to costs

Steel - we know as they bill Medicaid

Court - history post the right kind of warning post

Steel - and to the present

- Medicaid data provides information before and after
- Look at the disease being treated with medication and look at it after the warning

Court - and Alaska is not different and fair to translate to Alaska

Steel - yes, native experience is not part of Medicaid population, not useful

Court - your saying no data on natives as they are federal Indian health...

Steel - yes, valid by using Medicaid data and is it similar to reports form elsewhere

Court - if you depose every patient and doctor in terms of meeting your evidence and defend the case, they are not entitled to do this

Steel - yes

Court - why if you are able to put your case on the way you why can't they

Steel - in Alaska it is not a defense that a particular doctor won't do a particular thing but what an ordinary physician would do

Court - and you saying based on outside of Alaska but do it differently here in Alaska

- Way to challenge your epidemiological data and historical data
- or to do their own study and get their own base data to rebut this

Steel - not object to them speaking to Alaska physicians

- you get an expert to offer opinions on what ordinary physician expect in Alaska
- survey testimony on ordinary physician needs

- can opine on this in testimony and free to speak with Alaskan doctors but they want to bring in these physician, Alaskan, and talk about their patient and that is entirely different and irrelevant

Court - discovery to relevant evidence

- transferable to the Alaska experience and if they bring ten doctors and they say Deferred prosecution ordered not care what they do in Japan

Steel - to testify on theoretical experience, they can do this but not relevant under Product Liability is allow survey opinion

- burden the other side to make claim impractical, concerns here

Court - rule 82 has a provisions to deal with this but you need to prevail

- standard is can it survive a Motion for Direct Verdict
- why does it preclude them from their defense that would lead to relevant evidence

Steel - within courts discretion to fashion a reason limited form of discovery on that issue: what would ordinary physician need to be told, in terms of warning, but not specific to patient

Court - say depose 20 not 500 and not 20 doctors who prescribe this drug but say 5

Steel - five doctors who would say expectation of ordinary physician

Court - five as to how they dealt with this before they knew of the real risk of Zyprexa (allegation) and saying when further disclosure came out here is how I dealt with patients

Steel - could lead to relevant information and I have look at what they say they need to know but they can get that from IC9 code but for race and in Alaska not significant but natives are exclude and blacks are about 3 percent and Asian is about 3 percent

- and family history

Court - Dalbert hearing?

Steel - court possess foresight

Court -

- Consumer Protection Act claim they say there's an exception and regulated by the FDA so that drugs and claims involving drugs are not subject to that
- 2nd state is not person to bring claim this way
- state has remedies for Assistant Attorney General to act on behalf of public through injunctive relief and you are not going under this prong but as direct consumer with all the remedies

Steel - talking about AS 45.55.01 restraining prohibitive acts, two exceptions AS 45.50.501 and AS 45.50.531

- AS 45.50.501, this section is designed for deterrence and punishment of bad acts without demonstration of harm that is caused
- AS 45.55.531 is for recovery of money that people suffer by way of damage by corporation

Court - AS45.50.501 is preventive

Steel - deterrent can be civil penalty

- view of Assistant Attorney General is that "A" and "B" of AS45.55.501 are in the disjunctive and could pursue both
- if injunctive relief must be couple with civil penalties I ask them to enjoin Lilly's conduct
- this can be added at any time an no injunctive relief sought until end of case

Court – they say you are not a person who can bring these private kind of actions but Attorney General and state are different entities

- can sue for injunctive relief and restore those things to a person, but they say your not a person

Steel – clearly this section says, "when the attorney general has reason.."

Court – right, Consumer Protection Act and in this case the state is acting as consumer

Steel – not say that as they talk about state and Attorney General bringing action against someone, part "A"

- part "B" reading, and person in this case includes the state

Court - example, odometer case, roll back case, but "B" would allow the state to say 20 people were harmed and they ,state, would bring lawsuit or under 531 the person could bring the suit themselves

- but they say the state can enjoin but it's not really a person who can brings a 531 action, reading
- can stop prohibitive act, why can they get damages not so much for consumption but secondary part of damages

Steel – under 501 when talking about injunctive relief and talking about claim under 501, turn to AS45.55.501 the state can extract civil penalties form someone who violated the provision of the Act

Court – reading form 501, specific remedies the state can get

- can state also be a person who would have other remedies when not using terms of Attorney General or state

Steel – AS45.55.551(b) Attorney General may petition to recovery a civil penalty, reading form "B"

Court – not in front of me in terms of briefing but seems to say that

Steel – "A" and then for "B" but under AS45.55.501 if you get there "B" we can petition the court for civil penalties which are substantial

Court – amend complaint and claim 10,000 violations at 25,000 a pop but minimum of 1000.00 a pop and this is something you might be able to do, but not in front of me

Steel – covered by complaint

Court - but not in briefing

Steel – what a person is we have AS 01.10.060(a)(8) which defines person in terms of what a person is in Alaska, cited in our moving papers at page 23, AS 1.10.060(a)(8)

- under Murkowski v State, court held the state is a person with respect to disqualification statute...

Court – other cases and statute that say the state is indicated to be a person in some circumstances

Steel – yes, and when it says it includes things that follow is not all inclusive list

- Murkowski says to look at AS01.10.060(a)(8)
- and they read into this statute to include a state as person for purposes of a disqualification statute
- City of Fairbanks v Stanco, city can bring an action and they are not a person
- Remedial statute and needs to be interpreted broadly
- vast number of harm to vast number people it is not appropriate to allow the state to do this piece meal, undue burden
- Medicaid runs on money and to allow them, tort-feasor, to drain the system with no remedy, its serious problem

Court – which remedy not if there is...other reason they say there is no remedy under the Consumer Protection Act

Steel – did ask me about defendant's attitude, let the FDA handle this have you looked Judge Weinstein authority

Court – yes, have looked at it

Steel – page three, reading from Judge Weinstein decision

- in performing these task lawyers are last resort
- a burden and very complicated

Court – no class certified and cites case by insurance companies

- he is saying depends on the Consumer Protection Act

Steel – and our statute does allow you to sue

Court – section 48

Steel – AS 45.50.471(b) number 48 which is the Alaska Food and Drug section

- which then is 1720 and addresses misbranded drugs
- Judge Weinstein thought the system needed protection and the FDA is not going to do this and its left to the states and Judge Weinstein didn't think FDA wasn't capable of protecting people
- Conduct of Lily is that violates the Act is pervasive, varied and do it in all sort of ways, influence doctor's and in ways the FDA isn't involved in
- Pervasive course of conduct, FDA had no clue, clueless

Court – irregardless of subsection 48 of AS 45.54.471

- FDA doesn't qualify under the exception

Steel – right, not addressed at all by the FDA, clueless

Court – this motion comes as Proof of Claims is this SJ standard or Motion to Dismiss standard

- how am I judging this
- matter of law if evidence comes in that would be legal and Rule of Law motion

Steel – Demora if some where else

Court -12(b)(6) motion

- not to look at all this extraneous stuff but treat as SJ motion

Steel – would brief it more fully and in evidence we could understand

- Lilly deposing Zyprexa users, if considered we have a separate hearing
- Nothing they could add to this case, not a thing
- Talking about a sensitive population taking anti-psychotic medication and need to protect parties rights and we have HIPPA consideration
- If considered it is unnecessary and a burden, complicated matter

Court – Rogoff what kind of motion and what do I do with it

Rogoff – in January you said you directed the state to file a Motion for Rule of Law and we took it as SJ standard not 12(b)(6) or Demora

- you asked the state to come forward and tell how they would prove their case

Court – not 12(b)(6) motion either as evidence hasn't come in that way and not coming in as full blown...here's what the evidence is can we proceed and that's different from SJ and your not testing evidence

4:27:20 PM

Rogoff – dispute over discovery and you suggested the state to come forward ask tell me standard of proof

Court – no facts but proposals

4:28:29 PM

Rogoff – they say they can prove all counts by statistical evidence and Lilly's documents

Court – Consumer Protection Act is probably a 12(b)(6) motion

Rogoff – can it prove causation and reliance based on statistical evidence alone, impossible

- remoteness issues relating to...

Court - understand the position on standard

- why is this different from the tobacco companies cases seeking the same kind of damages sought here

Rogoff – but for Texas case most claims for reimbursement based on plaintiff physical injuries were to remote and could not be brought

Court – do not recall that being said in Alaska, Alaskan ruling

Rogoff – body of case rejected the claims, reading

- page 21 and 22 there are cases from across the country that rejected those claims, reading

Court – Iowa case, Maryland case, Minnesota case and a Washington state case, etc.,

Rogoff – third party payer cases

Court – yes, but trying to distinguish where the state brings those

Rogoff – state's remedy is through subrogation cases and state refuses to do here

4:33:19 PM

Court - why if they provide this epidemiological evidence, why doesn't this meet the burden of causation

Rogoff - no statistics can explain why or place restrictions on doctors...

Court - Judge Weinstein make it to the jury but doesn't diminish their ability to prove their case

Rogoff - we think he, Judge Weinstein, error in that case

- no restriction for physicians ability to prescribe the medication

Court - full disclosures and less cost in management

- get economist to tell me difference and they still need to prove something wrong with warnings, etc.,

Rogoff - MDL and why it can't be proven that way

- mentally ill person and fail on one drug after another and failed to get benefit from 2nd generation drugs and then the patient is placed on Zyprexa and its effective but then is diagnosis with diabetes, state would have them, Lilly, pay damages

Court - no, if epidemiology data is done correctly, dealt with in statistic

Rogoff - cases are different and in every case where a doctor's make decision based on patients history and numerous other factors that no statistical study could take into account

Court - need to see statistical studies and see if done correctly and you can challenge the study

Rogoff - no way to prove reliance and causation it's a first step in causation

- reading form article
- this is the study wants to replicate to prove something and that study doesn't prove causation in any particular case and that is the flaw in the argument and the state makes no attempt to refute our position of reliance

Court - why is this different from other epidemiological studies when the swine flu epidemic happen...forget name of symptoms, proof allowed

Rogoff - shift to administrative...

Court - one was, Mr. Sanders...

Sanders - government used epidemiological studies to show ...not caused by the medication but if you had MS your in this group...all epidemiological

Rogoff - not able to prove

Court - but through epidemiology study they say they can prove this

- Medicaid codes

Rogoff - finger on the state's flaw, heading for Dalbert hearing as not able to control every factor

- warning place on Zyprexa in Japan and sales dropped
- doesn't take into account other 2nd generation drugs to give competition in the market and warning was one factor

Court - good defense but if they tried it this way but not at this stage or Dalbert Hearing we are at

stage where do they proceed with this adventure

- and if they convince the jury doesn't it survive judgment notwithstanding the verdict

Rogoff – not address how statistic prove reliance or causation

- not block Lilly to prove their case, if allowed to go ahead with statistical evidence and to allow Lilly to make out their defenses

Court – if allowed to do discovery say only so many doctor's and is not Mr. Steel correct that before I make rulings on individual patients, HIPPA, we need more hearings and would it really be necessary as doctor's make decision and should look at them, ordinary doctor's

Rogoff – court has discretion in how discovery is conducted by parties and seems to me if you limit our discovery from the date, physical and patients... inform the parties the case could proceed statistically

- we want a number to be statistically relevant
- as to patients, I agree, its complicated but these patients they are on Medicaid
- discovery of state and physician to challenge their case and to prove our case

Court – appointed discovery master

Rogoff – not signed off yet

Court – Hensley to look at some of these issues...

- Consumer Protection Act claim

Rogoff – pointed out flaws in the state argument...

Court – pointed them out and got answers as to what person is and cities allowed to pursue things

- and you made argument on exception to take out from the Act and they cite me to AS that brings drug claims
- legislature intended these kind of claims involving drug advertisement, branding, promotion are allowed under Consumer Act

Rogoff – cities, person is defined in the statute to include corporations

- companies defined as person in the statute

Court – case law clear state remedial statute to be liberally construed

Rogoff – and do not dispute the criminal case litigated and Alaska Supreme Court said should include the state

- O'Neil investigation case, attorney powers are, reading

Court - Attorney General acting in that capacity as opposed to how they want to act in this case

Rogoff – subrogation powers through the Act

Court – argument is drugs are exempted but provision that say they are not exempt

Rogoff – Alaska Act not preempted by federal or other state acts but misbranding is covered by Food and Drug, Cosmetic Act

- appendix one, we show how each allegations is covered by the federal act
- state has power to seek injunctive relief and it has not

Court - and power to seek penalties of not less than 1000.00 and not more than 25,00 for each act after injunctive relief

Court - after Injunctive relief

Court - right

Rogoff - injunctive relief for what

- doctor have unfettered access to this drug in this state and may prescribe...what injunction can they provide need to reform...

Court - marketing and sales of Zyprexa not if its to be sold but how it is to be sold

Rogoff - marketing in the past and they would of known to bring an injunctive relief

- right to damages in cases where an individual in Alaska came down with diabetes after taking Zyprexa as it sounds like they want refund for all the prescriptions

Court - out of the area of the brief

Rogoff - would need in discovery on data base

4:56:46 PM

Court - experts to write report and you'd see

Rogoff - facts are statistic and to give Lily this 40 days before expert report is due is inadequate

Court - would give time to do expert reports and orders fashioned to allow this work to be done

4:57:54 PM

Rogoff - no way statistical can prove reliance and causation not able to control doctor's or action of state official on how they allow Zyprexa to be sold in this state

- not cigarette a case where there is national wide advertising and uninformed consumers
- informed decision based on factors and not explained by statistics

Court - Steel

4:59:33 PM

Steel – benefit to doctor on not knowing the truth or in believing a lie

- Lilly knows biggest customer is the government
- They have a whole division call Business to Government where they lobby with the state
- Its all about the state and Lilly knew exactly what they were doing
- We are given them the Medicaid data base and they have the ICP9 codes
- We are talking about individual
- Page ten of memorandum form Judge Weinstein
- If in the conjunctive
- Relates to sales and no talking about the past
- FDA to Lilly on new product; warning not adequate as to diabetes

Court – thank you, under advisement

- request for Oral Argument on motion for ..best for discovery master

Sanders

- they thought only you can decide this
- you allowed first wave of discovery to be heard by you
- request a hearing month form now

Court – assuming I will do this I'm not sure I would granted oral argument on a motion like this

Rogoff – for deposition and for first set of discovery request

- motion premature

Court - meet and confer

- will try to get this to this ASAP

5:06:11 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3AN4307-117

Judge: M. Rindner

Date: Friday, June 22, 2007

Clerk: M. Hendricks

Case No: 3AN06-05630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Status Hearing

Counsel Present:

Plaintiff: Eric Sanders P- in courtroom , David Suggs, and Christian Marcum - telephonic
Defendant: Andrea Jiolamo-Welp and Eric Rothschild

Court Orders: Will allow deposition of Mr. Torrell to be complete within 45 days
Oral Argument preset will remain set

Summary of Proceedings:

4:07:52 PM

On record
Court identifies case and parties

COURT:

- this is a Status Hearing and hearing on various motions filed
- would like to address a couple of issues
- issue of whether or not Mr. Torrell's deposition should go forward
- questions on pleadings on method of proof state intends to use
- when large pleadings are filed they are all clipped together
- please don't clip separate documents together
- as to scheduling order a lot of what you have is the same
- provision in Lilly scheduling using nature of case heading is non opposed
- would like to use states version of discovery
- Lilly version of who may be present will be used
- Will go with Lilly version of paragraph on use of discovery
- I think that resolves disputes on scheduling and discovery

4:13:11 PM

Mr. Sanders

- wasn't prepared to argue this
- can't answer question, someone else took responsibility in briefing that

4:14:30 PM

Mr. Suggs

- we can go forward having it be this way

COURT:

- this is a state case in state court in Alaska

4:16:21 PM

Mr. Rothschild

- other issue is on duplicative discovery
- we don't have to reproduce what we produce
- produce all marketing documents
- will be reopening MBL discovery

3AN06-05630CI-SH2

4:20:37 PM

COURT:

- this is a different case and don't want to use it as a stalking horse to get around MBL rulings
- I don't think that is happening if it does someone will lose credibility with me
- Not making any rulings but I do recognize it as an issue
- I think it is a good segway into the deposition of Mr. Torrell
- This is a person not even disposed in MBL proceedings

Mr. Rothschild

- his deposition should not be taken here
- this is an Alaska focused case
- he brings no knowledge in the Alaska related case
- had two depositions of the ten in this case
- Mr. Torrell's deposition has nothing to do with Alaska
- Nothing new here that they are seeking they are trying to pin the same knowledge on Mr. Torrell

Mr. Suggs

- no possibility of deposition
- discovery in the MBL is cut off

Mr. Rothschild

- just one other thing
- plaintiff has been requesting this for a while
- there is the possibility that this case will be resolved
- suggest that you consider reserving the ruling until you see what this case will look like
- necessity of deposition is in question

4:28:08 PM

COURT:

- suggestion is made by Lilly that Mr. Torrell has no additional knowledge
- he would only confirm what others have said
- why is he important, what is pertinent

Mr. Suggs

- I'll try to keep my voice up
- We know some things about the policy committee
- Relationship between Neprexa and diabetes was identified
- Number of adverse effects were reduced
- Lilly didn't warn patients about the risk of diabetes
- Depositions taken
- Learned Mr. Torrell was chairman of the committee
- clear evidence linking Neprexa and diabetes
- warning had a beneficial effect on the public by reducing the number of diabetes cases

4:31:54 PM

COURT:

- isn't Lilly charged with this

Mr. Suggs

- it is the strength of the evidence
- I want to represent my client to the best of my ability
- Decision not to depose Mr. Torrell in MBL case for two reasons
- Scrambling for discovery
- Didn't discover his position as chairman until after discovery closed

- You can see how desperate they are not to have him deposed
- still have to prove negligence, misrepresentation, and fraud
- trying to get one case back to West Virginia
- want to present this case in Anchorage
- no discovery going on in any other case except here in Alaska
- we are not doing this for the MBL we are doing this for this case
- our goal is for this case

4:41:01 PM

COURT:

- would there be any objections to me making this a confidential deposition only to be used in this case

4:43:10 PM

Mr. Rothschild

- they are able to describe actions/inactions taken by Lilly
- case doesn't change no matter what Mr. Torrell says
- every CEO would have to be deposed
- I think the events are important and will be contested
- I think it is an attempt to show case against Lilly can be attributed to Mr. Torrell
- Just piles on another person that has knowledge

COURT:

- it has been suggested that I postpone my ruling by Mr. Rothschild

4:46:46 PM

Mr. Sanders

- that is an offer we can make but we are not making it
- we have trial date and are confident we will not lose
- there is some other discovery that we want to do
- it is coming out of our pocket and do not want to wait we want to do it now
- you have commented many times about us using this as leverage in the MBL case
- simplest way to put aside that concern is to say anything in this case be confidential and for this case only
- I am prepared to live with that order
- I do not feel I need to argue the motion unless you think there are some things you need

4:49:45 PM

COURT:

- not prepared to rule on the motion today
- I would prefer you both to say go ahead and decide
- If someone asks for Oral Argument don't have a choice

Mr. Rothschild

- Oral Argument is already set
- Request that we proceed to Oral Argument

COURT:

- if I have to wait for Oral Argument then my decision must wait

Mr. Sanders

- our decision will remain the same as theirs

4:51:51 PM

COURT:

- will allow deposition of Mr. Torrell
- he may be relevant in this case

3AN06-05630CI-SH2

- will not second guess criticality of witness
- find this goes beyond the Apex case of a witness who has additional information that people lower than him have
- deposition will be subject to confidentiality and use for this case only

Mr. Sanders

- we want a deadline
- want deposition taken within the next two weeks

4:56:27 PM

Mr. Suggs

- it would be difficult for me to do it within the next two weeks
- by first week in August
- within 45 days

4:57:05 PM

Mrs. Rothschild

- have no answer to that but will report back
- executive will be subject to multiple depositions

COURT:

- any objection to giving them a week to talk to their clients

Mr. Sanders

- no objection

Mr. Rothschild

- request deposition be similarly limited

COURT:

- Alaska Court System rules set the time limits unless parties stipulate otherwise

5:01:53 PM

Mr. Sanders

- we are prepared to keep this case simple
- to make things confidential
- we have no hidden agenda

5:02:37 PM

COURT:

- I have this concern and I am not making findings

5:05:43 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3AN4307-73

Judge: M. Rindner

Date: Friday, April 06, 2007

Clerk: M. Borneman

Case No: 3AN06-05630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Status Hearing

Counsel Present:

Plaintiff: Eric Sanders, Esq.

Defendant: Andrea Girolamo-Welp, Esq., and Andrew Rogoff, Esq. and Mr. Rothchild, Esq.

Court Orders: Judge Weinstein confidential order is in effect in this case, documents are confidential

Summary of Proceedings: Mr. Sanders is allowed to notice up ten deposition but limited to Alaska case. Special Master Hensley is free to contact the federal master in writing.

On the record

Court – list case and parties

- issues

Rogoff – directed us in January to prepare an order for the court that would govern this case as a non-routine matter; confidential information and motion for rule of law

- Direct Eli to do first draft of scheduling order and we did this; four items in disagreement
- Several thousand personal injury cases and mostly center in federal court in New York
- Asking the court to coordinate with the federal court as Judge Weinstein is encouraging
- Four areas of disagreement, 1st and 2nd. Protective order in federal court should govern or should be Alaska have a specific protective order and the Deposition to be coordinated
- And third relates to special master in Alaska, we agree, and allow him to talk with federal master

Court – tell me position of Eli and Sanders can tell his and I'll tell you mine

Rogoff – case management order number 3 from federal should govern or Alaska specific protective order

- CMO 3 doesn't fit this as it involved federal court in New York and relates to federal rules of evidence
- Federal court in New York federal rules
- Depository established
- Alaska specific information
- We suggest Alaska specific documents not be co-mingled with federal and separate protective order same as CMO 3 but Alaska specific

2:11:43 PM

Sanders – if we wanted to be in federal court we would of filed there

Court – why not have special state confidentially order and govern for Alaska specific documents

Sanders – file in state court and they placed in federal court and be part of multi federal action

- Judge Burgess said no, it's a state action

3AN06-05630CI-SH

- Their trying to turn this into a federal case at every turn
- They want to adopt the federal order except more protection from the state
- We say operate under state rules
- We want this court to treat this case separately as a state action

Court – most of documents related to the depository in federal action adopt in large part language from federal action with specific provision that would govern documents that don't have to be include in the federal documents, they propose

Sanders – why is there an automatic confidentiality in this case, nothing magical about this case

- able to get Judge Weinstein to do this over the documents but a lot has happen in two years to include dissemination of documents
- congressional investigation and documents be subpoena

Court – you'd like nothing privilege until you decide it and regard to federal order on a document by document basis to decide this

- order in place

Sanders – why adopt a blanket order, broad as I have seen, and impose in this state case

- why are we entitled...will not disseminated those documents that are confidential but should be able to litigate and have you decide if this omnibus order is in place

Court – getting documents from where the omnibus order is in place or produce individually in Alaska

- affecting a lot of people in a lot of places and you want me to upset that with very little understanding on what else I'd be affecting in situation where it is working well

Sanders – upset what?

Court - what confidentiality order to be in place?

Sanders – not impose the order but would keep them confidential

- not involved in the federal action

Court – but using stuff from federal litigation for your case

- provision under federal order where someone can challenge a document and its confidential

Rogoff – yes, and motions pending before Judge Weinstein

- both parties and non-parties have so moved

Court – will follow the confidentiality order imposed by Judge Weinstein

- those documents not part of federal litigation but Alaska specific need confidentiality order and specific to Alaska documents
- with provision for parties to objection to the designation of that document

Sanders – everything is confidential

- MDL case, we will resist, as we do not want to be involved in this case, I disagree
- We do not view this to be a complex case and will tell you how we intend to proceed, March 1 we filed on this

Court – thought I was getting a motion but have explanation, no motion with it

- assume the memorandum is telling us how you will prove this and for me to rule as a

- matter of law to prove claim
- and they will file an opposition

Sanders – we agree to trial date and now they want to vacate all the pretrial dates, we object

- they did not want to give a trial date and we did and we want to keep this trial date
- Not vacate all the dates; we are prepared to discuss deadlines within that but...

Court – four things he laid out Confidential order, depositions, special master and nothing about vacating trial dates other than submitting a different non-routine trial order

- did pick trial date and Pretrial Conference
- order issued based on this
- free to say more time is needed and might change this and might not

Sanders – this contemplates all dates are vacated, their first paragraph

- he wants to vacate the dates and no schedule in place, we oppose this
- want a defined schedule so that people are not saying the trial date not able to be kept as there are no pretrial dates

2:26:45 PM

Rogoff – talk to his co-counsel and we were in agreement; have emails saying its ok

- first time I find out they disagree with us on paragraph one
- happy to talk with them on paragraph one

Court – preference if this is to be moved they get replaced with other dates, list the dates

- leave me time to deal with SJ motions; not on the eve of trial

Rogoff – happy to discuss this with Sanders

- will get back with you on a new paragraph

Sanders – Motion for Rule of Law; why is this in here

- Witnesses to prove such facts?
- We do not need anything why do we need this as we know deadlines
- Should say parties shall submit those pleadings as discussed in January

Court – purpose of this paragraph is to give me a briefing schedule

Rogoff – worked out with Mr. Hahn on this and no disagreement

- we do not object to their motion on form

Court – April 25 and May 10 for reply

Rogoff – correct

Court – sanders an Hahn need to talk

- would like a motion and order on what you are moving for

Sanders – he identified issue number one

- what is the purpose of the order

Court – would like vanilla order if we are to make changes to pretrial order

Sanders – everything is confidential until order not

Rogoff – paragraph 2(c) (4), talks about cross noticing if deposition in federal court an vise versus

-3(c)(5), not take deposition twice

Sanders – we get ten depositions in this case and have not abuse this and have attempted to take two in this case

- been down this road
- 2nd, they are trying to time me in with MDL
- our discovery is focused and narrow not all the stuff MDL attorney are doing
- go to discovery matter, if they have a problem

Court – problems with coordination issue Rogoff raised

Sanders – yes, not part of MDL

Court – effort by co-counsel to get second bite of the apple

- why not coordinate

Sanders – why am I being forced to get into case I'm not involved in and not causing problems

- do not want to worry about MDL

Court – 10 depositions and limited to Alaska stuff

- why not and avoid from repeat depositions
- some of co-counsel have something to do with MDL

Sanders – can live with you telling me to do this...

Court – notice up ten deposition and focus on not duplicating things and not get a lot of stuff on things said in the MDL case

- and focus on Alaska case

Sanders – entitle today to do ten deposition at any time we want with no limit on scope

Court – other than the concern I have; not use this case to get 2nd bite of apple for MDL case

Sanders – say I do June 1 deposition of Lilly employee and...

Court – will focus on Alaska specific matters

- they can make motion if they want to be here fro them

Sander – do not have to coordinate with MDL attorney?

Court – Jamison and Rogoff

Sanders – with Alaska counsel

Court – yes, and if ten is not enough come back and explain

- involves Alaska law

Sanders – if I inherited a case from an MDL attorney

Court – told me ten in the past and you got it

Sander – might not even use them

Rogoff – no questions

06-05630CI

- finally, authorize Hensley to consult with Mr. Wooden – 3(d) (4)

Court – objection to my giving Judge Hensley the option of finding out issue that are related in the MDL on discovery issues

- right to appeal to me if there is a problem, why object to allow Hensley to speak with MDL master

Sanders – as I do not know what is going on

- they are very happy with Wooden
- have everything in writing

Court – needs to be a record to know what conversation is about, email

Rogoff – if required, no problems

- special master has ruled against us a couple of times

Court – will allow Judge Hensley to contact the special master in federal case but do so in writing

Rogoff - can make revision and get to you next week

Court – put it in writing and submit to Sanders and work on language

- work it out, if unable file a proposed order and someone can file objection

Sanders – and will get motion and order to clarify relief being sought

Court – file with brief for now

Rogoff – file with us a week before we have to respond

Sanders – no problem

Court –

2:52:31 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3an4307-5

Judge: M. Rindner

Date: Monday, January 08, 2007

Clerk: M. Borneman

Case No: 3AN06-05630CI

Case Title: State of Alaska

Vs.

Eli Lilly

Type of Proceeding: Pretrial Conference

Counsel Present:

Plaintiff: Eric Sanders, Esq., Clyde Sniffen, Assistant Attorney General and Mr. Hahn, Esq.

Defendant: Brewster Jamison, Esq., Andrew Rogoff, Esq.

Court Orders:

Summary of Proceedings: March 1, 2007 for motion to be filed by Plaintiff, normal time for responses. Jury trial set for the week of March 3, 2008 with a PTC on February 22, 2008 at 3pm

3:04:07 PM On the record

Court – list case and parties present

- when and how long for trial
- rules on discovery and do we need a discovery master

Sanders – trial should be in March 2008

- our case is ten days

3:05:48 PM Jamison – enter Rogoff has file a motion to appear, not opposed

Court – will granted if everything is there, leave to participate

Rogoff

- not sure how long the trial is to take but we think in two years and will take 18 months to do discovery

Court –

Rogoff

- we oppose discovery at the beginning
- up to court for scope of discovery

Court – their problem not yours

- set for trial
- why is it taking two years as other have settled
- why two years as opposed to 18 months

Rogoff

- Zyprexa is on the market
- Do not know how many individual have been prescribe Zyprexa
- If each prescription was fraud or violation of consumer protection we have to find out why

- each prescription Waives attorney written and the injuries
- And injuries to state is result of prescription
- Needs to be misrepresentation of Lilly

Court –

Rogoff – ready within a week to give interrogatory for any request for documents – shows scope

- if state provides answer we are seeking

Court – will argue this is not relevant and information they do not have

Rogoff – within two weeks of responses or objection we could frame the argument

Court – if they are right and you are wrong; how long to try this case and how long

Rogoff – not sure hat they have to prove or scope of discovery

Court – state wants to take a limited amount of discovery

- epidemiology and other expert reports that will lay out your case

Sanders right

Court – give me response to expert and by then their case is laid out and this is ready for trial or they are wrong and not able to prove causation

- get question of burden taken care for the state

Sander – if they are right and we are wrong this case is dismissed and no trial

- can prove our case I describe as we say; ready in March and if we are wrong case to be dismissed

Rogoff

- you suggest that the stet of Alaska take discovery and we do none
- state specific

Court – they take multi district litigation and let them take additional deposition of same people in multi district with Alaska issues

- not sure they need written additional discovery from Lily or not but after they get everything they would have time to do expert reports, etc., and your free to take these expert depositions and SJ motions would be filed

Rogoff – would do limited discovery

Court – and then another round to find out your limits on defense and for discovery

Sanders – trial in a year or if wrong there is no trial

Court – trying to avoid a lot of extra discovery

Sanders – two phase case; we prove our case and they do SJ and then opposition ,etc.,

- and then they would want their discovery in the end

Court – but much more limited discovery

Sanders – if they are right this case is dismissed

Court – let you do discovery and...not sure they are right until I see expert reports

- not sure you approach is valid or not until I see discovery on your side of case plus experts

Sanders – if they have to prove each prescription and what the doctor did with each and why each patient received it; case dismissed

- epidemiology reports

Court – way for plaintiff to bring SJ to test the theory of law

- gives notice to all

Sanders – will let Hahn address the court on this

Hahn – follow the rules and let them file a motion to dismiss

Court – based on pleadings and based on that...

Hahn – cause of action as a matter of law or we tell you we need discovery

Court – causation proven

Hahn – general or specific; we think general

- defense not apply
- they will raise individual reliance; doesn't apply in this case

Court – they concede if all deposition would be taken, 100's, you could prove your case

- do I allow them to do this and allow you to do 100's of depositions
- do not want motions in the abstract

Hahn – can we do what we are saying, matter of law

- And can we put in the facts to meet the law

Sanders will know early on and they say each prescription is relevant and you say no

3:33:07 PM

Court – brief that as SJ or Motion for Judgment on the Pleadings?

Rogoff – 3 proposals raised Motion in the abstract, response to discovery request and let state do discovery

- Motion to Dismiss is based on papers

Court – what has to happen and the timing for you to do a Motion in the Abstract based on representations

Rogoff – can do without discovery

- set out how they prove liability
- state officials who were victims of fraud
- patients suffer disease the state if paying for
- will brief

3:36:50 PM

Sanders – why is this different than some defend asking to set forth theory of liability

Court – allow them to submit those and give you 30 days to answer

- and then briefing on SJ
- Sanders – they want to hear from every doctor and every patient; we are not going to do this
- have hem send us interrogatories and we'll lay it out for them

Court – give them fifteen days to draft the interrogatories asking for theory of case, witnesses, etc.,

Rogoff – no motion for SJ but it's a way to frame the issues

Court – Motion for Rule of Law

Rogoff – or motion to Compel

- can within 15 days to prove discovery request and the appropriate motion to compel

Court – good?

Sanders – all in favor of resolution

Court – if not doing things their way; if only way to do this, how are you going to do this

Sanders – no do 1000's tort claims

- questions is can the state prove claim and damages by a different method, epidemiology method
- not Motion to Compel but to establish law of the case
- they never have answer your question
- they can do it through an interrogatory

Court – limit discovery to that and then file Motion for Rule of Law

- they give you the theory of their case and you can say they proved it or not

Rogoff – asking names of physician defrauded and how it is Lilly committed

- names of victims of this fraud
- epidemiology is not consumer protection

Court – not sure it frames the issues in a Motion to Compel

Rogoff – would e more detailed

Court – if asking to give details of proving your case

- let them do discovery and provide reports and then it is framed, no abstraction

Rogoff – parties could confer...

Court – will give them a trial date and that's that

- and go through this process to see if its viable
- and then get the issues briefed

Rogoff – brief it first before discovery

- court to send out questions and how should they prove their case

Court – file elements of proof and allow response time

Rogoff - they have burden of proof

Court –

Sanders – but not stop this case in its track as we have a viable claim and they say this case is bigger than we say it is

Court – offered you all the discovery you wanted to do

Sanders – will brief it but we have limited amount of discovery room

- will file motion to establish the claim
- give us trial date and allow us to file this motion and let us do discovery

Court – motion by when

Sanders – six weeks to two months

Court – March 1

Sander – that is fine

Court – Motion to be filed March 1, 2007, Sanders motion

- they want ten days

Rogoff – ten days for them is fine

- ten days for our case

Court – March 1, 2007 for the briefing

- standard discovery

Sanders – I'm lead counsel in this case and I have hired others

- doing deposition without reviewing these documents
- MDLA has two depositions left to be taken

Court – will order that provisions and then there is provision two for you to pay for your own documents

- depositions, Lilly to produce within 30 days

Sanders – not needed, will ask them

Court – and then to re-depose and Sanders to have ten free depositions – just for this litigation

- deadline for witnesses
- interrogatories as to how you are to prove your case, free to do so

Rogoff – if they file brief on the first can we have thirty days to respond

Court – yes, 30 days to respond

- Week of March 3, 2008 for twenty day trial with Pretrial Conference o February 20, 2008 at 3pm.
- Will build in periods fro that as for expert rebuttal as well

Rogoff – provisions of CMO 3 apply to this case- protective order

Court – not sure what it says

Sanders - we object

- not sure how they have been successful in keeping this confidential
- if needs to be, let them tell you

Court - Mr. Hahn any of these MDLA not had one of these CMO 3

Han - first state court case I done, couple in California, and that state did not adopt CMO 3

- frustrate us on showing their practices

Rogoff - how has they been able to keep this confidential

Court - no, any other cases where CMO 3 used

Rogoff - all case have protective order and similar to CMO 3

- every case is subject to confidentiality

Sanders - can we have a master for discovery

Rogoff - any ruling by discovery master is coming to this court but will go through process if they want one

Sanders - waive right to discovery master for their first discovery to us

Court - will use the protective order as used in multi district case

Sanders - remain in case until objected to

Court - remains until objected to but will take off when asked; I have to decide

Sanders - first discovery the master is not involved, use of Dan Hensley

Court - Dan Hensley unless objected to him

- if objected each party to proposed three names to me with each getting a bump
- parties split cost of Judge Hensley
- give me an order or can I use the one I have

Rogoff - request ten free deposition be excluded from the discovery master

Court - will draft order for trial, etc., defense to do first draft

- submit to them and work out language and then submit as stipulated order
- mediation to happen before a jury is brought in

4:17:26 PM

Off record

In the Superior Court at Anchorage Alaska

Media No: 3AN4306-161

Judge: M. Rindner

Date: September 26, 2006

Clerk: M. Borneman

Case No: 3AN-06-5630CI

Case Title: SOA

Vs.

Eli Lilly and Company

Type of Proceeding: Motion Hearing

Counsel Present:

Plaintiff: Eric Sanders, Esq., telephonic

Defendant: Brewster Jamison, Esq., telephonic

Court Orders: Motion for Protective order is granted.

Summary of Proceedings:

11:38:20 AM On the record

Court - list case and parties present

- Motion for Expedite to Preclude discovery to include dispositions
- Previous enter this as a non-routine case
- Why allow these depositions

Jamison - agree current motion could be on shorten time and preparing a response to give you the full picture

- they have been schedule on behalf of the plaintiff steering committee
- Blair Hahn sits on the committee
- Process ongoing and not fair to duplicate this process so these are being conducted by plaintiffs on liability issues, common to most cases in the country
- In order to prevent duplicate discovery and issue is to put questions to them once
- This is a piece of a larger puzzle and the state has hired counsel as in the MDL litigation and they notice these depositions and in the MDL proceedings and not unreasonable to put questions on liability to the witness once and once only
- They want to re-depose...

Court - remanded form federal court

Jamison - retain counsel who are in he multi-state litigation

- fact witness

Court -no initial disclosures to allow him to take these

Jamison - but his co-counsel has done this to be identical issues, liability issues

- state not prejudiced

Court - Judge Burgess decide no federal claims and removed to state court

- is this different than the MDL case

Jamison - can provide a transcript of oral argument

- lot of overlap between this case and the MDL case
- but no federal jurisdiction

Court – to extend there are separate and discrete claims, what happens to them

- allow second deposition

Jamison – allows us to ask question no other lawyer asked on the drug develop and the FDA, testing done, when aware, side effects but if some sliver in Alaska law and the state says there is this issue then you could order a second depositions

- We want to avoid duplicative discovery on the same issue

Court – only attorney who has enter is Eric Sander

Jamison – bottom of pleading they list Blair Hahn and they have retain him as well as others

- is it fair under the circumstances to cross notice deposition in this case and let the state take its bite and not allow witness to be deposed

Court – tell me about Hahn

Sanders – have not talk to Hahn about any of this

- I represent the state in Alaska and the only law firm representing the state

Court – signed by you by two other firms serviced to include Hahn's firm

Sanders – correct

- Hahn is counsel for the state of Alaska?
- Lilly tried to join this with MDL, its not
- We are independent and have the right to take deposition in an orderly fashion

Court – intent to have these other attorney to appear before this court

- then not why allow them to take place
- if he, Hahn, is representing the state...

Sander – are other attorneys we are the only Alaska counsel

Court - if Hahn attends the depositions why can't they go forward

- why not, if schedule, allow them to go forward and give you a chance to do a second deposition

Sander – will go forward regardless what happens in this case

- no idea on what role the state has in this
- first deposition on the East coast
- not sure what is going to happen
- why do we have the burden, discovery in our case should go forward and procedure should be...no idea who the witnesses are and would like to depose them late
- why doesn't the defendant have the burden
- not join us with the MDL case

Court – will grant the motion to preclude the deposition form premature discovery

- if Hahn participates and the state tries to re-depose these witness I will give Jamison a chance to argue the state new what was going on and this is a second bite of the apple
- separate lawsuit and not part of MDL case
- will grant order for protective order

- Jude Burgess remanded to me and this is not a part of the MDL case and that case has nothing to do with this case

Jamison – will be asking you to order a close coordination of discovery between the two case so as not to re-invent the wheel

- if Blair decide not to show up and sends somebody else he preserves the second bite of the apple

Sanders – no idea what happens at the MDL deposition

Court – Jamison represents your co-counsel is on the committee, ask co-counsel

Jamison – and I'm the only Alaska counsel in state but do talk with other lawyers about the MDL case

Sanders – lot of concerns raised that are hypothetical

- if we notice the deposition in the future he can object then

Court – do scheduling planning tomorrow morning could you have you co-counsel involved

Sanders – outside counsel wish to appear for it

Jamison – same for me

Sanders – hope we do not revisit this as this is the third notice of deposition in the MDL case

Court – December 18 for conference with me

- prudent to have other counsel talk about the process

Sanders – person who noticed this up is unknown to the state and asking the first round of questions

- entitled to develop our case separate form MDL

Jamison - broad powers to prevent duplicative discovery

- not subject Lilly to all the depositions, limit

Court – burden would be on you if a second deposition is noticed up in this case, duplicative

- and I would have the first deposition and a sense of deposition in this case
- no discover yin this case has happen

Jamison – preventing discovery until the status conference

Court - correct, get together and contact he other counsel and see what has taken place

Jamison – why would they agree, nothing in it for them

- now they get a 2nd bite of the apple

Court – might decide it is duplicative

Sanders – if something opens up on your calendar my co-counsel would come up on short notice

Court – would be short notice

Sanders – understand the calendar

Court – if enough notice is possible will let you know

Jamison – agree

Court – time frame to allow for this

Sanders - a week

Jamison - 4 days to a week

Court – if something opens up my staff will notify you

Jamison – have parties file their pre-hearing, background information on how discovery should proceed before we actually do this

Court – makes sense to have position ahead of time in case we move quickly

Sanders - agree

Court – something some time next week

Sanders – will try

Jamison – us too

Court – Motion for Protective order is granted

Jamison -

12:14:54 PM Off record