3AN-06-05630CI Volume: 009

Volume 009

State of Alaska vs. Eli Lilly & Co

Volume 9

Begin: 2-21-08
End: 2-22-08

ON APPEAL

Appeal to COA/Supreme

Please Return to Appeals Clerk

AP-475 (6/90) (TCB green-remov.)(4¼"x2")
APPEAL ID LABEL

PLAINTIFF'S ATTORNEY

DEFENDANT'S ATTORNEY

TYPE OF PROCEEDING

MASTER ASSIGNED	DATE ASSIGNED	DATE DISQUALIFIED	BY WHOM DISQUALIFIED

JUDGE ASSIGNED	DATE ASSIGNED	DATE DISQUALIFIED	BY WHOM DISQUALIFIED

FILING FEE RECEIPT# _____

INDEXED _____

OTHER _____

15764

OVER

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CI

ORDER

Lilly's motion in response to Court's on-record comments is denied. The trial will proceed as scheduled as previously ordered. Should a second phase of the trial be necessary issues regarding additional discovery can be addressed at that time.

DATED at Anchorage, Alaska, this 22nd day of February 2008.

MARK RINDNER
Superior Court Judge

I certify that on February 22, 2008 a copy was mailed to:
E. Sanders B. Jamieson
Administrative Assistant

002476

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

Defendant Eli Lilly and Company's request for oral argument is GRANTED. Oral argument on Eli Lilly and Company's Supplemental Brief Seeking Dismissal of the State's Claims Pursuant to the UTPCPA Exemption and Federal Preemption is set for Feb. 27, 2008, at 11:00 a.m. ~~p.m.~~. Each party is granted 30 minutes.

ORDERED this 22 day of Feb., 2008.

Mark Rindner

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 5, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
Anchorage, Alaska 99501-5911

Nanci L. Biggerstaff, CLPS, PLS
009867.0038/164353.1

I certify that on 2-22-08 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

002477

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered plaintiff State of Alaska's Motion in Limine to Exclude Testimony or Argument Regarding Other Drugs Manufactured by Defendant Eli Lilly and Company, Lilly's Qualified Opposition and Cross-Motion, any responses thereto, as well as applicable law, it is hereby ORDERED that Plaintiff's motion is DENIED insofar as it only prohibits Lilly from introducing at trial any evidence referring or relating to medications manufactured by Eli Lilly and Company, other than Zyprexa. Instead, it is hereby ORDERED that Lilly's Cross-Motion is GRANTED, both Lilly and the State of Alaska are prohibited from introducing at trial any evidence referring or relating to medications manufactured by Eli Lilly and Company, other than Zyprexa.

ORDERED this 22 day of February, 2008.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 14, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
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069867.0038/486480.1

I certify that on 2-22-08 a copy of the above was mailed to each of the following at their addresses of record:
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered plaintiff State of Alaska's Motion in Limine to Exclude Testimony or Evidence Regarding the Lack of Restrictions on the Availability of Zyprexa or Lack of an Injunction Against Certain Conduct by Defendant, defendant Lilly's Opposition, any response thereto, as well as applicable law:

IT IS HEREBY ORDERED that Plaintiff's motion is DENIED.

ORDERED this 22 day of February, 2008.

Mark Rindner

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 14, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
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009867.0038/103477.1

I certify that on 2-22-08 a copy of the above was mailed to each of the following at their addresses of record:

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered plaintiff State of Alaska's:

(1) Motion in Limine to Exclude Evidence Relating to Zyprexa's Efficacy or Benefits of Zyprexa for Indicated Uses, and

(2) Motion in Limine to Exclude Evidence Relating to Zyprexa's Efficacy or Benefits of Zyprexa for Non-Indicated or "Off-Label" Uses, and

defendant Lilly's Oppositions, any responses thereto, as well as applicable law:

IT IS HEREBY ORDERED that Plaintiff's motions are DENIED.

ORDERED this 22nd day of February, 2008.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 14, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L Street, Suite 400
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009867.0038/163482.1

I certify that on 2-22-08 a copy of the above was mailed to each of the following at their addresses of record:

Sanders
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002480

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered defendant's Eli Lilly and Company's Motion in Limine to Exclude Evidence Relating to the State of Alaska's Alleged Damages or Economic Injury, all responses thereto, as well as applicable law:

IT IS HEREBY ORDERED that Lilly's motion is GRANTED. The State of Alaska is prohibited from introducing at trial any evidence referring or relating to its alleged damages or economic injury.

ORDERED this 22 day of February, 2008.

Mark Rindner

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 4, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
Anchorage, Alaska 99501-3911

009867.0038/163337.1

I certify that on 2-22-08 a copy of the above was mailed to each of the following at their addresses of record:

Sanders Jamieson

Administrative Assistant

002481

FEB 04 2008

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered defendant's Eli Lilly and Company's Motion in Limine to Exclude Evidence Relating to Other Litigation Involving the Defendant, all responses thereto, as well as applicable law:

IT IS HEREBY ORDERED that Lilly's motion is GRANTED. The State of Alaska is prohibited from introducing at trial any evidence referring or relating to other litigation, government investigations or settlements involving Eli Lilly and Company.

ORDERED this 22 day of February, 2008.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 4, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L Street, Suite 400
Anchorage, Alaska 99501-3911

009867.0038/163331.1

I certify that on 2-22-08 a copy of the above was mailed to each of the following at their addresses of record:

Sanders Jamieson

Administrative Assistant

002482

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

ORDER

THE COURT, having considered defendant Eli Lilly and Company's Motion to Exclude References to Foreign Regulatory Action, plaintiff's response thereto, and all applicable law:

IT IS HEREBY ORDERED that defendant's motion is DENIED.

ORDERED this 22 day of February, 2008.

BY THE COURT

Mark Rindner
Superior Court Judge

FELDMAN ORLANSKY
& SANDERS
500 L STREET
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99501
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I certify that on 2-22-08 a copy of the above was mailed to each of the following at their addresses of record:
Sanders
Jamieson

Administrative Assistant

002483

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

ORDER

THE COURT, having considered defendant Eli Lilly and Company's Motion to Exclude Testimony and Call Notes of Non-Alaska Based Sales Representatives, plaintiff's response thereto, and all applicable law:

IT IS HEREBY ORDERED that defendant's motion is DENIED. *

ORDERED this 22 day of Feb., 2008.

I certify that on 2-22-08 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

BY THE COURT

Mark Rindner
Superior Court Judge

* However this evidence will be disallowed unless the State presents additional evidence from which the Jury can conclude that this information was actually utilized in Alaska.

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,
Plaintiff,
v.
ELI LILLY AND COMPANY,
Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered defendant's Eli Lilly and Company's Motion in Limine to Exclude Evidence Relating to Defendant's Profits, Net Worth and the Price of Zyprexa, all responses thereto, as well as applicable law:

IT IS HEREBY ORDERED that Lilly's motion is GRANTED. The State of Alaska is prohibited from introducing at trial any evidence referring or relating to Lilly's profits, net worth, or the price of Zyprexa.

ORDERED this 22 day of February, 2008.

Mark Rindner

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 4, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
Anchorage, Alaska 99501-3511

009867\0038\163309.1

I certify that on 2-22-08 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

002485

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

ORDER

THE COURT, having considered defendant Eli Lilly and Company's Motion to Exclude References to Recent Regulatory Communications and Developments, plaintiff's response thereto, and all applicable law:

IT IS HEREBY ORDERED that defendant's motion is DENIED.

ORDERED this 22 day of February, 2008.

BY THE COURT

Mark Rindner
Superior Court Judge

FELDMAN ORLANSKY
& SANDERS
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99501
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I certify that on 2-22-08 a copy of the above was mailed to each of the following at their addresses of record:
Sanders
Jamieson

Administrative Assistant

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered defendant Eli Lilly and Company's Motion to Accept Overlength Trial Brief, and any response thereto:

IT IS HEREBY ORDERED that defendant's Motion to Accept Overlength Trial Brief is GRANTED.

ORDERED this 22 day of February, 2008.

Mark Rindner

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 19, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L Street, Suite 400
Anchorage, Alaska 99501-5911

[09867.0038/165528.1]

I certify that on 2-22-08 a copy of the above was mailed to each of the following at their addresses of record:

Sanders
Jamieson

Administrative Assistant

002487

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

ORDER

THE COURT, having considered Defendant Eli Lilly and Company's Motion to Exclude Certain Testimony of the State's Experts, plaintiff's response thereto, and all applicable law:

IT IS HEREBY ORDERED that defendant's motion is DENIED.

ORDERED this 22 day of February 2008.

BY THE COURT

Mark Rindner
Superior Court Judge

I certify that on 2-22-08 a copy of the above was mailed to each of the following at their addresses of record:
Sanders
Jamieson

Administrative Assistant

002488

FEB 14 2008

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

ORDER

THE COURT, having considered defendant Eli Lilly and Company's Motion to Exclude Evidence Relating to New York Times Articles, plaintiff's response thereto, and all applicable law:

IT IS HEREBY ORDERED that defendant's motion is DENIED to the extent defendant seeks to exclude evidence other than the *New York Times* articles themselves. The defendant's motion is specifically DENIED with respect to the February 20, 2007 submission by defendant to the U.S. Food and Drug Administration ("FDA") and the March 28, 2007 letter from the FDA to defendant.

ORDERED this 22 day of February, 2008.

BY THE COURT

Mark Rindner
Superior Court Judge

I certify that on 2-22-08 a copy of the above was mailed to each of the following at their addresses of record:
Sanders
Jamieson

Administrative Assistant

FEB 14 2008

FELDMAN ORLANSKY & SANDERS
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002489

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered defendant's Motion for Leave to File Supplemental Brief, all responses thereto, as well as applicable law:

IT IS HEREBY ORDERED that defendant's motion is GRANTED. Defendant shall file its Supplemental Brief no later than ____ a.m./p.m., January ____, 2008; plaintiff serve and serve its opposition no later than ____ a.m./p.m., January ____, 2008; and defendant shall file its reply, if any, no later than ____ a.m./p.m., January ____, 2008

ORDERED this _____ day of January, 2008.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on January 28, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
Anchorage, Alaska 99501-5911

Natalie L. Biggerstaff, CPS, PLS
009867.0038/692856.1

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Mot 2/22/08

1-28-08

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered defendant's Eli Lilly and Company's Motion in Limine to Exclude Testimony and Call Notes of Non-Alaska Based Sales Representatives, all responses thereto, as well as applicable law:

IT IS HEREBY ORDERED that defendant's motion is GRANTED.

IT IS FURTHER ORDERED that:

1. The State of Alaska may not introduce testimony of Lilly sales representatives who work outside of Alaska as evidence at trial;

2. The State of Alaska may not introduce the call notes generated by Lilly sales representatives who work outside of Alaska as evidence at trial; and

3. The State of Alaska may not introduce any other evidence of the conduct of Lilly sales representatives who work outside of Alaska as evidence at trial.

ORDERED this _____ day of February, 2008.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 4, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L Street, Suite 400
Anchorage, Alaska 99501-1911

009867.0038/163374.1

002492

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FEB 04 2008

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered defendant's Eli Lilly and Company's Motion in Limine to Exclude References to Foreign Regulatory Action, all responses thereto, as well as applicable law:

IT IS HEREBY ORDERED that Lilly's motion is GRANTED. The State of Alaska is prohibited from introducing at trial any evidence referring or relating to foreign regulatory action relating to Zyprexa.

ORDERED this _____ day of February, 2008.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 4, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
Anchorage, Alaska 99501-5911

000867.0038\163321.1

Mtn vsd 2/22/08

FEB 04 2008

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

ORDER

THE COURT, having considered defendant Eli Lilly and Company's Motion to Exclude Evidence Relating to Other Litigation Involving the Defendant, plaintiff's response thereto, and all applicable law:

IT IS HEREBY ORDERED that defendant's motion is DENIED to the extent defendant seeks to exclude evidence of any plea or agreement to plea in criminal investigations or prosecutions involving conduct similar to that alleged by the plaintiff in this case.

ORDERED this ___ day of _____, 2008.

BY THE COURT

_____
Mark Rindner
Superior Court Judge

Ntuad 2.12.08

FEB 14 2008

FELDMAN ORLANSKY & SANDERS
500 L STREET
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002494

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered defendant's Eli Lilly and Company's Motion in Limine to Exclude References to Recent Regulatory Communications and Developments, all responses thereto, as well as applicable law:

IT IS HEREBY ORDERED that Lilly's motion is GRANTED. The State of Alaska is precluded from introducing evidence at trial related in any way to (i) communications to or from the United States Food and Drug Administration ("FDA") after 2004; or (ii) other regulatory communications or developments concerning Zyprexa labeling occurring after 2004.

ORDERED this _____ day of February, 2008.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 4, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L Street, Suite 400
Anchorage, Alaska 99501-5911

609867.0038/163319.1

FEB 04 2008

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	Case No. 3AN-06-5630 CIV
Defendant.	)	
	)	

ORDER REGARDING PLAINTIFF'S MOTION IN LIMINE TO EXCLUDE TESTIMONY OR ARGMENT REGARDING EFFICACY OR BENEFITS OF ZYPREXA FOR INDICATED USES

IT IS HEREBY ORDERED that Plaintiff's Motion in Limine to Exclude Testimony or Argument Regarding Efficacy or Benefits or Zyprexa for Indicated Uses is GRANTED. Defendant is precluded from making any argument or reference to the efficacy or benefits of Zyprexa for the treatment of Schizophrenia or Bipolar I Disorder.

DATED this ____ day of _____, 2007.

BY THE COURT

_____
Mark Rindner
Superior Court Judge

Ntn 2/22/08

FEB 04 2008

FELDMAN ORLANSKY & SANDERS
500 L STREET
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99501
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FAX: 907.274.0819

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	Case No. 3AN-06-5630 CIV
Defendant.	)	
	)	

ORDER REGARDING PLAINTIFF'S MOTION IN LIMINE TO EXCLUDE TESTIMONY OR ARGUMENT REGARDING THE LACK OF RESTRICTIONS ON THE AVAILABILITY OF ZYPREXA OR LACK OF AN INJUNCTION AGAINST CERTAIN CONDUCT BY DEFENDANT

IT IS HEREBY ORDERED that Plaintiff's Motion in Limine to Exclude Testimony or Argument Regarding the Lack of Restrictions on the Availability of Zyprexa or Lack of an Injunction Against Certain Conduct by Defendant is GRANTED. Defendant is precluded from making any argument or reference to the availability of Zyprexa without restrictions in Alaska or the State's decision not to seek an injunction against any of defendant's conduct that is the subject of this action.

DATED this ____ day of _____, 2008.

BY THE COURT

_____
Mark Rindner
Superior Court Judge

FEB 04 2008

FELDMAN ORLANSKY & SANDERS
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

ORDER

THE COURT, having considered defendant Eli Lilly and Company's Motion to Exclude Evidence Related to Plaintiff's Damages or Economic Injury, plaintiff's response thereto, and all applicable law:

IT IS HEREBY ORDERED that defendant's motion is DENIED to the extent defendant seeks to exclude evidence related to the nature of damages that the State alleges it suffered or the nature of the injuries that Zyprexa can cause.

ORDERED this ___ day of _____, 2008.

BY THE COURT

_____
Mark Rindner
Superior Court Judge

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	Case No. 3AN-06-5630 CIV
Defendant.	)	
	)	

ORDER REGARDING PLAINTIFF'S MOTION IN LIMINE TO EXCLUDE TESTIMONY OR ARGUMENT REGARDING OTHER DRUGS MANUFACTURED BY DEFENDANT ELI LILLY AND COMPANY

IT IS HEREBY ORDERED that plaintiff's Motion in Limine to Exclude Testimony or Argument Regarding Other Drugs manufactured by Lilly is GRANTED. Defendant may not offer any argument or evidence referring to other prescription drugs manufactured by Lilly.

DATED this ____ day of _____, 2007.

BY THE COURT

_____
Mark Rindner
Superior Court Judge

2/22/08

FEB 04 2008

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FAX: 907.274.0819

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

ORDER

THE COURT, having considered defendant Eli Lilly and Company's Motion to Exclude Evidence Relating to Defendant's Profits, Net Worth and the Price of Zyprexa, plaintiff's response thereto, and all applicable law:

IT IS HEREBY ORDERED that defendant's motion is DENIED.

ORDERED this ___ day of _____, 2008.

BY THE COURT

_____
Mark Rindner
Superior Court Judge

FELDMAN ORLANSKY & SANDERS
500 L STREET
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ANCHORAGE, AK 99501
TEL: 907.272.3538
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

The Court having considered Defendant Eli Lilly and Company's Motion for Summary Judgment, and any opposition thereto, and being fully advised in the premise,

IT IS HEREBY ORDERED that the Motion for Summary Judgment is GRANTED.

ORDERED this _____ day of _____, 2007/2008.

_____

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on December 10, 2007, a copy of the foregoing was served by mail, on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
Anchorage, Alaska 99501-5911

_____

009827.0038/162470.1

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

DEC 14 2007

002501

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	Case No. 3AN-06-5630 CIV
Defendant.	)	
	)	

ORDER REGARDING PLAINTIFF'S MOTION IN LIMINE TO EXCLUDE TESTIMONY OR ARGUMENT REGARDING EFFICACY OR BENEFITS OF ZYPREXA FOR NON-INDICATED OR "OFF-LABEL" USES

IT IS HEREBY ORDERED that Plaintiff's Motion in Limine to Exclude Testimony or Argument Regarding Efficacy or Benefits of Zyprexa for Non-Indicated or "Off-Label" Uses is ~~GRANTED~~ DENIED. Defendant is prohibited from arguing or referring to the efficacy or benefits of Zyprexa for the treatment of any non-indicated uses.

DATED this 22 day of Feb, 2007.

BY THE COURT

Mark Rindner
Superior Court Judge

Not used 2/22/07

FEB 04 2007

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99501
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Chrusler

Not ugl 2/22/08

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff, v. ELI LILLY AND COMPANY, Defendant.	Case No. 3AN-06-05630 CI **ORDER**

THIS COURT, having considered defendant's Eli Lilly and Company's Motion in Limine to Exclude References to Recent Regulatory Communications and Developments, all responses thereto, as well as applicable law:

IT IS HEREBY ORDERED that Lilly's motion is GRANTED. The State of Alaska is precluded from introducing evidence at trial related in any way to (i) communications to or from the United States Food and Drug Administration ("FDA") after 2004; or (ii) other regulatory communications or developments concerning Zyprexa labeling occurring after 2004.

FEB 22 2008

ORDERED this _____ day of February, 2008.

____
The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 12, 2008, a copy of the foregoing was served by ~~hand on~~ mail:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L Street, Suite 400
Anchorage, Alaska 99501-5911

[signature]

009867.0038/163319.1

002503

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

DEFENDANT ELI LILLY AND COMPANY'S FINAL WITNESS LIST

COMES NOW, Defendant Eli Lilly and Company ("Lilly") and hereby identifies the following witnesses that it may call live or by deposition at Phase I of the trial. In addition to the witnesses below, Lilly previously served and filed designations and counterdesignations for witnesses whose testimony may be presented by deposition. Those designations and counterdesignations are incorporated by reference as if specifically listed below. Lilly reserves the right to amend this witness list and the right to call additional witnesses at trial. If other witnesses to be called at the trial become known, their names, addresses, and phone numbers will be reported to opposing counsel in writing as soon as they are known; this does not apply to rebuttal or impeachment witnesses.

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1. Robert Baker, M.D.
   c/o Eli Lilly and Company
   Lilly Corporate Center
   Indianapolis, IN 46285
   (317) 276-2000

2. David Campana, Medicaid Pharmacy Program Manager
   c/o State of Alaska's Dept. of Health and Social Services
   Division of Health Care Services
   4501 Business Park Blvd., Suite 24
   Anchorage, AK 99503

3. Patrizia Cavazzoni, M.D.
   c/o Eli Lilly and Company
   Lilly Corporate Center
   Indianapolis, IN 46285
   (317) 276-2000

4. Lucy Curtiss, M.D.
   3127 Wesleyan Drive
   Anchorage, AK 99508
   (907) 563-1000

5. Joey Eski
   c/o Eli Lilly and Company
   Lilly Corporate Center
   Indianapolis, IN 46285
   (317) 276-2000

6. Timothy Franson, M.D.
   c/o Eli Lilly and Company
   Lilly Corporate Center
   Indianapolis, IN 46285
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7. R. Duane Hopson, M.D.
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(907) 269-7100

8. Silvio Inzucchi, M.D.
c/o Pepper Hamilton LLP
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Philadelphia, PA 19103
(215) 981-4000

9. David Kahn, M.D.
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3000 Two Logan Square
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10. David Noesges
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Lilly Corporate Center
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(317) 276-2000

11. Mark Olfson, M.D., M.P.H.
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(215) 981-4000

12. Thomas Schwenk, M.D.
c/o Pepper Hamilton LLP
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Philadelphia, PA 19103
(215) 981-4000

DATED this 22nd day of February, 2008.

Attorneys for Defendant

PEPPER HAMILTON LLP
Nina M. Gussack, admitted *pro hac vice*
George A. Lehner, admitted *pro hac vice*
John F. Brenner, admitted *pro hac vice*
Andrew R. Rogoff, admitted *pro hac vice*
Eric Rothschild, admitted *pro hac vice*
3000 Two Logan Square
18th & Arch Streets
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(215) 981-4000

LANE POWELL LLC

By _____
Brewster H. Jamieson, ASBA No. 8411122
Andrea E. Girolamo-Welp, ASBA No. 0211044

I certify that on February 22, 2008, a copy of the foregoing was served by hand delivery on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
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_____

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	Case No. 3AN-06-5630 CIV
Defendant.	)	
	)	

ORDER PROHIBITING CORRESPONDENCE TO JUDGE

IT IS ORDRED that the parties in this case shall not submit correspondence or letters to the trial judge.

DATED this ____ day of _____, 2008.

BY THE COURT

_____
Mark Rindner
Superior Court Judge

Not used - ruled on orally 8/27

FELDMAN ORLANSKY & SANDERS
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff,	)	
v.	)	Case No. 3AN-06-05630 CI
ELI LILLY AND COMPANY, Defendant.	)	FILED IN OPEN COURT Date: 2/22/08 Clerk:

PLAINTIFF'S AMENDED PAGE/LINE DESIGNATIONS

In response to Defendant's counter designations and objections, Plaintiff hereby amends deposition designations as follows:

MIKE BANDICK
JUNE 9, 2006

START PAGE/LINE	END PAGE/LINE
49:12	49:24
54:5	54:10
55:22	56:10
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113:23	114:1

FELDMAN ORLANSKY & SANDERS
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114:7	114:11
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496:9	497:3

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499:14	499:18
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519:17	519:19
521:13	521:15
521:21	522:9

DATED this 22 day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

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Kenneth T. Fibich
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(713) 751-0025

Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of **Plaintiff's Amended Page/Line Designations - Bandick** was served by messenger on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

By Peggy S. Crowe
Date 2/22/08

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

PLAINTIFF'S AMENDED PAGE/LINE DESIGNATIONS

In response to Defendant's counter designations and objections, Plaintiff hereby amends its deposition designations as follows:

CHARLES BEASLEY
JULY 26, 2006

START PAGE/LINE	END PAGE/LINE
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31:18	31:22
32:6	33:3
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236:6	236:16
237:1	237:14

FELDMAN ORLANSKY
& SANDERS
500 L STREET
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ANCHORAGE, AK
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TEL: 907.272.3538
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238:7	238:19
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343:5	343:18
344:2	349:1
372:18	372:23
386:4	386:22
390:9	391:2
391:19	392:1
393:1	395:18

FELDMAN ORLANSKY
& SANDERS
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DATED this 22 day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
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GARRETSON & STEELE
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Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of **Plaintiff's Amended Page/Line Designations – Beasley** was served by messenger on:

Brewster H. Jamieson
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301 West Northern Lights Boulevard, Suite 301
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By Peggy S Crowe
Date 2/22/08

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FAX: 907.274.0819

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

PLAINTIFF'S AMENDED PAGE/LINE DESIGNATIONS

In response to Defendant's counter designations and objections, Plaintiff hereby amends its deposition designations as follows:

ALAN BREIER
JANUARY 11, 2007

START PAGE/LINE	END PAGE/LINE
19:3	19:5
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25:24	26:9
26:21	27:13
29:12	30:1
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64:9	65:7
65:11	65:21

FELDMAN ORLANSKY & SANDERS
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ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

66:6	68:9
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FELDMAN ORLANSKY
& SANDERS
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200:21	201:2
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FELDMAN ORLANSKY
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361:18	361:24
BREIER, ALAN	**VOLUME 2**
401:16	404:7
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FELDMAN ORLANSKY
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440:1	440:4
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455:13	457:9
457:12	457:12
458:16	461:1
477:1	477:15
478:3	478:9
478:17	479:4
479:22	480:4
480:10	481:10
483:6	484:9
484:18	485:9
485:20	486:6
486:7	486:22
487:12	487:16
487:21	488:9
489:4	489:10
490:15	490:23
493:12	493:24
494:21	495:3
496:12	498:7
499:22	500:7
500:20	501:13
502:15	502:24
503:15	503:16
503:20	503:24
505:19	506:2
512:10	512:23
516:18	517:16

FELDMAN ORLANSKY
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517:19	517:19
518:16	519:7
521:5	521:15
524:12	524:14
525:6	525:13
527:4	527:13
576:23	577:4
582:12	582:14
603:20	604:4
604:7	604:7
611:3	611:7
611:10	611:12
633:16	634:2
634:19	635:7
641:1	641:3
642:18	643:9
650:3	650:6
651:13	651:18
653:5	654:9
669:6	669:11

DATED this 22 day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

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& SANDERS
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Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of **Plaintiff's Amended Page/Line Designations - Breier** was served by messenger on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

By Peggy J. Cowl
Date 2/22/08

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff, v. ELI LILLY AND COMPANY, Defendant.	)	Case No. 3AN-06-05630 CI

PLAINTIFF'S AMENDED PAGE/LINE DESIGNATIONS

In response to Defendant's counter designations and objections, Plaintiff hereby amends its deposition designations as follows:

JACK JORDAN
OCTOBER 26, 2006

START PAGE/LINE	END PAGE/LINE
21:20	22:2
22:10	22:14
24:3	24:19
30:14	31:11
43:18	44:3
48:18	48:21
49:24	50:7
55:18	55:24
59:8	59:20
60:22	61:1
61:14	62:12
66:3	66:9

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99501
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66:11	66:11
84:16	84:17
84:20	84:22
102:18	102:22
105:6	105:11
113:6	113:13
113:24	114:4
136:7	136:12
136:15	136:16
136:22	137:7
137:10	138:6
157:4	157:6
157:9	157:22
158:1	158:17
163:9	164:4
164:13	164:19
166:21	166:22
167:1	167:2
167:10	167:20
168:14	168:17
171:14	171:21
174:24	175:10
175:24	176:21
177:16	177:24
189:17	190:2
209:15	209:20
219:9	219:16
220:20	221:2
223:13	223:17
223:22	223:24
235:4	235:16
236:4	236:7
237:24	238:6
243:24	244:8
246:9	246:13

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FAX: 907.274.0819

246:16	247:4
261:21	262:2
267:7	267:9
264:17	265:1
283:5	285:11
296:17	296:24
297:18	297:20
301:20	302:2
306:1	306:7
307:4	307:9
307:15	307:17
308:18	309:21
318:15	318:23
320:22	321:5
321:8	321:16
339:6	339:11
342:8	342:9
342:11	342:15
343:2	343:8
344:16	345:9
346:1	346:13
347:12	348:12
349:20	350:2
325:8	325:14
352:24	353:7
354:22	354:24
355:20	356:2
357:5	357:8
357:22	358:20
358:23	359:8
362:20	363:3
363:16	364:21
366:11	366:23
368:5	368:14
369:2	369:11

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& SANDERS
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99501
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FAX: 907.274.0819

372:17	372:20
373:22	375:7
388:7	388:23
389:6	389:20
396:7	397:8
413:6	413:8
420:1	420:4
421:5	421:13
422:16	423:6
423:20	424:4
436:14	436:22
437:20	438:7
444:15	444:20
444:23	445:7
445:10	445:14
448:15	449:18
456:6	458:10
459:14	459:21
461:2	461:7
461:12	462:10
464:18	465:6
465:8	465:19
473:15	473:21
490:22	491:8
492:18	493:23
494:16	494:21
494:24	495:6
521:10	521:15
523:7	523:9
523:21	524:3
525:7	525:15
525:21	526:8
528:12	529:19

FELDMAN ORLANSKY
& SANDERS
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FAX: 907.274.0819

DATED this 22 day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
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Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of **Plaintiff's Amended Page/Line Designations – Jordan** was served by messenger on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

By Peggy D. Crowe
Date 2/22/08

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901
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

PLAINTIFF'S AMENDED PAGE/LINE DESIGNATIONS

In response to Defendant's counter designations and objections, Plaintiff hereby amends its deposition designations as follows:

ROBIN WOJCIESZEK
DECEMBER 11, 2007

START PAGE/LINE	END PAGE/LINE
6:10	6:12
6:15	6:17
10:2	10:4
11:6	11:25
12:15	12:17
14:2	14:20
15:20	16:4
16:7	17:1
17:23	18:19
19:1	22:22
23:4	23:8

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& SANDERS
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FOURTH FLOOR
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TEL: 907.272.3538
FAX: 907.274.0819

24:2	26:9
28:13	28:15
28:17	29:17
29:19	30:23
31:20	31:23
33:24	37:8
37:16	38:13
38:22	38:23
48:1	48:22
55:24	56:12
56:16	56:21
56:23	57:22
58:1	62:17
73:1	73:21
74:25	75:22
78:25	80:3
81:3	81:22
83:6	83:13
83:20	85:1
86:21	87:7
87:14	87:24
94:4	94:19
95:18	95:19
95:25	96:5
96:22	97:16
98:19	101:4

FELDMAN ORLANSKY
& SANDERS
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FAX: 907.274.0819

DATED this 22 day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
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AK Bar No. 7510085

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Certificate of Service
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Anchorage, Alaska 99503-2648

By Peggy D Crowe
Date 2/22/08

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FAX: 907.274.0819

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff,	)	
v.	)	Case No. 3AN-06-05630 CI
ELI LILLY AND COMPANY, Defendant.	)	

PLAINTIFF'S AMENDED PAGE/LINE DESIGNATIONS

In response to Defendant's counter designations and objections, Plaintiff hereby amends its deposition designations as follows:

DENICE TORRES
DECEMBER 15, 2006

START PAGE/LINE	END PAGE/LINE
30:24	31:11
38:7	38:11
42:5	42:11
46:20	47:16
54:16	54:17
54:20	55:7
62:13	63:14
68:19	68:20
75:11	75:14
75:19	76:3
77:18	77:24

FELDMAN ORLANSKY
& SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK
[redacted]501
TEL: 907.272.3538
FAX: 907.274.0819

78:3	78:4
79:18	79:20
79:23	80:1
84:19	85:19
85:22	85:22
86:1	86:8
87:2	87:4
88:18	88:24
121:21	121:24
125:3	125:18
127:6	127:11
127:16	127:22
134:24	135:6
136:6	136:15
146:13	146:22
147:3	147:7
148:6	148:22
150:8	150:11
152:12	152:20
154:18	154:23
165:12	165:14
165:20	166:6
171:9	171:17
173:18	174:2
174:17	174:21
177:8	177:14
178:14	178:23
179:19	180:2
181:11	181:18
181:21	182:20
185:15	186:9
186:22	187:12
189:5	189:18
198:18	198:22
199:18	200:6

FELDMAN ORLANSKY
& SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK
501
TEL [redacted]272.3538
FAX: 907.274.0819

201:10	201:14
234:16	235:4
241:19	241:22
242:3	242:18
243:2	243:20
244:1	244:10
248:9	248:20
249:6	249:12
249:19	249:22
250:5	250:9
251:9	251:13
334:6	334:18
357:23	358:8
359:15	360:10
361:3	361:14
394:20	395:2
395:13	395:17
396:3	396:8
397:2	397:5
400:16	401:7
404:7	404:11
411:20	412:3
414:20	415:18
416:19	417:6
419:24	420:18
422:12	422:20
474:17	474:21
476:7	477:10
480:9	480:17
488:23	489:8
491:1	491:5
491:9	491:18
492:9	492:13
493:7	493:9
495:1	495:15

FELDMAN ORLANSKY
& SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK
[illegible]01
TEL: [illegible]272.3538
FAX: 907.274.0819

510:5	510:8
510:18	510:23
514:7	514:15
527:17	528:2
528:16	529:2
530:23	531:14
535:17	536:24
537:7	538:7
538:13	538:15
538:19	538:20
538:22	539:3
539:10	540:19
545:15	546:5
546:7	547:13
547:15	547:17
548:17	548:21
549:8	549:12

DATED this 22 day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

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Counsel for Plaintiff

Certificate of Service
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Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

By Peggy J. Crowe
Date 2/22/08

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

PLAINTIFF'S AMENDED PAGE/LINE DESIGNATIONS

In response to Defendant's counter designations and objections, Plaintiff hereby amends its deposition designations as follows:

GARY TOLLEFSON
NOVEMBER 6, 2006

START PAGE/LINE	END PAGE/LINE
11:9	11:11
13:6	13:9
13:18	14:4
14:23	15:3
29:16	31:13
35:10	35:22
36:7	36:19
39:17	40:16
51:11	51:24
52:3	52:14
77:9	77:23

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78:4	82:5
91:24	92:4
92:7	92:14
92:19	92:22
93:15	95:16
95:19	96:22
101:8	101:19
101:22	102:6
102:13	103:14
103:17	103:23
104:2	105:15
107:13	109:1
109:16	109:16
111:22	111:24
112:3	113:4
113:9	114:11
114:24	115:13
118:9	118:19
119:3	119:11
119:22	119:24
120:1	120:7
122:6	122:13
122:16	123:17
124:5	124:9
124:21	126:9
134:20	134:22
135:1	135:23
136:2	136:13
177:2	177:15
195:13	195:22
197:1	198:13
199:2	201:9
204:4	206:1
206:4	208:9
208:24	210:8

FELDMAN ORLANSKY
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DATED this 22 day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
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Counsel for Plaintiff

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By Peggy S Crowe
Date 2/22/08

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff, v. ELI LILLY AND COMPANY, Defendant.	)	Case No. 3AN-06-05630 CI

PLAINTIFF'S AMENDED PAGE/LINE DESIGNATIONS

In response to Defendant's counter designations and objections, Plaintiff hereby amends its deposition designations as follows:

SIDNEY TAUREL
SEPTEMBER 19, 2007

START PAGE/LINE	END PAGE/LINE
10:12	10:23
11:2	11:6
16:1	16:12
62:19	64:10
64:12	64:18
64:20	65:16
65:18	66:4
66:6	66:24
68:3	68:8
68:16	69:24
70:2	72:14
72:16	72:18

FELDMAN ORLANSKY & SANDERS
500 L STREET
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ANCHORAGE, AK 99501
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75:8	75:24
110:10	110:13
110:15	110:24
111:2	111:11
115:3	115:6
115:9	115:14
115:16	115:17
117:24	120:1
122:3	122:5
124:3	124:8
124:10	124:24
125:2	125:2
125:4	125:13
127:7	127:15
128:5	129:5
132:12	133:6
180:8	180:13
180:16	180:22
189:23	191:4
191:6	191:17
192:3	192:7
192:10	192:24
203:18	204:19
205:11	206:4
207:23	208:2
208:5	208:8
210:3	210:6
210:14	211:11
211:13	211:14
211:22	213:1
215:3	215:5
215:15	215:23
216:20	217:8
218:1	218:17
223:2	223:9

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223:12	224:20
227:13	227:17
227:20	227:20
227:22	228:9
230:1	231:23
232:2	232:4
236:23	237:7
237:19	237:24
238:3	239:14
239:17	240:14
240:16	242:16
243:20	244:2
244:5	245:13

DATED this 22 day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

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Counsel for Plaintiff

Certificate of Service
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Brewster H. Jamieson
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301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

By Peggy J Crowl
Date 2/22/08

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

PLAINTIFF'S AMENDED PAGE/LINE DESIGNATIONS

In response to Defendant's counter designations and objections, Plaintiff hereby amends its deposition designations as follows:

JOHN C. LECHLEITER, PH.D.
MARCH 28, 2007

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DATED this 22 day of February, 2008.

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STATE OF ALASKA,	)	
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Plaintiff,	)	
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ELI LILLY AND COMPANY,	)	
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DATED this 22 day of February, 2008.

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STATE OF ALASKA,	)
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Plaintiff,	)
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v.	)
	)
ELI LILLY AND COMPANY,	)
	)
Defendant.	)
	)

Case No. 3AN-06-05630 CI

OPPOSITION TO LILLY'S MOTION FOR RECONSIDERATION AND RESPONSE TO COURT'S ORDER

On the eve of the first phase of trial in this case, Lilly has filed a "Motion in Response to the Court's On-Record Comments" that asks the Court to reconsider (1) "its discovery rulings" and (2) "its bifurcated trial plan."[1] Lilly's untimely and misleadingly titled motion offers the Court no valid reason to reconsider either.

The State has several times predicted that Lilly will do everything it can to avoid going to trial in this case. With its latest motion, Lilly again confirms the accuracy of the State's prediction. The State trusts that the Court will recognize Lilly's present motion for what it is, and it asks the Court to deny Lilly's eleventh-hour attempt to prevent the State from holding Lilly to account. The parties have marshaled their resources, pre-trial

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[1] Eli Lilly and Company's Motion in Response to the Court's On-Record Comments During the January 29, 2008 Hearing (Motion for Reconsideration) at 1.

activities are coming to an end, and Lilly's motion should not be allowed to obscure the essential fact that this case is ready to go to trial in 10 days.

DISCUSSION

Lilly's motion asks the Court to reconsider discovery rulings of possible relevance only to the second phase of trial, and nonsensically asserts that bifurcation should be abandoned because preparations for the next phase will be contentious and difficult (assuming Lilly loses the first trial). Lilly has offered the Court no reason to reconsider any of its prior rulings, and its motion should be denied.

I. LILLY HAS OFFERED THE COURT NO REASON TO RECONSIDER ITS DISCOVERY RULINGS.

Lilly first asks the Court to "reconsider[] its discovery rulings" and allow "discovery of individual prescriber decisions, including medical records and prescriber depositions."[2] The request is untimely, less than admirably candid, and meritless. Lilly has at all times in this litigation been free to depose physicians and inquire about their "individual prescriber decisions" and the fact that it has not done so is a reflection only of Lilly's litigation strategy. The Court has precluded Lilly only from obtaining individuals' "patient identifying" medical records, and Lilly's present motion gives the Court no reason to reconsider that ruling.

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[2] *Id.*

A. LILLY'S REQUEST FOR RECONSIDERATION OF THE COURT'S DISCOVERY RULINGS IS UNTIMELY.

In asking the Court to allow "discovery of individual prescriber decisions, including medical records and prescriber depositions,"[3] Lilly is now asking the Court to order discovery that Lilly acknowledges is not at all relevant to the first phase of trial.

Lilly asserts that the Court must allow discovery of "individual prescriber decisions" because it insists that such discovery will reveal that physicians would have continued to prescribe Zyprexa even if they had received different warnings from Lilly.[4] Even if true, the contention goes only to the issue of specific "causation," a fact that Lilly has itself acknowledged.[5]

"Causation" is a phase two issue that the Court correctly noted has been placed "down the road" by bifurcation.[6] The Court's order was designed to allow the parties to focus on the threshold issues of liability, and Lilly's motion offers the Court no insight into why it felt the need to burden the State and the Court with a phase two discovery

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3 *Id.*

4 *Id.* at 2-5.

5 *Id.* at 6 ("the State cannot prove causation"); *cf.* Defendant's Reply Brief in Support of Its Motion to Compel Discovery (Aug. 20, 2007) at 5 (arguing that the "testimony of individual treating physicians" is relevant to "proximate cause"); Oral Argument at 14:18 – 15:5, Exhibit A (comments of Lilly's counsel noting that the issues presented in the first phase of trial in this case are "separate and distinct from proximate causation").

6 *See* Oral Argument on Motions for Summary Judgment at 54:11–18, attached as Exhibit A. ("The trial has been bifurcated to put the causation issue down the road and discovery on the causation issue down the road. Doesn't [Lilly's] motion really go to the causation issue? That's my first question.").

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motion at this particularly busy and inopportune time. The Court should feel free to deny Lilly's request on that basis alone.

B. LILLY HAS AT ALL TIMES IN THIS LITIGATION BEEN FREE TO DEPOSE TREATING PHYSICIANS AND TO INQUIRE ABOUT THEIR "INDIVIDUAL PRESCRIBER DECISIONS."

Lilly's request also comes precariously close to asking the Court to "reconsider" a ruling that Lilly knows the Court never made.

In the January 29, 2008 hearing on the parties' motions for summary judgment, the Court asked whether it should "reconsider [its] decision as to whether or not to allow individual decisions of physicians in this case."[7] In response, counsel for the State informed the Court that reconsideration is unnecessary because Lilly has at all times in this litigation been free to collect whatever information about individual physicians' decisions that it feels is necessary to its defense.[8]

The State's response could not have come as a surprise to Lilly. The Court has made only two discovery rulings in this case. The first, which the State quoted for the

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[7] Oral Argument at 21:20 – 22:22, Exhibit A.

[8] *Id.* at 46:24-47:22:

> What you told the defendants and what you said in your order is if you want to pursue discovery in [that] way you can do it. . . . You told them way back when, when you did your order: You can do it; if you want to defend yourself in this way, you can do it. They just haven't done it.

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Court at the argument,[9] confirmed that Lilly is free to defend against the State's case in whatever manner it desires and that it can obtain all discovery permitted by the Civil Rules:

> The manner by which the State intends to prove its case . . . should not, by itself, limit Lilly's method of defending against the State's claims. Lilly is free to obtain discovery in accordance with the Rules of Civil Procedure.[10]

As counsel for Lilly noted in a hearing before the discovery master in this case, Lilly understands that this ruling empowers it to discover how individual doctors made their "prescribing decisions":

> What Judge Rindner has ruled is: . . . Lilly is free to defend the case as it needs to defend the case. [T]he argument was made to Judge Rindner that what individuals think or how doctors make prescribing decisions are completely irrelevant and Judge Rindner ruled [that] Lilly is free, subject to constraints of Rule 26, to go ahead and defend itself.[11]

The discovery master confirmed for Lilly that this Court "did not limit Lilly's discovery solely to the defense of epidemiological evidence,"[12] and the Court itself removed any basis for possible confusion when it affirmed the discovery master's order in full.[13]

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[9] *See* Oral Argument at 57:21-25 (counsel for the State quoting Order re: Plaintiff's Claim of Proof (Aug. 1, 2007) at 5).

[10] *See* Order re: Plaintiff's Claim of Proof (Aug. 1, 2007) at 5 (emphasis added).

[11] Transcript of Motions Arguments Before Discovery Master at 43:16 (Sept. 11, 2008), attached as Exhibit B.

[12] *See* Discovery Master Order at 3 ("[The Court] noted that that Lilly was free to defend the claim in whatever ways might be appropriate, and thus did not limit Lilly's discovery solely to the defense of epidemiological evidence.").

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Lilly's present motion obscures this history and, incredibly, fails to mention that Lilly actually noticed the depositions of five prescribing physicians *after* the Court made its second, and final, discovery ruling.[14] Lilly later cancelled the depositions (on the telling basis that the depositions went only to "damages"[15]), but its failure to conduct the depositions is reflective only of its litigation strategy—Lilly has at all times understood that it is free to ask doctors about the specifics of their decisions to prescribe Zyprexa and that it may in particular ask, among other things:

- why the doctor prescribed Zyprexa in a particular patient's case;
- what condition (or conditions) the doctor hoped to treat by prescribing Zyprexa to a particular patient;
- whether the prescription was on-label, off-label for indications supported by medical compendia, or off-label for any other use;
- whether the doctor prescribed Zyprexa as a first-, second-, third- or fourth-line treatment,
- whether the doctor prescribed Zyprexa as "emergency treatment by a state hospital," or in any other emergency situation,
- whether the doctor's decision was influenced by Lilly's representations, and
- whether the doctor would have made a different decision if Lilly had issued different warnings.[16]

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13 *See* Order (Nov. 14, 2007).

14 *See* Affidavit of Eric T. Sanders at ¶ 3 (noting that Lilly noticed depositions for Drs. Von Hafften, Magee, Nassar, Schults, and Stillner).

15 *Id.* at ¶ 5.

16 *Cf.* Motion to Reconsider at 2 (listing many of these questions).

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Lilly has never suffered from the delusion that this Court denied "discovery of individual prescriber decisions,"[17] and its present motion should not create confusion on that point.

C. LILLY HAS AGAIN FAILED TO SHOW THAT IT NEEDS ACCESS TO INDIVIDUAL PATIENTS' MEDICAL RECORDS.

The single thing that Lilly seeks in its present motion that it is not already entitled to receive is the right to discover patient-identifying medical records.[18] But Lilly's renewed request for patients' medical records can be readily discharged on the basis that it is both procedurally flawed and substantively deficient.

Lilly's desire to review patients' highly private and federally protected medical records was extensively briefed and exhaustively addressed during a nearly five-hour hearing before the discovery master.[19] After the hearing, the discovery master issued a lengthy opinion in which it held that Lilly had failed to show that its purported need for individual patients' medical records outweighed the substantial "cost, burden, and harm" that would be caused by Lilly's obtaining the data.[20] Lilly appealed the discovery master's decision, and this Court affirmed, holding that the discovery master had

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17 *Id.*

18 *See id.* at 1.

19 *See* Defendant's Motion to Compel Discovery at 5-7(Aug. 6, 2007); Plaintiff's Response to Defendant's Motion to Compel Discovery at 3-9 (Aug. 15, 2007); Defendant's Reply Brief In Support of Its Motion to Compel Discovery at 1-4 (Aug. 20, 2007); Motion Arguments Before the Discovery Master (Sept. 11, 2007).

20 *See* Discovery Master Order at 6 (Sept. 24, 2007).

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"correctly balanced the competing interest[s]."[21] Lilly moved for reconsideration, and the Court summarily denied its request on November 27, 2007.

Procedurally, the time for Lilly to file a motion for the Court to reconsider that decision has long since passed,[22] and (the title of Lilly's motion notwithstanding) the Court gave no indication in its "on-record comments" that it would now entertain a late-filed motion to reopen the issue. (And it is also long past the time for Lilly to file a second motion for reconsideration, if the rules permitted one.) But the most critical defect in Lilly's request is substantive: Lilly's request for "reconsideration" contains no suggestion that the Court's original decision was wrong, and it fails even to *attempt* to explain how access to individual patients' medical records would now enable Lilly to learn or do anything that it is not presently able to learn and do. Both are prerequisites for reconsideration in this circumstance.[23]

Lilly's motion therefore plainly offers the Court no reason to reconsider its decision to protect from discovery individuals' highly personal and "patient identifying" medical records. Lilly's request for reconsideration of the Court's "discovery rulings" should be denied in total.

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21 Order (Nov. 14, 2007) (affirming the Discovery Master's Order).

22 *See* ALASKA RULE OF CIVIL PROCEDURE 77(k) ("a motion to reconsider [a] ruling must be made within ten days").

23 See *id.*

II. LILLY OFFERS THE COURT NO REASON TO RECONSIDER ITS BIFURCATION ORDER.

Although the Court made no "on-record comments" about the issue, Lilly concludes its "Motion in Response to the Court's On-Record Comments" with a wishful request for the Court to "revisit" its bifurcation order.[24] Ignoring the fact that the time to move for reconsideration has long since passed,[25] and that supreme Court found no fault with the Court's order,[26] Lilly first summarily asserts that the Court should have been persuaded by previous arguments.[27] Then, in what amounts to the latest in Lilly's ongoing series of legally unfounded attempts to prevent the State from presenting its case to a jury, Lilly argues that trial must be now postponed because (a) the State was unable to produce additional portions of its Medicaid database to Lilly by January 31;[28] (b) Lilly would like to take numerous depositions before the second phase of trial begins and it disagrees with the legal theory that the State will present in the second phase;[29] and (c) the State "dismissed its design defect claim."[30] But Lilly is now in possession of all portions of the Medicaid database that the State was ordered to produce, and the

24 Motion for Reconsideration at 6.

25 *See* ALASKA RULE OF CIVIL PROCEDURE 77(k).

26 *See* Order [Denying] Petition for Review (Jan. 14, 2008).

27 Motion for Reconsideration at 6-7 ("As Lilly previously argued . . .").

28 *Id.* at 7.

29 *Id.*

30 *Id.*

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remainder of Lilly's arguments, if anything, only further underscore the wisdom of holding an immediate trial on the issue of Lilly's threshold liability.

A. THE STATE HAS PRODUCED ITS DATABASE TO LILLY.

In its order to the parties, the Court asked the State to address "why (as represented in Lilly's motion) it [did not] produce[] a complete database" to Lilly by January 31.[31] Responsive to the Court's request, the State attaches an affidavit of counsel that recounts the history of the State's database-production efforts in detail.[32]

In brief, after providing Lilly on or before Sept. 1, 2007 with the Medicaid data files that it needed to test most, if not all, of the State's claims in this case,[33] Lilly

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31 Order (Feb. 19, 2008).

32 *See* Declaration of Mathew Garretson filed herewith.

33 *See id.* at 2:

> [O]n or before September 1, 2007, the State of Alaska (SOA) provided Lilly with State Medicaid data files which were sufficient to calculate the following:
>
> A. Number of Medicaid users from 1996 until the fourth quarter of 2006.
>
> B. The number of Medicaid users who were prescribed Zyprexa.
>
> C. The number of Medicaid users who took Zyprexa and contracted diabetes. This includes the number of individuals who took Zyprexa before treatment for Diabetes as well as those who received Zyprexa after treatment for diabetes.
>
> D. The total number of Zyprexa prescriptions from 1996 until 2006.
>
> E. The number of Zyprexa prescriptions which went to geriatric and pediatric patients.
>
> F. The number of Zyprexa prescriptions for uses not supported by FDA regulations including compendia.

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demanded that the State provide it with additional database entries and then filed a motion to compel.[34] During the hearing before the discovery master on the motion, the State agreed to provide Lilly with numerous additional database entries, and later estimated that it would be able to do so by January 31.[35] The data that Lilly requested was first delivered to the State by its contractor in an unusable form (for unforeseen technical reasons), causing the State to miss its estimated delivery date,[36] but it has since made good on its promise:

> At 11:30 AM, February 20, 2008, the State turned over files reflecting eligibility and the State formulary. Thus, the State has produced all data agreed to by Mr. Steele and requested by Lilly. This includes all material ordered to be produced by Judge Hensley and the Court.[37]

The State's supplementary production should end discussion on a point that should always have been clear: no issues related to the production of the State's Medicaid database merit delaying the first phase of trial.[38]

G. The average dosage for pediatric, geriatric and off label use.

34 *Id.*

35 *Id.*

36 *Id.*

37 *Id.*

38 *Cf.* Memorandum in Support of Bifurcation at 1 (Nov. 1, 2007). ("If Lilly believes that it needs additional time to scrutinize the state's Medicaid database, Lilly is entitled to receive, at most, a delay narrowly tailored to address that need.").

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B. LILLY'S INSISTENCE THAT IT WILL NEED TO TAKE NUMEROUS DEPOSITIONS AND THAT IT WILL VIGOROUSLY OPPOSE THE STATE'S SECOND-PHASE LEGAL THEORY PROVIDES MORE, NOT LESS, JUSTIFICATION FOR THE COURT'S BIFURCATION ORDER.

Lilly's second purported basis for seeking reconsideration is its belief that it will be necessary to engage in extensive discovery and contentious motion practice before the second phase of trial in this case begins.[39] It asserts that its desire for additional second-phase discovery and belief that the State cannot, as a matter of law, use "aggregate evidence" to establish causation are "consideration[s]" that justify "postpon[ing] phase one."[40] In fact, these arguments only further underscore the efficiency advantages of holding a first trial limited to the issue of Lilly's threshold liability.

Lilly continues to vigorously assert that Zyprexa does not cause diabetes, that its warnings about Zyprexa were at all times adequate, and that it did not improperly promote Zyprexa in Alaska.[41] If Lilly is correct, it will prevail in the first phase of trial, and bifurcation will ensure both that Lilly's purported need for additional second-phase discovery will be entirely eliminated, and that the Court and the parties will be spared the expense and ordeal of the looming and protracted legal battle that Lilly has promised to wage against the State's specific causation and damages cases.

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39 Motion for Reconsideration at 6-7.

40 *Id.* at 1, 6-7.

41 *See* Eli Lilly and Company's Trial Brief at 8-12.

It should be clear, then, that Lilly's present objection does not stem from a bona fide objection to the merits of bifurcation, but rather represents Lilly's latest attempt to prevent the State of Alaska from holding Lilly to account in front of a jury. In fact, that Lilly will insist upon taking numerous depositions and will vehemently object to the legal theories that underpin the State's specific causation and damages cases, are considerations that make bifurcation only more attractive.

C. Dismissal of the State's Design-Defect Claim Simplifies The First Trial and Makes Bifurcation More Efficient.

Lilly finally claims the Court should be motivated to reconsider its bifurcation order in light of the State's decision to simplify this case by dismissing its design-defect claim.[42] By reducing the number of issues that will have to be tried in the first phase of trial – which remains potentially case-determinative – the State's dismissal, if anything, only further increases the "advantages of bifurcation" in this case.[43]

The State has now repeatedly demonstrated that severing the issue of Lilly's threshold liability serves each of the several interests set out in Alaska Rule of Civil Procedure 42(b): by vastly increasing the likelihood of settlement,[44] mitigating (to the

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[42] Motion for Reconsideration at 7.

[43] Order (Feb. 19, 2007).

[44] *See* Memorandum in Support of Bifurcation at 10-11 (Nov. 1. 2007) ("The most powerful argument in support of the State's motion, however, may be that bifurcation will greatly increase the likelihood of an expeditious and economic settlement. The history of the Zyprexa litigation shows that the Lilly tend to settle on the Courthouse steps. Earlier this year, Judge Weinstein entered an order in the MDL proceedings related to Zyprexa that denied Lilly's request for summary judgment and set three cases for trial;

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State's recognized detriment[45]) a possibility of jury confusion[46], and potentially eliminating the need for a trial on specific causation and damages altogether,[47] bifurcation is "conducive to expedition and economy," "further[s] . . . convenience,"[48] and causes prejudice to neither party.[49]

The State's recent agreement to dismiss its design-defect claim does not alter this analysis. At the time that the state originally moved for bifurcation, it noted that its claims were based on "three bedrock principles of liability" that, as applied to this case, would require the State to prove:

Lilly then immediately settled those cases. This was not an isolated occurrence: to date, Lilly has entered into entered into eve-of-trial settlements with thousands of litigants together totaling more than one-billion dollars. To date, Lilly has not allowed any Zyprexa case to go to trial.").

[45] *See id.* at 9-10 (citing 9 CHARLES ALAN WRIGHT AND ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2390, p. 508 (noting that "defendants win in 42% of the cases tried routinely, [but] win in 79% of the cases in which the liability issue is submitted alone")).

[46] *See id.* ("[B]ifurcation . . . avoids the potential that the State's damages case might inappropriately prejudice jurors in their determination of Lilly's liability. It is well-known that jurors who hear testimony related to damages are more likely to hold a defendant liable. Bifurcation ensures that evidence related damages will not improperly influence the jury's liability determination, a result that the State embraces, even while it recognizes that bifurcation may have the effect of making its own liability case more difficult to prove.").

[47] *Id.* at 8-9 ("[if] Lilly escapes liability, the Court is spared the need to hold any trial on damages, and the parties will not need to expend huge sums to develop an analysis of the State's Medicaid database or present much of the expert testimony that they presently anticipate offering in this case").

[48] ALASKA RULE OF CIVIL PROCEDURE 42(b).

[49] Memorandum in Support of Bifurcation at 11.

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(1) that Zyprexa is defective,

(2) that Lilly failed to issue adequate warnings about Zyprexa's defects, and

(3) that Lilly's marketing and labeling of Zyprexa involved numerous unfair and/or deceptive acts.[50]

Dismissal of the State's design-defect claim merely simplifies the first two prongs of this rubric: now the State will endeavor to prove, not that Zyprexa was or is defective in design, but that (1) Zyprexa "posed a risk of injury to people who used the drug in a reasonably foreseeable way" and (2) Lilly failed to issue adequate warnings about that risk.[51] The nature of the proof that the State will present to establish these simplified claims is not fundamentally different from the nature of the proof that it believed it anticipated presenting in support of its design-defect claim,[52] and it of course remains true that "the State's threshold liability case does not depend on any analysis of the state's Medicaid database and [can] be judiciously established at . . . trial in March 2008."[53]

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50 *Id.* at 3.

51 *See* State's (Proposed) Jury Instructions And Verdict Form at Proposed Instruction No. 23 (Feb. 4., 2008); *Cf.* Lilly's Trial Brief at 8.

52 *See* Memorandum in Support of Bifurcation at 4 ("To prove its liability case on design defect and Lilly's failure to adequately warn, the State will rely on the testimony of Lilly's employees, the testimony of experts, and evidence of Zyprexa's labeling.").

53 *Id.* at 3.

In its Order of Feb. 19, the Court also invited the State to address the effect that its opposition to Lilly's "pending in limine motion to exclude evidence relating to plaintiff's damages and economic injury" has on merits of bifurcating trial. By withdrawing its

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It should be clear, then, that Lilly's present suggestion that dismissal of the State's design-defect has somehow "diminished" the possible efficiencies and advantages of bifurcation is entirely unfounded.[54] Indeed, far from being a bona fide objection to the merits of bifurcation, Lilly's present motion seems plainly to be but the latest in Lilly's long series of legally unfounded efforts to avoid trial. As the Court's files reflect, Lilly's present objection to bifurcation represents at least its *seventh* attempt to avoid having to present a defense to a jury composed of Alaskans:

- Though it had no legal basis for doing so, Lilly removed the case to federal Court and then opposed the meritorious motion to remand.
- When this Court asked Lilly a year ago to propose a trial date, Lilly's counsel declined to propose any date.
- After a trial date was set, Lilly made repeated efforts to extend pretrial deadlines, which would have had the effect of requiring the Court to vacate the date.
- Simultaneously, Lilly made onerous and irrelevant discovery demands, in which its only apparent motive was to delay the trial.
- When it appeared that discovery issues related only to specific causation and damages could not be resolved before March, Lilly vigorously opposed this Court's suggestion to bifurcate the trial, despite the fact, if Lilly is innocent, bifurcation is plainly in its best interests.

and

- Finally, after the Court nevertheless ordered a bifurcated trial, Lilly petitioned the Alaska Supreme Court to review the bifurcation order; the Supreme Court denied the petition.

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Opposition to Lilly's motion to exclude, the State hopes to clarify that it has never intended to present evidence of the State's damages during the first phase of trial.

54 *See* Motion for Reconsideration at 7.

Lilly's strategy of delay and avoidance is consistent with its nationwide litigation practice, which inexorably leads to one end: every time that a Court has refused to give in to Lilly's delaying tactics and has ordered it to prepare for trial, Lilly has settled the claims. Of the thousands of claims that have filed, Lilly has tried none.

In this case, the time has come for the parties to go to trial and Lilly has offered no valid reason for the Court to indulge its latest request for delay. This Court should adhere to the plan that it sensibly adopted in November. Lilly can, as it has in the past, avoid a trial if it elects to settle this case.

D. VACATING TRIAL AT THIS LATE DATE WOULD IRREPARABLY HARM THE PARTIES.

Finally, it should not escape the Court's attention that any decision to delay the first phase of trial at this late date will cause irreparable harm to the parties. Trial is now only 10 days away. Members of the State's trial team – composed of lawyers, paralegals, secretaries, technicians and jury consultants from many different states – have finalized their travel plans and are now arriving in Anchorage.[55] The State has spent $20,000 to reserve lodging to host its trial team, and the parties have each assembled rooms at the Hotel Captain Cook, complete with computers, copiers, audiovisual hardware and the myriad other equipment needed for trial.[56] Lilly's last-gasp attempt to reschedule trial ignores these costs entirely, yet they in-and-of-themselves supply the Court with an

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[55] Affidavit of Clyde E. Sniffen, Jr. at ¶ 3, filed herewith.

additionally sufficient basis upon which it can deny Lilly's request: Lilly's motion ignores the fact that the Court's bifurcation order is a bell that cannot now be costlessly unrung.

CONCLUSION

Lilly's eve-of-trial "Motion in Response to the Court's On-Record Comments" provides the Court with no basis to reconsider either (1) its discovery rulings or (2) its bifurcated trial plan. The motion is untimely, misleadingly titled, and meritless. It should be denied.

Dated this 21st day of February 2008.

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56 *Id.*

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Opposition to Motion for Reconsideration and Response to Court's Order was served by messenger on:

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IN THE SUPERIOR COURT OF THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,
Plaintiff,
vs.
ELI LILLY AND COMPANY,
Defendant.
Case No. 3AN-06-05630

ORAL ARGUMENT
BEFORE THE HONORABLE MARK RINDNER

Tuesday, January 29, 2008
9:02 a.m.

APPEARANCES:

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PROCEEDINGS

THE COURT: We're on the record in case number 3AN-06-5630 civil, State of Alaska versus Eli Lilly and Company. Present in the courtroom we have got Mr. Sanders, Mr. Sniffen and Mr. Steele for the plaintiff, and Mr. Jamieson and Mr. Brenner for the defendant.

And then do we have some people in front?

UNIDENTIFIED SPEAKER: No, Your Honor.

THE COURT: I had a list of other people that I thought were here. This is the time set for oral argument, Eli Lilly's motion for summary judgment.

Mr. Brenner, are you going to argue this?

MR. BRENNER: I am, Your Honor.

THE COURT: Just a couple of preliminary things so that the parties are aware. Yesterday, I received the expedited motion from Eli Lilly asking for relief to file a supplemental brief given that the state had filed supplemental exhibits in opposition to the motion for summary judgment.

As of yesterday, when I got the motion for expedited consideration, I had not received any of the supplemental exhibits, so I didn't do anything about this yesterday, but figured we would deal with it today, if those exhibits came in.

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Those exhibits did come in this morning and I have read those exhibits, although I had about five or ten minutes, so I can't really say I have looked at them hard, but I sort of have a flavor.

What is the state's position on the supplemental brief?

MR. STEELE: Your Honor, we don't think it's necessary. The principal issue that they raised on the supplemental brief is that somehow they did not know until last Thursday or Friday that we would claim that every prescription that was written that was accompanied by a package insert, as they all are --

THE COURT: Mr. Steele, I'm going to tell you that I was a little surprised at that, and it may affect what I do in this case significantly, so do you want -- are you going to oppose them filing a brief?

Do you want a chance to file something and they file something. And I will let everybody know after Thursday. I'm gone until the 19th, so the time of doing this is -- there is no point in getting it in by Friday because it won't get read until the 20th, or the weekend of the 16th at the earliest.

MR. STEELE: The first point I would make, Your Honor, is that they are factually incorrect. On December the 20th, we filed supplemental responses that

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told them that every prescription was a violation of the UTPA because the package insert was -- (indiscernible) -- so they are simply factually incorrect on that point.

And we could provide the court with the discovery to responses of the court, which is --

THE COURT: Well, if that's the case, why did you need to file a supplemental exhibit instead of filing this stuff with your brief if it was so clear and obvious and this is what you were relying on?

MR. STEELE: We were ordered to by Judge Hensley to provide a further answer. We had not, at the time we filed our brief, provided the further answer, so when we provided the further answer, which reiterated the position of the state that every prescription was a violation, we thought it wise to attach that as well since it sets out at some length what we claim to be violations as well as accompanying exhibits that document the violations.

And since motions for summary judgments are to be decided, among other things the interrogatories, we thought it wise to have those before the court.

THE COURT: I will allow the supplemental brief. When do you want to file it?

MR. BRENNER: Your Honor, we could file it on Thursday, if that's useful.

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THE COURT: It's not. I don't want anybody to have to -- I realize I'm dealing with at least one large firm and that they can do things in different ways than smaller firms can do, but there is no point for people to work late into the evening given that it won't get read until I get back from vacation, so --

MR. BRENNER: Would a week from today be appropriate, Your Honor?

THE COURT: Sure. That's fine. Why don't -- if they file a supplemental brief by a week from today, it will be the fifth. How about the 12th?

MR. BRENNER: The 12th will be fine.

THE COURT: And then it will be waiting for me when I get back. Why don't you go ahead, Mr. Brenner.

MR. BRENNER: Very good, Your Honor. If Your Honor please, as this motion was originally submitted, the bulk of it was directed to the state's design defect claim; the assertion that Zyprexa's risks outweighed its benefits and in effect should never have been marketed at all.

As discovery proceeded, it became clear that the state had no proof in support of that claim. Everyone from former commissioner Gilbertson on down --

THE COURT: That claim is gone. All we have

left in this case now, am I correct, is the warning claim and the UTPA claim?

MR. BRENNER: Yes. The UTPA claim is subject to two parts, a claim for civil penalties, a violation of the UTPA and then compensatory damages under the UTPA.

THE COURT: Okay. Good.

MR. BRENNER: And that is left -- remains within this motion. With respect to the state's claim under section 551, civil violations portion of the UTPA claim, Your Honor has already alluded to the fact the state made this submission on Friday, and the state has set out basically two grounds in opposition to our motion.

One, that every prescription was a violation of the UTPA. I think that Your Honor has allowed additional briefing on that. That's probably an argument left for another day.

Essentially --

THE COURT: I'm a little concerned about arguments left for another day, so I would rather do them now. I'll give you a chance to elaborate and provide case law and those kinds of things, but we're running out of time for arguments for another day before the trial is set.

MR. BRENNER: Very simply, under the 551 claims, State of Alaska seeks to penalize Eli Lilly and Company for using the FDA and mandated and approved product label that it had to use pursuant to federal law.

That presents a classic issue of conflict preemption, whether it is two sovereigns debating over what the course of conduct of a defendant has to be. And unlike the products liability context where this preemption issue is now currently hotly debated, this is an instance where a state is seeking to penalize a defendant.

That is, well overstating it, that's an issue of constitutional proportion. It's a preemption issue. Embedded with that is so-called exemption within Alaska's own UTPA that provides that while another state or federal agency regulates the conduct, there is not to be enforcement under the UTPA, and that's what we want to advance in the brief that will be submitted to Your Honor next week.

The other thing that the state did in opposition to this portion of the motion was to submit these records that, Your Honor, I think indicated he had a chance to look at very briefly. These are the so-called call notes.

Those are the brief, and I would describe them as pretty cryptic notes of contacts between Lilly sales representatives and doctors.

They are not self-explanatory, Your Honor, and the problem with them as we see, certainly on our motion for summary judgment is, they have been offered without any affidavit or deposition of anyone who was party to the conversation.

And without that, counsel for the state can give their interpretation, I can give my interpretation, but there are respectfully no facts of record that will tell us what the notations mean.

You are left to draw inferences based on oral argument. We would respectfully submit that's not the appropriate method for defeating summary judgment. And if we're right in that assessment, then Lilly should be entitled to summary judgment on that claim.

Turning to what I'll call the other two claims for compensatory damages under either -- (indiscernible) -- failure to warn count or the compensatory damages provision of the UTPA.

Under either cause, the action the state has to prove proximate causation. It has to prove to a different warning, if the warning was in fact inadequate, that a different warning would have altered

prescribing physicians' conduct, it would have yielded a different result.

With respect to the state's claim that Lilly promoted Zyprexa off-label, meaning that it improperly promoted the drug for other than its FDA approved indications, under the UTPA, as we understand it, the state will have to show that doctors relied on some specific misrepresentation.

That is the proximate cause element of that claim. The state has no such proof under either prong of their test. The state's basic position has been, as we understand it, that they don't have to provide such proof, that they can use some form of aggregate evidence.

That was addressed, at least in part, in the very early stages of this case. I know look at Your Honor's July 2007 order, as I read it, the court basically declined to rule on that until discovery had unfolded.

We think the arguments we made then still prevail today and we have offered you the most recent case from the Southern District of New York, the Rezulin case, which we think is the most closely on point case that we can find, because it is a mirror image of a claim brought by the State of Louisiana essentially

identical in its claims.
THE COURT: Well, it's not. I mean, Louisiana -- the state characterizes that case as an over-pricing case.
Now, when I look at the language of what was at issue in this case, it seems to be more than that. And I guess the state sort of concedes that. They say, I think to characterize them, and they can correct me when they have a chance, it's an over-pricing case and so it doesn't apply to that extent.
And to the extent it's not an over-pricing case, it's wrongly decided, but isn't a large part of that decision and a large part of the analysis over-pricing, and that's not what we're talking about here?
MR. BRENNER: I would respectfully disagree with your characterization. Judge Kaplan starts out by describing the claims of Louisiana as seeking reimbursement of medical expenses incurred by Medicaid recipients injured by the drug Rezulin.
That's very -- (indiscernible) -- with the case we have here, and reimburse prescriptions that allegedly should not have been written. Again, that is essentially verbatim tracks the claims with the State of Alaska here.

And there, Louisiana, like Alaska here, argued that the pharmaceutical manufacturer had misled the entire medical community. And Judge Kaplan said that is quintessentially a fraud on the market theory, which he found, as many courts have, not applicable to anything other than the --
THE COURT: But there is two parts in what he says. He says they argue they are entitled to recover because defendants misled patients and the medical community concerning the safety and efficacy of Rezulin, in consequence of which they claim Louisiana was called upon to reimburse for prescriptions that otherwise would not have been written.
That sounds to me like this case -- at prices they would otherwise not have been charged. That doesn't sound to me like this case.
MR. BRENNER: Clearly, that's -- Your Honor is right, but I would submit that's in addition to the other two elements, which I think are all fours with Alaska's claim here.
So we reassert, Your Honor, with this new authority that this entire aggregate evidence approach really should not be adopted. This is just more authority to consider in remedying that issue.
With respect to the nuts and bolts of

proximate causation, again, the state doesn't really deny that there is a proximate element.
What it says is well we are -- (indiscernible) -- it in places where adequate warnings were produced Zyprexa use declined.
As I have read the materials in this, they have offered no such proofs that that happened in Alaska. What they have offered to the court are two things; a memo from a Lilly representative making his personal observations about the impact in Japan of a warning change there, which is unlike any warning change that was effected in the United States; and a report of one of their experts, Dr. William Washing (phonetic), who wrote in his report that an adequately informed physician would not have used Zyprexa first line, meaning wouldn't use it first out of the box.
Well, at deposition, Dr. Washing recanted that. That's in our papers. He answered, "Sure, there are patients for whom he would use it first line."
And, secondly, Dr. Washing doesn't say anything about use of Zyprexa second line, and we know that that happened in Alaska, even from the somewhat limited data that the state has produced to this point.
In the world of schizophrenics and atypical or even typical antipsychotics, often the first one

doesn't work. We know that patients who fail on a drug like Risperdal or Saraprol (phonetic) and were then put on Zyprexa, that is some portion of the punitive claims before Your Honor. So none of the expert proofs addressed that point.
With respect to the UTPA claim, the same arguments apply. We submit that you have to show individual alliance by physicians, that the physician read the warning, that he or she took it into account, and that a different warning would have yielded a different outcome, they wouldn't have prescribed, they would have done something different.
That's pretty much black letter law in the world of pharmaceutical products cases.
With respect to the state's claim that Lilly promoted off-label and that therefore some people got Zyprexa who shouldn't have, that, we think, is fundamentally a case -- requires a case-by-case analysis.
How will you know whether a particular patient received it off-label unless we know all the details of that patient's treatment. And that, of course, the state has successfully resisted in terms of making any of those disclosures.
That's fine that they have, and we

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respectfully disagree with the order, but that's the order. But now they can't have it both ways. This is a critical element of their claim and they don't have those proofs.

Incidentally, off-label use by a physician is not unlawful or improper. It's completely proper. Doctors may use in their best judgment a drug for any purpose they think appropriate. That's clear in the law, and it's particularly common in the case of psychiatry where the conditions are so vague and the efforts are sometimes so extreme to try to help people.

So to say that there was off-label promotion, even if they could make that threshold that there was, and we submit that they cannot, there is still no linkage between any statement, any message, any anything from Lilly and an actual prescription in Alaska that would rise to the level of a UTPA.

THE COURT: Let me go back to your second-line argument. You talk about physicians reading the warnings and making a determination and that the physicians may have used the drug anyway having read the warning, but isn't a big part of their claim that the warnings were inadequate and that the inadequacies were that Lilly was aware of things that they didn't warn the physicians about?

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MR. BRENNER: That is certainly the first level. They don't get anywhere unless they can show the warning was inadequate, but that is separate and distinct from proximate causation as it plays out in these cases.

You have a myriad of different situations. You have doctors who never look at the label. That happens sometimes. You have doctors who -- let's look at weight gain. Although weight gain was in the labelling from day one, the state asserts it was inadequately disclosed.

But you had many, many doctors early on who believed because of their own experience, because of continuing medical education, because of discussions with their colleagues that Zyprexa was associated with weight gain, and they took that into account in their prescribing practices.

THE COURT: So you are saying even -- there would be proof, you believe, if individual physicians were questioned that even though, assuming that the facts they say are true for the purposes of this discussion, that in fact there were things known to Lilly that weren't disclosed and were in fact deliberately not disclosed, that the medical community, by seminar, gossip, whatever method, kind of was aware

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of the problem and that, you know, maybe it was on the internet, I don't know, that physicians -- there would be some physicians that may in fact have taken that into account and had everything that was supposed to be disclosed been disclosed in the labels, some physicians would have said, "Yeah, I knew this already"?

MR. BRENNER: Yes, Your Honor. In fact, that's essentially the testimony of Dr. Hopson (phonetic), who is the medical director at API, that he was aware early on that Zyprexa was associated with weight gain, and he was aware of that from his own practice, and that today Zyprexa is used without restriction at API.

Today, API has patients involuntarily treated with Zyprexa. Sometimes the attorney general's office has gone to court to get orders to require use of Zyprexa.

I hate to put on a hypothetical, Your Honor. It's actually a fact item we are seeing in the multi-district litigation. You have a physician who is treating a patient with Zyprexa. The patient suffers significant weight gain.

The doctor says, "I think this is caused by Zyprexa. I have seen this before. I'm taking her off Zyprexa." The patient's condition then worsens on

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another drug and comes back and says, "Really, the Zyprexa works. We can deal with the weight gain."

He counsels the patient and decides, "We understand there is this risk of weight gain, but for you, this drug was so efficacious we're putting you back on it."

My point there, Your Honor, is not so much that there are myriad fact patterns, there are, but that that's why the state's approach that we can fill some kind of aggregate proof, some kind of gross analysis proximate causation, we think can't be done. It just cannot be done.

THE COURT: Let me ask you, and I want you to be free to be critical of me, up until now, my approach has sort of been I'll deal with the summary judgment motion as a summary judgment motion.

If there are material facts, there are material facts, and summary judgment should be denied. As I'm sure you are probably aware by now, material facts in Alaska don't take very much.

But on the other hand, my intention has always been that when I hear this expert testimony, if the expert testimony doesn't get you -- doesn't get -- doesn't deal with the issues that you are talking about, then that's the subject after I have heard the evidence

of different kinds of motions that are more easily granted, or at least the restrictions I'm granting it are a little bit different.

And why shouldn't I still adhere to that approach? I mean, you are sort of asking me to not to say, as I understand your argument, not really to say there aren't facts in dispute, but sort of say their evidence is inadequate, or facts they can muster or arguments they can muster really won't satisfy their burden of proof at the end of the day.

That seems to be a little bit different to me than the motion I have got in front of me.

MR. BRENNER: I think I would argue to Your Honor it is not. If we look at the proofs of record, what is here, there is nothing from any prescribing doctor in Alaska, no deposition, no affidavit, no anything.

The expert that's been cited to you doesn't actually address in any way sufficient to defeat summary judgment, the proximate cause issue. All his report said was an adequately informed physician would not have used Zyprexa first line, not that he shouldn't have used it, wouldn't have used it first line, A.

And, B, in his deposition, as I say and it's in the papers submitted to Your Honor, he recanted that.

He said, "Sure," was his answer to the question, for some patients it is a first-line drug.

(Indiscernible) -- Alaska's approach to summary judgment and the evidentiary standards, but even under that liberal standard, there has to be some facts. I think the case -- (indiscernible) -- that said more than a scintilla.

I would argue we don't even have that scintilla here. If the crux of proximate cause in this kind of case, as it typically is, and is here, is testimony from a prescribing physician, the record is completely devoid of that.

And because of that absence of proof, either in respect of the strict liability claim or of the off-label promotion, UTPA claim, the state's proofs fail. And we would respectfully submit that Lilly is entitled to summary judgment.

Thank you, Your Honor.

MR. STEELE: Before I address the court, would it be all right if I asked does the court have any questions of me?

THE COURT: Well, I do actually. First, I would like you to talk a little bit about the Rezulin case. In particular, you characterize it -- again, I think I previously in this discussion characterized it

how I think you characterized it.

If I have got it wrong, let me know why, but that's one thing I would like to talk about. I would like you to talk about Judge Weinstein's decision that you talk about, and as I read that decision, there seems to be a lot of discussion about what individual doctors or individual patients claimed.

And I realize that's not a -- he doesn't seem to be dealing with a state claim like this one, but it certainly suggests that what individual doctors would have done and wouldn't have done.

And then lastly, and maybe even firstly because I'm telling you -- I will tell you right now I'm troubled -- I would like you to talk about, as I understand it, the way Zyprexa is utilized, there are several ways.

It can be used as a first-line drug for conditions that -- there doesn't seem to be a lot of dispute what people should use it for. The question is what are the side effects and whether the risks and benefits of this particular drug, for a particular patient, is worth using.

Then there is people that you have tried a different drug because perhaps you thought that the risks of Zyprexa, for those same conditions, the risks

of Zyprexa were too great or another drug might be a little bit safer or more effective, and it turned out not to be, that it didn't give the relief that the parties wanted, and so now you are moving onto a second drug or third drug of choice despite risks because the first drug hasn't been used.

Then there is the what you call the off market uses, which I'll say there is a little more controversy perhaps as to whether or not Zyprexa would be used for that kind of thing, and kind of -- I guess with all of those things, there is a question of what are the risks that a doctor would consider and warn a patient about and did Lilly adequately advise people about that.

But then there is the issue of what doctors would have done had they been adequately advised. Would they still have used the drug or did they know about it already. We had that conversation with Mr. Brenner about that issue.

I guess one question I have for you is: Is there any indication in the discovery so far about how many of what kind of uses we're talking about or don't you know, and then, secondly, which I suppose is the elephant in the room, if there are all of these uses and all of those possibilities and the state is now claiming

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labelling and that the labels and the calls were your UTPA misrepresentations, should I reconsider my decision as to whether or not to allow individual decision of physicians in this case?

Particularly for a UTPA claim, isn't that necessary? And, again, you can feel free to point out to me kind of what my approach was so far and whether or not why that would be the better approach or that I should continue to adhere to that approach, but I'm just concerned that, you know, it would be one thing if you said Zyprexa shouldn't have been used in this condition.

And then I would have expected Zyprexa should have been used off the market and we could have that debate, but given that Zyprexa, even with perfect disclosure and everything, that would still be an appropriate drug, my question is how are we going to know which of these cases is that case and which of these cases are the cases where people wouldn't have used that, because if people still would have used Zyprexa, I can't see you got a damages claim for them.

It's only if Zyprexa wouldn't have been used, I suppose, at all, or if Zyprexa was used and it caused other conditions that the state is now paying for that Zyprexa wouldn't have been used for do you have a damages case.

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So take them in whatever order you want.

MR. STEELE: Thank you. It's a little bit like going to the Academy Awards; you can prepare a speech, but you are not sure you get to give it.

THE COURT: That tends to be how oral argument goes with me.

MR. STEELE: I have got a speech. The speech addresses every one of the issues that you raised, and if I forget one, perhaps the court would be kind enough to prompt me.

Let's start with Rezulin first. Rezulin is not related to our theory. The case that we are pursuing is not a fraud or misrepresentation case, so we started out with a fraud or misrepresentation case.

If the court will recall on your memorandum or your order that was written with respect to our offer of proof; in other words, how we're going to prove the case, that was number five, and that has since been dismissed.

THE COURT: Yeah, but don't you -- I mean, here is what Judge Kaplan says the Rezulin case -- what Louisiana was arguing.

They argue that they are entitled to recover because defendants misled patients and the medical community concerning the safety and efficacy of Rezulin.

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Isn't that what you are saying --

MR. STEELE: It is.

THE COURT: -- as for Zyprexa? And then go on, it says in consequence of which Louisiana was called upon to reimburse for prescriptions that otherwise would not have been written.

Isn't that what you are also asking? And then there is language at prices that otherwise could not have been charged.

So isn't three-quarters of Judge Kaplan's description of what Louisiana is claiming the exact same thing that you are claiming in this case?

MR. STEELE: Or at least two-thirds.

THE COURT: Okay.

MR. STEELE: The answer to that is "yes," and as to why he dismisses the other two claims, he doesn't say, and, of course, a federal court decision in Louisiana is not binding on the Alaska court.

And if they don't offer any reasoning as to why they did what they did, it's not particularly useful in answering the question. The theory that the court invalidates is one that goes to essentially the last claim for damages, and that is the fraud on the market theory.

I think if we pursue this sort of in a

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logical order it will become clearer. We don't have a fraud theory with respect to liability.

We don't have a fraud theory with respect to cause. We don't have a fraud theory with respect to damages.

Now, what is fraud on the market? Fraud on the market is -- it's an element skipping case. In other words, typically if I'm trying to prove fraud, what I would have to do is I would have to prove that the defendant made a fraudulent misrepresentation, that I relied on the fraudulent misrepresentation and acted upon it and I was damaged, right?

Fraud on the market allows you to skip the second element, that is that you relied, you specifically relied on the fraudulent misrepresentation.

The theory was in securities is that the defendant goes out, makes fraudulent misrepresentations, that is picked up by the market, that inflates the price of the stock, and everybody, whether they relied or they didn't rely, pays the higher price for the stock.

Now, what the Louisiana court is saying is you can't import that element-skipping case into a pharmaceutical case.

THE COURT: And why does he say that?

MR. STEELE: Because when you are buying

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pharmaceuticals, the question is not really, at least in our case, it's not really a price sensitive issue.

Lilly has a monopoly. Rezulin, whoever was making Rezulin, they have a monopoly. Okay. They can price it the way they want to price it, so it's not a price sensitive kind of a case.

THE COURT: What is -- I mean, isn't what Judge Kaplan is suggesting is that what happens in a pharmaceutical case, it's not a price sensitive case, it's a doctor determining in consultation I suppose with the patient that doctor determining case as to what the doctor believes is the best drug for the patient, and understanding what the risks are, whether it's worth taking those risks and also consideration of whether you have tried other drugs that you think might have less risks or might be better and whether they would work or not?

MR. STEELE: Right. And that would all be instructed if we were in Louisiana and that were the cause requirement, but we're in Alaska and that's not the cause requirement.

So my third point is that with respect to the cause requirement in Alaska, in other words, to prove cause do you have to prove reliance by a specific physician? Do you have to do that in order to prevail

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on any cause of action in Alaska?

The answer to that is you do not. Under 45.50.551(b), there is no cause requirement, period. 45.50.551(b) is like traffic ticket liability. If you go faster than the speed limit, even if you don't hit somebody, you have got to pay the fine.

If in Alaska you go out and as a corporation, as a business, you go out and you make misrepresentations that are prohibited, you get the fine whether it causes anybody to do anything at all.

THE COURT: Doesn't there have to be an ascertainable loss?

MR. STEELE: That is under 531(a).

THE COURT: Okay. I know what you are talking about.

MR. STEELE: Under 551(b), there is no cause requirement.

THE COURT: So you are talking about the state acting as parents patria as opposed to the state suing as an individual?

MR. STEELE: Absolutely.

THE COURT: Okay.

MR. STEELE: So in other words, to unconfuse ourselves in this context, what we have got to look at is what's the Alaska law on the causation issue?

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Louisiana law on the causation issue may be that you have to have specific reliance by a specific doctor in a pharmaceutical case. It probably is, at least what I can infer from looking at the case.

But that's not the deal here. The deal here is under 551(b), no causation requirement. Under 531(a), ascertainable loss, which is defined in the Alaska pattern jury instructions, and I'll get to that.

And then under strict liability failure to warn, according to the Alaska Supreme Court, the conduct of the defendant needs to be a substantial factor in bringing about the injury. Okay.

It's not the substantial factor. It's not the only substantial factor. It's a substantial factor in bringing about the loss.

The Alaska Supreme Court or the appellate courts have never held in Alaska, that in a failure to warn case involving pharmaceuticals, that specific doctor reliance is required.

The case on point is Shanks. If the Supreme Court wanted to say that in Shanks that you have to show that, but for the misrepresentations of the company, the doctor would not have prescribed the medication, if they had wanted to make that an element, they could have made it an element.

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And I would agree that in some jurisdictions it is, but it's not in Alaska. It has to be a substantial factor, and I'll get to how you would show it's a substantial factor.

THE COURT: And also how you will deal with ascertainable loss under --

MR. STEELE: Yes.

THE COURT: Okay.

MR. STEELE: Yes.

THE COURT: Go on.

MR. STEELE: So Rezulin doesn't have anything to do with this because it's not our theory. It's not our theory most significantly on the causation issue, which is what we're talking about here.

Different -- we have different causes of action than they had in Louisiana. We have got Alaska UTPA, and Alaska failure to warn, and because we have different causes of action, there are different elements to prove, and that is true with respect to the causation issue.

So let me get to one point that is bothering me, and that is this: This case is bifurcated. This case is bifurcated, and the court's order is the trial on liability will commence on March the 3rd.

Trial on the issue was causation, which is

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the issue we're discussing in this motion for summary judgment, and damages, is scheduled later. The parties shall by December meet and confer and reach an agreement on how discovery with issues unrelated to liability should proceed.

This is an issue unrelated to the liability issue. It's a specific causation issue, and discovery is proceeding. If they had teed up this motion properly with a description of what the undisputed issues were and affidavits in support of those issues, we would have filed a 56(f) and said discovery is ongoing, just as the court has said in the bifurcation order.

But we're not there yet. The causation, specific causation issues are still being developed. Discovery is ongoing. And if they ever tee up the issue -- see, this is the court's point: What you were asking counsel was, look, when I get the evidence in front of me in some comprehensive form so I can look at it, I'll decide if it's good enough. All right.

In Alaska, in order to tee up that issue, what they have to do first, before we're obligated to put in evidence, is they need to do their description of what the undisputed facts are and then they need to put in their affidavits and then they need to put in their evidence.

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And at that point in time, we will put in sufficient evidence to create a triable issue of fact. But we're not there yet. Clearly, we're not there yet because discovery is ongoing with respect to causation issues.

Now, currently, the theories that we are pursuing is, as I have said, they have violated Alaska UTPA 45.50.471, so we're saying that the things that are enumerated there that Alaska says you can't do, they did.

If you violate 45.50.471, then you are subject to penalties under 45.50.551(b) and 45.50.531. Under 551(b), no causation. Under 531(a), it's ascertainable loss.

Now, since we're in Alaska, it would behoove everybody and behoove really to look at what the statute requires with respect to 531(a). And they are plain, flat wrong in their statements to the court this morning about what it requires.

They are wrong as a matter of law. There is an Alaska pattern jury instruction. The Alaska pattern jury instruction is 10.04, ascertainable loss defined. This is an ascertainable loss. I'll read it, and I'll put in the State of Alaska so that it makes sense.

"You have to prove that the State of Alaska

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suffered a loss of money or property if the State of Alaska received something other than what the State of Alaska bargained for. The State of Alaska's loss is ascertainable if it is measurable, even though the precise amount of the loss is not known."

Now, the comment which was produced by the committee that was appointed by the Alaska Supreme Court goes onto explain what they mean by this, and this is what they say:

"Given the opportunity for full review, it seems likely that the court would construe ascertainable loss, as other courts have done, to mean more than simply loss of money.

Other courts have found that ascertainable loss is a standing requirement, which like the rest of the act, must be liberally construed, and that the plaintiff suffers ascertainable loss whenever he or it receives something other than what was bargained for, whether better, worse or simply different."

Now, that is our favorite Rezulin case, which is West Virginia Rezulin litigation. And there is no doubt that with respect to Zyprexa, the State of Alaska received something different than what was bargained for.

What they got for their money was a product

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that Lilly was systematically misrepresenting to the people who were prescribing it so that we would have to buy it.

So there is under 531 --

THE COURT: Run that by me again because I'm having trouble with it. I mean, I would think that what the State of Alaska bargained for was that they would pay for the prescriptions under, is it Medicaid or Medicare, Medicaid that doctors prescribed.

And don't we still get back to if the doctors still would have prescribed it, or if they had no quote, unquote, "truth," doesn't the state get what they bargained for?

MR. STEELE: Not at all. I can get back to that point when I talk a little bit about what Lilly's scheme is, but what the State of Alaska is bargaining for is to get a product that is --

THE COURT: I mean, just to interject another thing is how you can say they didn't get what they bargained for if now having had this scheme uncovered they are still paying for, asking that it be used.

Mr. Steele tells me, I'll assume that it's true, that when in some of those involuntary medication things, the state comes in and says use Zyprexa.

Doesn't that tell me they are getting what they bargained for, at least in some instances?

MR. STEELE: It doesn't, and, actually, I'm Mr. Steele.

THE COURT: I'm sorry. I will probably do it -- I'll probably do that four times, but I'm sorry.

MR. STEELE: It's no problem. Forewarned is forearmed. The point of a warning is so that a problem, if it appears, can be addressed appropriately, but there is all kinds of adds for statins on the market.

For example, Lipitor. And when they do the ads and say, "Ask your doctor about Lipitor," they say, "Look, if while you are taking this statin you get unexplained muscle pain or weakness, tell your doctor."

That's a warning, right? Now, are we saying, "Gee, if there was -- that warning didn't come with the statin, then no problem, statins would be just great." Statins have lots of uses. They are going to lower your cholesterol. With some of them, they are going to make it less likely that you have a heart attack, but there is no benefit to you of being misinformed about what the risks are.

And if you, while you are taking your statins, develop unexplained muscle weakness, then the problem can be addressed. All right?

So what we are saying with respect to warning is forewarned is forearmed, so what the counsel is now and what has been going on since October of 2007, is if you are considering giving somebody a powerful psychotropic drug, then into the mix you have to weigh the risk versus the benefit. And now you know what the risk is accurately; before, you didn't.

And number two, if it is appropriate, and most of the time it is, then what you need to do is you need to, number one, give them an informed consent about what the risks of the medication are, and now that you know what those are, you can. Let them decide if they want to take it.

Number two, monitor them appropriately. If they need a fasting blood glucose, give them a fasting blood glucose and then monitor intermittently. If they are at risk for dyslipidemia, check their cholesterol.

And tell them to be on the lookout for the signs of diabetes, so diabetes carries with it signs or symptoms that the patient can be alerted to, and if those pop their head up, then what you can do is you can deal with them.

And there are many ways to deal with them. We are not helpless in this day and age in terms of either avoiding diabetes by changing the medication

and/or dealing with it so that it does not cause damage by alerting the patient so that treatment can begin early or the medication can be stopped.

So the point is not just should you give people statins or should you give people Zyprexa? The point is that it should be given with appropriate warnings so that you can take the appropriate action.

Now, what happens is they go out and they lie about -- what they do is they under sell the risk and they over sell the uses of the product.

That's what they do. That's what this scheme is about. Why do they do it? They are doing it for the reason. They want to sell more of the product. They want to sell more of the product to who?

They want to sell more of the product to the State of Alaska. 70 percent of Zyprexa is bought by the State of Alaska. Of those 70 percent that's bought by the State of Alaska, about 37 and a half percent of those prescriptions are not only off-label, they are outside of compendia.

There are compendia. The compendia tell you what the off label recognized uses are of the drug.

In order to be reimbursable under Medicaid, you have got to fit within either the approved indications by the FDA, or one of three recognized

compendia. 37 and a half percent of the prescriptions that are written in Alaska fit with neither.

What Alaska thought they were paying for was reimbursable uses of the drug. What Lilly did is they went out and they promoted the heck out of non-reimbursable uses of the drug and we paid for it.

What we thought we were getting was reimbursable uses of the drug. What we got was non-reimbursable uses of the drug, and we paid for it and we want our money back.

So of course, we got something different than what we bargained for.

THE COURT: Explain that to me. I realize this is argument and not evidence, but explain if you are only supposed to pay for recognized -- uses recognized by the FDA or one of these three compendia, how is it that the state paid for things outside of these three compendia?

MR. STEELE: That's the way it works here in Alaska, and that's the way it works most places. We have a Medicaid department that is what it is and has the resources that it has.

And they do not have the ability to deal with this particular issue and they don't. So here is how it works: In order to have a Medicaid program, what

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you have got to do is you have got to comply with a set of federal regulations that patterns every Medicaid program.

Under federal regulations, something is a covered outpatient drug if it is an on label use or it fits within one of the compendia. Okay. That's how it works.

THE COURT: Are you telling me that -- I mean, suppose one of these non-compendia uses is effective for a patient. Are you telling me that the state is claiming as damages a drug that a patient has been taking, is being effective for them, but because it didn't fall within the right categories, you shouldn't have to pay for it and that's damages in this case because they promoted this usage, which in my hypothetical turns out to be effective?

MR. STEELE: No. Number one, it's an ascertainable loss, right, because, look --

THE COURT: Mr. Steele, it sort of sounds to me like an insurance company who says, "We'll pay for that operation," and then after you have the operation and it saves your life is now saying they are not going to pay.

MR. STEELE: But what the court is assuming is that it's effective.

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THE COURT: That's my hypothetical. I don't know whether it's effective or not, and that's my hypothetical, is that -- and then the question will become how do we know for an individual patient whether these non-compendia losses that you -- ascertainable losses that you are asking for compensation for gave the patient no benefit or whether it gave the patient appropriate benefits and whether it fit within the compendia or not as prescribed by a doctor who continued to use it seeing that it benefitted the patient?

MR. STEELE: In part, that's a Dalbert question, but let me give you an example. It's a lot easier if we take an example.

One of the things that Lilly did is they came along --

THE COURT: Let me ask you another question with that, which may get a little far fetched, but I think it gets to some of the concerns I have.

Under this theory, does Lilly have the ability to bring in the doctors and the patients basically for subra of some sort?

MR. STEELE: Well, they can claim -- in other words, it depends. Under the UTPA, under 531(a), under proving ascertainable loss, it's not a comparative fault problem.

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Under the strict liability failure to warn, there is a comparative fault issue. We have to prove it's a substantial factor. If they want to say it's somebody else's fault, they can do it.

So if they want to, they can do it, but, look, one of the things, one of the issues that we have briefed, Your Honor, is, look, if somebody comes into yours jurisdiction and they behave obnoxiously and they lie about their warning and they promote the drug for all kinds of things that they know it's not useful for -- let's assume my hypothetical.

Okay. That's what they do. They lie about your risk of getting a life-threatening disease that will either kill you, cause you amputations, cause you to go blind. They lie about it. They do it a lot. They talk to every doctor in the state. They send drug detail people in there sometimes 20 times a month.

And in addition to under selling the risk, they lie about what it's good for, and they tell them it's good for this, and it's good for that, and they know it's not good for that.

So that's my hypothetical. They are lying about it. They are lying about the deadly disease and they are saying pass this stuff out like candy. All right.

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So you go, well, let's see. How do I get out of this if I'm the defendant? The way that I get out of it is I say we have got to depose every single doctor and every single patient in the state because they know we can't do it. They know that it makes it too onerous.

That's why, discussing Judge Weinstein's case, Judge Weinstein says when you have got a sophisticated, broad-based scheme, statistical proof of causation or reliance is appropriate because otherwise, like in tobacco, you leave people without a remedy.

That's why. That's why it has to be done that way. Because as a matter of policy, they should not be allowed to come into the state, pull off a pervasive scheme that was better planned than most wars --

THE COURT: But the problem, the big problem I'm having is there is so many ways I'm hearing that this drug can be used and so many purposes.

It can be used for FDA-approved things and the doctor might choose it as its first line drug. They could be used for those reasons as a second or a third or fourth I suppose line drug where you are willing to take more risks because the first-line drugs with less risks having been used.

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There is these off use labels. There is these what now I'm hearing are, and I'll call non-compendia uses, which seems to be may be different than the other ones and may be the same.

How, without knowing what a doctor used the drug for, can you separate any of those?

MR. STEELE: We know what the doctor used the drug for.

THE COURT: But don't you have to talk to the doctor as to do you know whether the doctor -- whether it's a second or third or fourth?

MR. STEELE: Sure, you do.

THE COURT: Okay.

MR. STEELE: The Medicaid data is voluminous and in the Medicaid data, the doctor is required by law to say what he is treating the patient for. They are called ICD9 codes, international disease coding.

THE COURT: This is the Medicaid data that hasn't been produced yet?

MR. STEELE: Oh, no. They have in large measure the Medicaid data. In other words, there is enough Medicaid data that they can look at what the ICD9 codes were that the patient was being treated for, what the diseases that were being treated for and what prescriptions they were given, how long they were given

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the prescriptions for.

The stuff that hasn't been produced is stuff that an expert that they said we would like to have this and look at it and see if it's helpful, that's a big pile of stuff, and I think it's being Fed-Exed today. I think that's the day we -- the 30th is the day we agreed to do it. I think it will get there on the 30th or the 31st.

So you can tell from the data what the doctor is doing by looking at the disease classification. And you can know what it is that he prescribed, and you can know what he prescribed before.

So if the patient was on Rezulin, it will appear in the records. If they are switched to Zyprexa, it will appear in the records. You will know what the diagnosis is when it appears in the records, so it's not difficult to tell what it's being prescribed for, which is why we look at the data and which is why we tabulate it statistically and describe what the heck is going on.

Now, let's take an example, okay, because it's hard to talk about this in a vacuum. There is a metaphor that Lilly used. The metaphor is Donna, the drab housewife. And Donna the drab housewife shows up in your office and she is kind of drably dressed. She is a single mom. She has been having trouble sleeping

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lately.

You need to talk to her about Zyprexa, which is useful in treating complicated mood disorders. That's the metaphor that they went in to Alaska doctors and over and over and over again, if you look at the call notes, they are talking about I talked to the doctor about Donna. I told him that Donna needs this gentle, safe and effective psychotropic.

Well, that is a total crock. If you take the head Lilly people and you sit them down and you describe Donna to them and say, "Does Donna need Zyprexa? Does she need a powerful antipsychotic that may cause her to get diabetes," they will say, "No way, no way."

And do you want to be giving drab housewives a powerful and expensive antipsychotic for something where Zyprexa is in no way thought to be effective by anybody and risk giving them diabetes, but that's what these guys are doing.

So, you know, if you look at what they do, it's a situation where they develop a battle plan, they develop a plan of action. So we have got Zyprexa, primary care strategy and implementation overview, what they are doing is this: The psychiatrists are relatively sophisticated with respect to the uses of

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antipsychotics.

Primary care physicians are not. They are more naive. They don't treat very many people in that category, and they are scared of powerful antipsychotics.

So since there is only so many schizophrenics and only so many bipolars in this world, how are we going to sell Zyprexa and make up for the fact that Prozac is going off patent and we are losing our big money drug? Well, we are going to sell the heck out of Zyprexa to primary care physicians.

So what do they do? They implement the strategy, and they implement it right here in Alaska, and their call notes prove that they did.

THE COURT: Well, the call notes say something. Mr. Brenner's point about --

MR. STEELE: We'll get them interpreted.

THE COURT: I mean, that's why --

MR. STEELE: We'll bring in an expert that states what's going on. We'll bring in the drug reps that say this is what's going on.

We deposed the head guy who develops this script and develops this program and we say, look, are the drug reps required to go out and spout the Lilly line? Are they required to go out and say these things

to the doctor? Yes.
Are they prohibited from saying it any other way? Yes. Is it part of their job to do it? Yes. Do they have a script? Yes.
We have got the script. We know what they have to say.
THE COURT: Shouldn't I, again, revisiting prior decisions, let Lilly depose the doctors to say what were you told in this script? Did they really follow the script? What impact did it have on you?
Why -- if these are the communications that caused the violation of the UTPA, shouldn't I do more than let an expert interpret a script? Shouldn't I know from the people who received the communication that violates the UTPA exactly what they received?
MR. STEELE: It is possible that evidence from a selected group of doctors, it is possible that evidence from a selected group of doctors might produce, might produce some relevant and admissible evidence.
You and I had this discussion before. Okay. What I'm saying is don't burden us too much. Don't make it impossible for the state to pursue a remedy for this obnoxious conduct.
What you told the defendants and what you said in your order is if you want to pursue discovery in this way you can do it. Have they done it? No.
We had a whole bunch of depositions set with physicians that were Alaska physicians that I thought was going to be about this issue, and what they did is they called up my colleague, Mr. Sanders, and said, " Gee, these are second trial depositions. Let's cancel them and do them later."
So they could have done this. You told them way back when when you did your order you can do it. If you want to defend yourself in this way, you can do it. They just haven't done it.
And the fact is, that's right, you said you can have discovery in this area.
THE COURT: I thought there was a change in that, but maybe I'm wrong.
MR. STEELE: Say it again.
THE COURT: I thought I then limited that again, but maybe I'm wrong. Go on.
MR. STEELE: Well, what you said was Lilly can pursue this question of asking doctors questions. If the state needs to ask the discovery master for reasonable limitations, the state can.
We never got that far because they set the depositions and then they said -- called us up having -- everybody made their travel plans and said, "Wait a minute. These are damage depositions, next trial depositions. We'll get to that later." And that's right, we'll get to that later.
Discovery is ongoing. If they want to notice those guys up, if they want to ask them those questions, help yourself. I can't wait. I can't wait.
Now, it may be that like some doctors they will say, "I don't remember what was said." They visit them 20 times a month, you know, every month. My God, they spend millions of dollars sending this Army of drug reps out to read a script that they prepared in Indianapolis.
I don't know whether the doctor will remember it or not, but if they want to ask a few of these guys some questions, bring it on. We'll ask them whether they wanted to know the truth or not.
THE COURT: Okay.
MR. STEELE: So here is what these guys did: Because the point is they know who is buying this drug. We buy 70 percent of it. They know it's expensive.
THE COURT: Mr. Steele, I don't want to get too much into kind of what the version of the evidence that I haven't seen. And I'm sure Mr. Brenner is dying to tell me the other side of the story, but what I really want to focus on is the issues on summary judgment and what implications that may or may not have for discovery and how this trial should proceed.
MR. STEELE: This address is sort of the opposite side of your hypothetical. In other words, were I to read this, it would become very clear to you that what these guys did was target 60,000 prescribers who were primary care docs.
It's a situation similar to like they get them to gateway drugs like marijuana, you know, so it's -- this is how you do it, you go mental disorders is intentionally broad and vague. Provide them latitude to frame the discussion around symptoms and behavior other than --
THE COURT: But, again, I mean, I don't want to get into the, as you put it, the other side of my hypothetical. What my hypothetical is really asking is how I know what's the other side of the hypothetical and what's the hypothetical, and how do you know that if you don't talk to the doctors?
MR. STEELE: They had -- we have to show that it's a substantial factor. Causation -- there is no specific kind of cause required.
In other words, reliance is a specific kind of cause. It's a specific type of cause. I made a fraudulent misrepresentation. You relied on it and you

did something, I was damaged.

It's a kind of causation. There are other kinds of causation. Everybody knows that Lilly is spending millions of dollars. They have a carefully crafted message. They send an Army of people out to deliver the message.

They get in the doctor's office and the call notes show that they got in the office. They deliver the message to the doctor and then the doctor behaves in a particular way.

That is a substantial cause. What difference does it make whether we call that thing reliance or we don't? There is no smoker in the world who started as a kid who is going to come in and say, "I relied on Joe Camel to start smoking," but everybody knows that cigarette manufacturers are using cartoon characters to increase the sales of their product in children.

The head of Lilly is a marketer, not some research scientist. It used to be true that the drug companies were run by research scientists, but they are run by marketers and the marketers know, guess what, marketing works.

So what they do is they go out, they develop broad-based schemes, they spend millions of dollars to

carry them out, they are successful, and then they come in to Alaska and say, "You can't win unless we can talk to every doctor and the doctor will say I relied."

That is completely antithetical to the spirit of the UTPA, which is a remedial statute and which under 551(a) has no cause requirement, or under 531(b) has a cause requirement that is simply ascertainable loss, meaning you didn't get what you thought you were getting.

It is a very low standard. And not only that, Your Honor, once you have known you have got some kind of ascertainable loss, in other words, you don't have to show that every prescription was one that caused us a loss, it just has to be an ascertainable loss.

Now, after we have got to ascertainable loss, meaning we didn't get what we paid for, either better, worse or different, then it's a minimum of $1,000 per violation, so every time you go in and you do the act, there is an ascertainable loss, it's $1,000 to $25,000.

So it's not $1,000 to $25,000 per ascertainable loss. It's $1,000 to $25,000 per prohibited act. That is a lot of money. And when we get done with the first trial, it is going to be very clear that these people repeatedly violated the UTP here

in Alaska, and they did the prohibited acts. It's going to be very, very clear to everybody, because it's obnoxious what was done here.

So I don't think that we have to worry really about teeing up the causation issue until after the first trial, and it can be teed up. And the court is correct, if they want to tee the issue up, if they want to depose a few doctors within reason, let them do it and they can put in their affidavits and they can -- if they can get a doctor to come in and say we were warned about all the risks that were known and knowable, and say that's not an issue, our warning is fine, if they can get somebody to do that --

I mean, look, to know what the risks were what do you need? You need fasting blood glucose or random blood glucose. Well, that test has been around since about the 40s. You need to check for the lipids. That test has been around for 20 or 30 years. And you need a scale to weigh the people.

Well, it's a led pipe cinch that these guys did not warn about the risks or -- (indiscernible). And then what they did is they misrepresented that in their warning. And then what they did is they sent an Army of drug reps out into the field to lie about it. And then what they did is they generated off label, off-compendia

prescriptions to the tune of almost 40 percent in Alaska at $10 and $15 a pill.

That's what it's about. That's what the case is about. And whether some doctor will come in and say, "Wow, when I wrote this prescription in 1999, I didn't rely on or I did rely on what I didn't know," what difference does it make really?

I mean, that testimony, you look at it in the individual cases and it doesn't ring very meaningful to me. You have got to do it in some jurisdictions.

But, look, promoting, marketing, advertising, it works. It's effective. We all know why, and it doesn't matter whether a smoker comes in and says, "I relied on Joe Camel." It doesn't matter. And it doesn't really matter, in my opinion, here.

And if they want to try to bring that in, let them try. We're not there yet, so that's what I think is going on here.

It's really simple. Rezulin has nothing to do with us. The case is bifurcated. The issue will be teed up after the first trial. And as a matter of law, these guys are wrong about what causation is under Alaska law.

Look, it's legal cause. It's not proximate cause. It's a cause, not the cause. And it's a

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substantial factor. It's not the only factor. They are just wrong. And they are wrong about what ascertainable loss is, which is really something worse, better or different.

THE COURT: Why don't we let Mr. Brenner respond? Mr. Brenner, I know that you are dying to tell me your side, but please --

MR. BRENNER: I will not, Your Honor. What I will say is there is a lot of bait, but you will forgive me if I don't rise to it.

THE COURT: That's okay. What I would like you to respond to are basically two things. If there are other things you want to respond to, please do.

The trial has been bifurcated to put the causation issue down the road and discovery on the causation issue down the road. Doesn't your motion really go to the causation issue? That's my first question.

And then second, would you -- the state has strongly argued that whatever the laws in other cases, Alaska law has specific elements or requirements or I suppose less stringent requirements than some other places do and they talk about Prince and they talk about Upjohn, and why don't you talk about how that affects this motion?

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MR. BRENNER: Can I take them in reverse order, Your Honor?

THE COURT: Any way you want.

MR. BRENNER: Proximate causation. This is not a cigarette case. It's not a consumer product case of any type.

The consumer, if you will, is the doctor. And I don't believe Alaska law is contrary to the prevailing law in every jurisdiction of which I'm aware in the United States, which is because of the unique place in the marketplace of prescription drugs, the effect of the warning must be measured on the physician.

And I don't believe Shanks is in opposition to that. It's just an issue that was not presented squarely in Shanks. It is what does proximate cause mean in the case of a warning case?

Any other consumer product case in Alaska, as elsewhere, you have to show the warning had some impact on the user. Here, for these purposes, the user is the doctor. You cannot take the doctor out of the equation, and we cannot do it in an aggregate way, and that is all the state has offered to us at every phase.

And that's why, jump a little bit ahead here, Your Honor, that's why it is right now, not after so called phase one, because the state has said we don't

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have to do that.

The state continues to say, "Lilly, go ahead and take doctor's depositions." We took two. The state did not ask a single question, but it's not our burden to show either ascertainable loss or proximate cause.

I think Your Honor put your finger right on it, particularly on ascertainable loss. What do you do with a doctor who knowingly used the drug off label. Many psychiatrists did, and had a great result for his patient. The patient was cured, no harm.

That would be a very odd cause of action. That would be a very odd form of compensable loss. Indeed, I think it wouldn't be consistent with due process.

But this amalgam approach, that is what the state is -- (indiscernible) -- and that somehow can be worked out later. It cannot, respectfully, it cannot.

Proximate cause and prescription medicines in Alaska and elsewhere always comes down to the doctor. We have deposed some doctors, but the reality is, as the discovery master and I think -- (indiscernible) -- ruled, we could not get any records. That is not a particularly efficacious way of taking a doctor's deposition to understand the target has changed slightly.

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Design defect used to be the crux of this case, and I could be so presumptuous to make this comment, Your Honor. Maybe that made sense to have a bifurcated trial and risk versus benefit, but that's out of the case now.

And you cannot -- I disagree with Mr. Steele. You cannot simply extract causation from the failure to warn case, because to establish failure to warn you have to show that the drug caused a problem. That's what would make the product inadequate.

It can't be as neatly severed as the state suggests. I think those are both the issues Your Honor raised.

Unless the court has other questions, I'll sit down.

Thank you, Your Honor.

THE COURT: I'm going to take this under submission and I'm --

MR. STEELE: Mr. Sanders asked me to remind the clerk that on page five of your ruling on plaintiff's claim of proof what you said was the manner in which the state intends to prove its case should not limit Lilly's method of defending against the state's claim. Lilly is free to obtain discovery in accordance with the rules of civil procedure.

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Both parties, if necessary, may request the court or the discovery master to impose appropriate limitations.

That was the doctor deposition section. You told them they could do it.

THE COURT: Okay. I'm going to take this under submission. I'm going to wait until the supplemental briefing is done anyway, and so you are not likely to get a ruling from me on this motion until end of February.

Mr. Sanders?

MR. SANDERS: I don't want to be presumptuous, but there is a lot of fire power in this case, as you can see from all the pro hoc attorneys.

THE COURT: I think Pepper Hamilton I have got half of the firm pro hoc.

MR. SANDERS: And obviously there will be a planeload of people coming from Philadelphia perhaps. There will be people coming from all over the United States. We have got people in South Carolina, Texas, Utah, on and on.

Presuming that the case is going to go forward on March 3rd, that the court is not going to grant summary judgment, it might be helpful in terms of scheduling if we could have a pretrial conference --

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THE COURT: Don't we have one scheduled?

MR. SANDERS: We do, but it's kind of late in the game. Let me just ask you a quick question, if I could for scheduling.

Could we presume that the first day the state needs to present witnesses is the third day? In other words, we'll take out the first day would be jury selection or maybe some --

THE COURT: Hold on a second. Mark, could you ask my calendar to come in? I just need to check some other things with that, because I normally do settlement conferences for other judges on Mondays and so that may still be the case.

I want to let you know what things are going on. While that's happening, Mr. Sanders, or whoever, remind me of what you are doing to mediate this case.

MR. SANDERS: What are we doing to mediate this case? I'll let Mr. Jamieson or Mr. Brenner speak to that.

THE COURT: I do have settlement on the third already scheduled, set all day. Actually, I have two. It's Judge Joannides' day, and then the rest of the week is fine. What you are suggesting is it will likely take two days to pick a jury? Is that what you are suggesting?

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MR. SANDERS: No, not really. I think the case, you could have a jury in a day, but what I'm trying to do is for purposes of planning just assume that we'll have one day or a little bit more for jury selection, one day for kind of administrative issues that are going to come up. I'm sure that everybody is going to want to practice their speeches for you, and then a little bit of time for opening statements.

And so what I was suggesting is if we could just be told regardless of what pace we go at, the state does not have to put on any witnesses until the third day of the -- so if we start on Tuesday with jury selection and Wednesday with administrative stuff and opening statements, the state, you can assume that Thursday morning is the soonest you have to put on witnesses. That's kind of what I'm suggesting.

THE COURT: Mr. Brenner? I mean, that doesn't sound unreasonable to me, given the --

MR. JAMIESON: Your Honor, Brewster Jamieson for Lilly. We think that does sound reasonable, but added to that is this may be a case that's appropriate for a juror questionnaire, and what we would suggest in that situation is once we have an appropriate questionnaire approved by Your Honor, assuming you agree to that, then we would have the jury panel come in on

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Monday, fill that out, Tuesday begin with jury selection with the benefit of the juror questionnaires, and then it sounds like --

THE COURT: Given that I won't be able to -- that I'm otherwise engaged on that Monday, I think we can do that.

I will tell everybody -- I don't know how I can help you with this, but I'm just going to advise you with this. I have no idea for the week of the third how many jury panels will be otherwise needed, how many criminal cases are going, but there is a juror parking problem, which has, if a lot of criminal cases are going, creates a problem where sometimes we can't get to our jurors the first day anyway and may not have enough of them, so how it's all going to work out, I have no idea.

You may have to talk to the jury clerk as the trial gets closer to figure that out a little bit.

MR. JAMIESON: Assuming those issues can be worked through, I guess the concept of administering the jury questionnaire where the jurors come in, fill it out, go home for the day, we have the benefit of both sides -- both sides have the benefit of those responses to be used in jury selection the following day, and then the day after that would be openings and then the day

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after that would be the state's first witness.
Does that sound like a reasonable plan for Your Honor?
THE COURT: I mean, the jury would come in on the third, be down in the jury room, fill out your questionnaire, turn it in to everybody. You would have the benefit of that. We would start jury selection on the fourth.
Wednesday would be openings and any other issues we need to take up. And then we would start the trial Friday, Thursday and Friday. I have what's supposed to be an all-day meeting on something Friday morning, but I'm going to cancel that if this case goes.
The week of the 10th, right now, that Monday is free and I'm going to put something to try to hold that.
Tuesday and Wednesday are free. I'm supposed to have a two-day termination trial starting that Thursday, but I'll find another judge to take those as well. And then Saint Patty's day, Monday the 17th, I do have a settlement conference set on Monday morning, so we might not go that day.
The rest of the week is totally clear, so, again, I'm not sure yet. I don't have a clear understanding from you as to how long this first phase

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of the trial is going to take.
MR. JAMIESON: That actually raises a point. One of the things that we have talked about internally is the state's deposition designations.
THE COURT: Well, I know that I have gotten big stacks from both of you under seal and I haven't looked at any of them yet.
MR. JAMIESON: One thing we have done, just sort of back of the napkin sort of estimate, if the state truly is going to play all of the portions of the depositions that it has designated, that's probably 15 trial days alone. And we're concerned about the length of the trial if that's really how it's going to go.
If it's not, I guess we would like to know really --
THE COURT: Given that this was originally scheduled for a 20-day trial for the whole kit and caboodle for total with half of it allocated to each side, the state will have to give me some indication -- I want both sides to be able to give me some indication of how long their case is going to be.
MR. JAMIESON: And I think that just raises the issue of the designations may have been the product of we have got a designation deadline, let's over designate just to be on the safe side and that the true

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designations will be decided later.
We would like to know that sooner rather than later because presumably we're going to spend 15 days trial time playing depositions to jurors.
And then the second issue would be are you going to conduct trials to Fridays?
THE COURT: Yes.
MR. JAMIESON: And then is the 8:30 to 1:30 --
THE COURT: The only restrictions you will have is if I have already scheduled some settlement conferences for other judges on Mondays, because I get a slight reduction in case load in exchange for doing other people's settlements, so I feel obligated not to tie up, unless I'm free on those Mondays, to tie them up with this case, but everything else that I might have during the week, I will try to move.
You will definitely go on Fridays.
MR. JAMIESON: And we'll go -- we won't be going full days?
THE COURT: 8:30 to 1:30.
MR. JAMIESON: And Your Honor, I do have one citation to advise Your Honor of. It's Meyers versus Alaska Psychiatric Institute, 138 Pacific 2nd 238.
THE COURT: I know the case.

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MR. JAMIESON: Involves the forceable medication.
THE COURT: I know the case.
MR. JAMIESON: Okay. Thank you.
THE COURT: Again, there was some suggestion that the pretrial that we have for the 22nd might be too late, but I don't get back in the office until the 19th, Mr. Sanders, so I'm not sure how I could move it up.
MR. SANDERS: Just in terms of broad planning, I'm assuming that roughly the trial that we have got laid out 20 days is going to be divided possibly in half?
THE COURT: Right, except it was 20 days for the whole case when we first set this, so is it now a 20-day trial for just liability without causation?
MR. SANDERS: Probably. I don't know. I mean --
THE COURT: I'm going to tell you this, when we have our pretrial, I'm going to expect each side to tell me how long this case is going to be and I have been known to keep time, and I will.
I mean because the -- I mean, I need to tell the jury how long their lives are going to be disrupted, and so I need to know that.
MR. SANDERS: No question about that. Just

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in terms of what Mr. Jamieson was suggesting was that now the state is coming in here thinking they are going to have 20 days for their case. I just wanted to make clear, no. I mean, we understand that --

THE COURT: And I will probably -- I'll say that it would surprise me greatly if the state took 15 days of just playing TV depositions or reading deposition. I would be surprised if that happened.

MR. SANDERS: I think Mr. Jamieson needs to turn the --

THE COURT: They are entitled to know what depositions are really going to be used. If you designated 15 days worth of depositions and you are only going to spend three days reading depositions, they need to know which three you are really going to do. That's certainly fair, and vice versa.

MR. SANDERS: Okay. Can I just ask you just because every judge does this a little bit different and I have got lawyers that are flying up for these things and sometimes it may just not be necessary for them.

What do you want to take up at that pretrial conference on the 22?

THE COURT: The pretrial conference on the 22, I want to -- I'll talk to you about how I pick a jury so you know what that process is.

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I'm going to let you know that I let jurors ask questions and how that process works. And see if there are technological issues or any other things we need to talk about about the courtroom and how the courtroom is going to be used, and exhibits.

Part of it is answering questions. Part of it is to let you know what my practices are. If there are things we got to take up and resolve before the trial actually starts, then I'm going to want to at least know what they are and see if we can either deal with them or figure out where we are going to take some time to deal with that.

It's as much for you to know what my processes are going to be for picking a jury for how the trial will be conducted for those kinds of things as it is -- but also it's to clear up any pending stuff and make sure the trial is going to go -- I mean, this motion and what the fallout of this motion will be is not clear to me.

I need to see your briefing and how that's all going to work. And I will -- I mean, I think I have mentioned this before, but I am extremely reluctant to bring in jurors whether it's 10 days, 20 days or whatever days, if there hasn't been some formal settlement negotiations with a settlement judge or one

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of the private guys.

And I don't think that's fair to jurors to do that if you guys haven't made an effort. And so that's going to be a question I'm going to want to know what you have done.

MR. SANDERS: So, I mean, based on what you are saying I think what I'm going to do is advise the trial counsel, lead trial counsel they need to be here on the 22nd, because if I hear what you are saying --

THE COURT: Again, they can -- I'm happy to have the questions, you know, happy to talk to the speaker, so people can make that determination.

MR. SANDERS: I want to address the question of settlement in a minute, but before that, this is going to be a very technologically-oriented presentation by the state.

Who would we talk to about the mechanics of that, what we can use, what we can't use, how do we set it up, break it down every night, those kinds of questions? I'm not sure whether you are the person or --

THE COURT: Actually, Mr. Boardman, do you want them to talk to you first about getting things set up in the courtroom or should they talk to IS?

UNIDENTIFIED SPEAKER: I can contact IS.

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THE COURT: I mean, why don't you use Mr. Boardman as your point person. It may well be that some of your questions as to whether something can be done in the courtroom need to be dealt with with IS.

The other thing is you will need to -- to the extent that things need to be installed in here -- I mean, I know there are some phone calls we got that were sort of -- from Mr. Jamieson's firm that seemed to be vague and we didn't quite understand what it was.

We took it to mean that somebody wanted to use video conferencing for today, and we didn't quite understand that.

MR. JAMIESON: Your Honor, that appears to be a mystery on our side. We don't know where that call came from.

THE COURT: My secretary is now on vacation and won't be back for a while, but she took the calls and I'm not sure that it didn't come from somebody initially in Philadelphia, but to the extent that things are going to be installed, we got to figure out when it's going to be installed and that will be an issue too that you will need to check with.

But you can use Mark here as the sort of point person and he'll get it -- part of the question will be when can you get things installed and I'm not

sure.

It is possible that on February 27th, I'm going to be at one of the chief justice's, something the chief justice has that's going to be an all-day thing, and so if that's the case, this courtroom will be free all day Wednesday the 27th. That is still up in the air, but right now, that day is totally blocked out on my calendar.

Other than that, I tend to be on the bench a lot. And so finding the time for installation -- but we'll work it out.

MR. SANDERS: In terms of the settlement potential, I would say it's way above my pay grade in this case. I mean, these people have been working I guess you could say against each other or for each other or with each other for years.

Maybe somebody else can speak to -- I mean, if you want to set a date now, I can safely say that we will be there when we're expected to be there, but maybe Lilly can --

THE COURT: I'm not going to set a date now. This is what I'm going to say: If you come in for trial, and so I'll ask the question again at the pretrial, but if you come into trial and I say what have you done to settle this case, have you had a settlement

conference and everyone says, "No, I'm going to send everybody home until they have the settlement conference," so I guess the order is before I'm going to require a jury to come in for ten or 15 or whatever number of days it's going to be, I expect that there will have been a formal effort to settle the case.

And if that doesn't happen, I'm not bringing in the jury.

MR. SANDERS: Okay. Thank you.

THE COURT: Any question from the defense?

MR. JAMIESON: Yeah, Your Honor. Thank you. Just one, Your Honor. Could I get a sneak peek at your jury selection method? Is it more or less the same as Judge Gleason?

THE COURT: I don't know what you mean by that, but I will tell you what I try to do with a two-party civil case.

I'm going to put 24 people in -- no, 22 people in the box. I might -- it will probably be 22. The reason for 22 would be 12 jurors, two alternates who we won't pick as alternates if we need to until the end of the case, so that's 14.

You each get three preempts a side, plus one extra for the alternate, so that's eight total preempts, so 8 and 14 is 22.

There will be 22 people. We will move these tables. We will have chairs in front. We'll have more chairs at the side so we can seat 22. And each side is free then, and we'll all figure out how much time you need given the complexity of the case and jury questionnaires and this sort of stuff, but I'll give you a certain amount of time to question those 22 in the box.

And you can use whatever method you want to use. You can individually question them, what I call the old-fashioned method, or you can use the Oprah or Donahue method, where you question the whole panel and have people raise hands and ask questions.

You are free to use whatever method you want to, and as people ask questions, you can challenge them for cause and we'll take those up and make rulings.

And if we need to, bring in somebody else. I assume that with something this size, before we even get to that, I'm going to -- there is the statutory questions I ask. And one of the questions I ask is whether or not anyone has a hardship or an emergency, and I define that.

And I'm sure that a lot of people are going to pop up with that, and I'll get some idea of that, but unless it's really clear to me, I usually save those

challenges to see if they get in the box and what the nature is and then we take them up, depending on how the selection is going, and I may excuse some of those.

But eventually we're going to have 22 people all past for cause that are in the box, and when that happens, I bring you all back into my chambers and starting with the plaintiff they exercise their first preempt, you exercise your first preempt, and I make you use all four, because I want to get rid of the extra eight so I only have the 14.

And once that's done, we have got our panel. So that's --

MR. JAMIESON: That is the Gleason method.

THE COURT: Okay. That's the process that I'll use. I think -- well, I still am not clear how long it will be, but I think having two alternates should be sufficient. Usually in a five-day trial, nobody gets -- has problems, but to the extent everybody is really worried about that we'll think about whether or not we need three alternates or not.

And again, the alternates, you know, if somebody gets sick or has an emergency and stuff, they get excused, but if we have still got more than 12 when the case goes -- is ready to go to the jury, then after closing and instructions, we just randomly pick the

names, but that's how it's done.
I guess I'll tell you now, I do allow jurors to ask questions. The way that process works is after a witness testifies, assuming they are life, I ask if any of the jurors have any questions.
If somebody raises their hand, they write it down on a piece of paper and hand it on up to Mr. Boardman. He usually marks which juror asks the question. And I call you up, share the questions with you, see if there are any objections to the questions or not.
Sometimes the questions are such that I might even ask them directly. In other words, if a witness has used a term and the question is what does such and such term mean, I'm going to assume that no one is going to have objections to that and I'll just ask the question.
I ask the questions that the jurors -- that we decide that can be asked. I have -- as part of the instructions I give to the jurors before the case even begins, there is something about the use of questions, that it's not designed for them to pursue their own theories or to kind of help out one side or the other or become advocates and there is a bunch of cautions about using it and why you would use it and what the process

is.
And then after the jurors questions are read and answered, if anybody has any follow-up questions, I allow those to be asked by the attorneys.
MR. JAMIESON: Thank you, Your Honor.
THE COURT: Then the motion for summary judgment is taken under advisement. I'll wait until the supplemental briefing is -- the supplemental briefing will be finished by the time I get back and I'll -- as soon as I get back, it will be one of my priorities.
UNIDENTIFIED SPEAKER: Can you just give us a heads up on the deadline of that? They are going to file something first.
THE COURT: They were going to file something a week from today, and you were going to do a reply a week from then.
UNIDENTIFIED SPEAKER: So ours is due a week after theirs?
THE COURT: That's correct. I will wait and get the briefs. I mean, I kind of see coming straight at me is a big preemption question, and what I'll have -- and how I'll have to deal with that I'm less than clear, but this case will probably be my priority once I get back from vacation other than catching up.
UNIDENTIFIED SPEAKER: Do you have any other

cases than this one? Sorry.
THE COURT: We'll be off record. Thank you.
(Off record.)

TRANSCRIBER'S CERTIFICATE

I, SONJA L. REEVES, hereby certify that the foregoing pages numbered 1 through 77 are a true, accurate and complete transcript of proceedings in Case No. 3AN-06-05630, transcribed by me from a copy of the electronic sound recording to the best of my knowledge and ability.

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,
Plaintiff,
vs.
ELI LILLY AND COMPANY,
Defendant.

Case No. 3AN-06-05630 CI

MOTION ARGUMENTS BEFORE THE DISCOVERY MASTER

Pages 1 - 168
Tuesday, September 11, 2007
11:00 A.M.

at
LANE POWELL
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

need is in there or not, and then we can address it from that point. That I think would be a sensible procedure.

DISCOVERY MASTER: All right. Thank you. Mr. Boise.

MR. BOISE: Okay. The first part of Mr. Steele's argument went as to how the plaintiff is going to pursue their claim. At the very start of the litigation, Judge Rindner looked at the issue and said, "Well, can they even prove the claim in that fashion?" Because we don't even have to go down any of this path if in fact that's not a way that the State can proceed. And Lilly certainly disagrees that how the State is proceeding is an appropriate way to prove their case.

What Judge Rindner has ruled is: I can't rule on it yet. I decline to rule on whether that's appropriate or not, but the parties are free to defend the case, and Lilly is free to defend the case as it needs to defend the case. As well, the argument was made to Judge Rindner that what individuals think or how doctors make prescribing decisions are completely irrelevant, and Judge Rindner ruled Lilly is free, subject to constraints of Rule 26, to go ahead and defend itself.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff, vs. ELI LILLY AND COMPANY, Defendant.	Case No. 3AN-06-5630 CIV

AFFIDAVIT OF ERIC T. SANDERS IN SUPPORT OF THE STATE OF ALASKA'S OPPOSITION TO LILLY'S MOTION FOR RECONSIDERATION AND RESPONSE TO COURT'S ORDER

STATE OF ALASKA)
) ss.
THIRD JUDICIAL DISTRICT)

Eric T. Sanders, being first duly sworn on oath, deposes and states as follows:

1. Defendant Eli Lilly and Company's motion in response to the Court's on-record comments cites the following statement from the January 29, 2008 hearing: "[S]hould I reconsider my decision as to whether or not to allow [discovery of] individual decisions of physicians in this case?" Later in the hearing the State noted that, in fact, the Court's July 31, 2007 Order permitted such discovery.

2. The Court's July 31, 2007 Order provided in relevant part:

FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK
99501
TEL: 907.272.3538
FAX: 907.274.0819

> The State is free to proceed with its discovery and to develop the statistical evidence that it intends to use at trial. The manner by which the State intends to prove its case, however, should not, by itself, limit Lilly's method of defending against the State's claims. Lilly is free to obtain discovery in accordance with the Rules of Civil Procedure. . . . (pg. 5, emphasis added.)
>
> Both parties may proceed with discovery subject to further motion practice and rulings that may otherwise limit such discovery. (pg. 12)

3. Thereafter, Lilly noticed the depositions of the following Alaskan psychiatrists and psychologists:

- Dr. Ramzi Nassar on January 22, 2008, in Anchorage;
- Dr. Alexander Von Hafften on January 23, 2008, in Anchorage;
- Dr. Jeffrey Magee on January 24, 2008, in Soldotna;
- Dr. Richard Schults on January 24, 2008, in Juneau; and
- Dr. Vern Stillner on January 24, 2008 in Juneau.

4. The State of Alaska had attorneys from Texas, South Carolina and Minnesota make travel plans to appear at this depositions. Airplane tickets were purchased so that attorneys could appear in Anchorage, Juneau and Soldotna at the designated times and places.

5. On January 17, 2008, I was informed that all five of these depositions were being cancelled by Lilly's counsel, and this was formally noticed by mail on January 18, 2008. *See* Exhibit 1. I was advised that Lilly decided to postpone these depositions

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because the testimony was relevant to damages, not liability, and could be taken after the March 2008 trial, if necessary.

6. Consistent with that position, on January 23, 2008, Lilly's counsel wrote a letter to the five witnesses stating in part: "Any rescheduling of your deposition, if needed, would not occur for approximately four to five months, and would occur in full consultation with you." *See* Exhibit 2.

7. At no time has the State of Alaska done anything to prevent Eli Lilly from communicating with or deposing physicians that may have information relevant to this lawsuit.

Eric T. Sanders

SUBSCRIBED AND SWORN to before me this 21 day of February, 2008, at Anchorage, Alaska.

Notary Public, State of Alaska
My commission expires: 1/10/2011

OFFICIAL SEAL
STATE OF ALASKA
NOTARY PUBLIC
STEPHANIE K. CARPER
My Comm. expires January 10, 2011

FELDMAN ORLANSKY & SANDERS
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FAX: 907.274.0819

Certificate of Service
I hereby certify that a true and correct copy of
Affidavit of Eric T. Sanders was served by messenger on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

Barry Boise, via email (boiseb@pepperlaw.com)
Pepper Hamilton

By YCarson
Date 2/21/2008

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& SANDERS
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

NOTICE OF CANCELLATION OF DEPOSITION OF DR. RAMZI NASSAR

PLEASE TAKE NOTICE that the deposition of Dr. Ramzi Nassar, scheduled for 10:00 a.m. on January 22, 2008, at the offices of Lane Powell, is cancelled.

DATED this 18th day of January, 2008.

Attorneys for Defendant

PEPPER HAMILTON LLP
Andrew R. Rogoff, admitted *pro hac vice*
Eric J. Rothschild, admitted *pro hac vice*
3000 Two Logan Square
18th & Arch Streets
Philadelphia, PA 19103
(215) 981-4000

LANE POWELL LLC

By _____
Brewster H. Jamieson, ASBA No. 8411122
Andrea E. Girolamo-Welp, ASBA No. 0211044

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

I certify that on January 18, 2008, a copy of the foregoing was served by mail and fax, on:

Eric Sanders, Feldman Orlansky & Sanders
500 L St., Ste 400, Anchorage, AK 99501

_____

009857.0038/162758.1

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

NOTICE OF CANCELLATION OF DEPOSITION OF DR. ALEXANDER VON HAFFTEN

PLEASE TAKE NOTICE that the deposition of Dr. Alexander von Hafften, scheduled for 1:00 p.m. on January 23, 2008, at the offices of Lane Powell, is cancelled.

DATED this 18th day of January, 2008.

Attorneys for Defendant

PEPPER HAMILTON LLP
Andrew R. Rogoff, admitted *pro hac vice*
Eric J. Rothschild, admitted *pro hac vice*
3000 Two Logan Square
18th & Arch Streets
Philadelphia, PA 19103
(215) 981-4000

LANE POWELL LLC

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Brewster H. Jamieson, ASBA No. 8411122
Andrea E. Girolamo-Welp, ASBA No. 0211044

I certify that on January 18, 2008, a copy of the foregoing was served by mail and fax, on:
Eric Sanders, Feldman Orlansky & Sanders
500 L. St., Ste 400, Anchorage, AK 99501
009867.0038/162759.

RECEIVED
JAN 22 2008
FELDMAN ORLANSKY & SANDERS

LANE POWELL LLC
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Anchorage, Alaska 99503-2648
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

NOTICE OF CANCELLATION OF DEPOSITION OF DR. JEFFREY MAGEE

PLEASE TAKE NOTICE that the deposition of Dr. Jeffrey Magee, scheduled for 1:30 p.m. on January 24, 2008, at his office in Soldotna, Alaska, is cancelled.

DATED this 18th day of January, 2008.

Attorneys for Defendant

PEPPER HAMILTON LLP
Andrew R. Rogoff, admitted *pro hac vice*
Eric J. Rothschild, admitted *pro hac vice*
3000 Two Logan Square
18th & Arch Streets
Philadelphia, PA 19103
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I certify that on January 18, 2008, a copy of the foregoing was served by mail and fax, on:

Eric Sanders, Feldman Orlansky & Sanders
500 L St., Ste 400, Anchorage, AK 99501

_____

009867.0038/162761.1

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

NOTICE OF CANCELLATION OF DEPOSITION OF DR. ROBERT SCHULTS

PLEASE TAKE NOTICE that the deposition of Dr. Robert Schults, scheduled for 10:00 a.m. on January 24, 2008, at the Travelodge, in Juneau, Alaska, is cancelled.

DATED this 18th day of January, 2008.

Attorneys for Defendant

PEPPER HAMILTON LLP
Andrew R. Rogoff, admitted *pro hac vice*
Eric J. Rothschild, admitted *pro hac vice*
3000 Two Logan Square
18th & Arch Streets
Philadelphia, PA 19103
(215) 981-4000

LANE POWELL LLC

By _____
Brewster H. Jamieson, ASBA No. 8411122
Andrea E. Girolamo-Welp, ASBA No. 0211044

I certify that on January 18, 2008, a copy of the foregoing was served by mail and fax, on:

Eric Sanders, Feldman Orlansky & Sanders
500 L St., Ste 400, Anchorage, AK 99501

_____

008857-0038/162760.1

RECEIVED
JAN 22 2008
FELDMAN ORLANSKY & SANDERS

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301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

NOTICE OF CANCELLATION OF DEPOSITION OF DR. VERNER STILLNER

PLEASE TAKE NOTICE that the deposition of Dr. Verner Stillner, scheduled for 2:00 p.m. on January 24, 2008, at the Travelodge in Juneau, Alaska, is cancelled.

DATED this 18th day of January, 2008.

Attorneys for Defendant

PEPPER HAMILTON LLP
Andrew R. Rogoff, admitted *pro hac vice*
Eric J. Rothschild, admitted *pro hac vice*
3000 Two Logan Square
18th & Arch Streets
Philadelphia, PA 19103
(215) 981-4000

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By _____
Brewster H. Jamieson, ASBA No. 8411122
Andrea E. Girolamo-Welp, ASBA No. 0211044

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301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

I certify that on January 18, 2008, a copy of the foregoing was served by mail and fax, on:

Eric Sanders, Feldman Orlansky & Sanders
500 L St., Ste 400, Anchorage, AK 99501

_____

005867.0038/162762.1

RECEIVED
JAN 22 2008
FELDMAN ORLANSKY & SANDERS

Pepper Hamilton LLP
Attorneys at Law

3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103-2799
215.981.4000
Fax 215.981.4750

Eric Rothschild
direct dial: 215 981 4813
direct fax: 215 981 4750
rothschе@pepperlaw.com

January 18, 2008

VIA FIRST CLASS MAIL

Robert J. Dickson, Esquire
Atkinson, Conway & Gagnon
420 L Street, Suite 500
Anchorage, AK 99501-1989
(907) 276-1700

Re: **State of Alaska v. Eli Lilly and Company**
Case No.: 3AN-06-5630CIV

Dear Bob:

This letter will serve to confirm that the depositions of Dr. Ramzi Nassar and Dr. Alexander von Hafften, scheduled for January 22, 2008 and January 23, 2008, have been cancelled.

Any rescheduling of their depositions, if needed, would not occur for approximately four to five months, and would occur in full consultation with you.

Please do not hesitate to contact me with any questions. Thank you for your cooperation.

Very truly yours,

Eric Rothschild

cc: Christiaan Marcum, Esq.
Eric T. Sanders, Esq.
Joseph W. Steele V, Esq.
Brewster H. Jamieson, Esq. (via email only)

Pepper Hamilton LLP
Attorneys at Law

3000 Two Logan Square
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215.981.4000
Fax 215.981.4750

Eric Rothschild
direct dial: 215 981 4813
direct fax: 215 981 4750
rothsche@pepperlaw.com

January 23, 2008

VIA FIRST CLASS MAIL

Jeffrey S. Magee, M.D. - Psychiatry
Central Peninsula Counseling Services
506 Lake Street
Kenai, AK 99611

Re: **State of Alaska v. Eli Lilly and Company**
Case No.: 3AN-06-5630CIV

Dear Dr. Magee:

This letter will serve to confirm that your deposition, scheduled for January 24, 2008, has been cancelled.

Any rescheduling of your deposition, if needed, would not occur for approximately four to five months, and would occur in full consultation with you.

Please do not hesitate to contact me with any questions. Thank you for your cooperation.

Very truly yours,

Eric Rothschild

cc: Christiaan Marcum, Esq.
Eric T. Sanders, Esq.
Joseph W. Steele V, Esq.
Brewster H. Jamieson, Esq.

Pepper Hamilton LLP
Attorneys at Law

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215.981.4000
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Eric Rothschild
direct dial: 215 981 4813
direct fax: 215 981 4750
rothsche@pepperlaw.com

January 23, 2008

VIA FIRST CLASS MAIL

Robert Schults, M.D.
613 Alta Court
Douglas, AK 99824

Re: **State of Alaska v. Eli Lilly and Company**
Case No.: 3AN-06-5630CIV

Dear Dr. Schults:

This letter will serve to confirm that your deposition, scheduled for January 24, 2008, has been cancelled.

Any rescheduling of your deposition, if needed, would not occur for approximately four to five months, and would occur in full consultation with you.

Please do not hesitate to contact me with any questions. Thank you for your cooperation.

Very truly yours,

Eric Rothschild

cc: Christiaan Marcum, Esq.
Eric T. Sanders, Esq.
Joseph W. Steele V, Esq.
Brewster H. Jamieson, Esq.

Pepper Hamilton LLP
Attorneys at Law

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Eric Rothschild
direct dial: 215 981 4813
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rothsche@pepperlaw.com

January 23, 2008

VIA FIRST CLASS MAIL

Verner Stillner, M.D.
3240 Hospital Drive
Juneau, AK 99801

Re: **State of Alaska v. Eli Lilly and Company**
Case No.: 3AN-06-5630CIV

Dear Dr. Stillner:

This letter will serve to confirm that your deposition, scheduled for January 24, 2008, has been cancelled.

Any rescheduling of your deposition, if needed, would not occur for approximately four to five months, and would occur in full consultation with you.

Please do not hesitate to contact me with any questions. Thank you for your cooperation.

Very truly yours,

Eric Rothschild

cc: Christiaan Marcum, Esq.
Eric T. Sanders, Esq.
Joseph W. Steele V, Esq.
Brewster H. Jamieson, Esq.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	Case No. 3AN-06-5630 CIV
Defendant.	)	
	)	

AFFIDAVIT OF CLYDE E. SNIFFEN, JR. IN SUPPORT OF THE STATE OF ALASKA'S OPPOSITION TO LILLY'S MOTION FOR RECONSIDERATION AND RESPONSE TO COURT'S ORDER

STATE OF ALASKA)
) ss.
THIRD JUDICIAL DISTRICT)

Clyde E. Sniffen, Jr., being first duly sworn on oath, deposes and states as follows:

1. I am a Senior Assistant Attorney General for the State of Alaska and the client representative for the State in its lawsuit against Eli Lilly and Company.

2. The State of Alaska has retained an Anchorage law firm, as well as outside counsel from several different states to prosecute this lawsuit. The State of Alaska has a contingent responsibility to pay all costs incurred by its private attorneys related to this lawsuit.

FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK
99501
TEL: 907.272.3538
FAX: 907.274.0819

3. In preparing for the March 3, 2008 trial, the State's attorneys have expended substantial sums for jury consultants, expert witnesses, airfare, lodging and other essential items. More specifically, it was necessary for the State's private counsel to place on deposit the sum of $20,000 to reserve rooms at the Captain Cook Hotel. This was required because there is now limited capacity at the hotel as a result of Fur Rendezvous and the beginning of the Iditarod sled dog race. Twelve individuals, including lawyers, paralegals, secretaries and technicians are now or soon will be staying at the Captain Cook for the duration of the trial. There are several additional rooms at the hotel which are being used as office/work rooms; they are now furnished with copiers, computers, equipment and miscellaneous hardware needed for the trial.

4. A delay in this trial will result in significant harm to the State because it will continue to be responsible for these and other pretrial costs as we prepare for trial -- costs that will need to be duplicated if trial is scheduled at a later date.

Clyde E. Sniffen, Jr.

SUBSCRIBED AND SWORN to before me this 21st day of February, 2008, at Anchorage, Alaska.

Notary Public, State of Alaska
My commission expires: 7/29/2010

OFFICIAL SEAL
STATE OF ALASKA
NOTARY PUBLIC
PEGGY S. CROWE
My Comm. expires: July 29, 2010

FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK
99501
TEL: 907.272.3538
FAX: 907.274.0819

Certificate of Service
I hereby certify that a true and correct copy of
Affidavit of Clyde E. Sniffen, Jr. was served by messenger on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

Barry Boise, via email (boiseb@pepperlaw.com)
Pepper Hamilton

By S Capra
Date 2/21/2008

FELDMAN ORLANSKY
& SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK
99501
TEL: 907.272.3538
FAX: 907.274.0819

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff, vs. ELI LILLY AND COMPANY, Defendant.	Case No. 3AN-06-5630 CIV

NOTICE OF FILING UNSIGNED DECLARATION OF MATTHEW GARRETSON

PLEASE TAKE NOTICE that plaintiff is filing an unsigned copy of the Declaration of Matthew Garretson in support of its Opposition to Lilly's Motion for Reconsideration and Response to Court's Order. Mr. Garretson is traveling and unable to provide a signature. A signed copy of this declaration will be filed as soon as possible.

DATED this 21 day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK
99501
TEL: 907.272.3538
FAX: 907.274.0819

GARRETSON & STEELE
Matthew L. Garretson
Joseph W. Steele
David C. Biggs
5664 South Green Street
Salt Lake City, UT 84123
(801) 266-0999

RICHARDSON, PATRICK,
WESTBROOK & BRICKMAN, LLC
H. Blair Hahn
Christiaan A. Marcum
David Suggs
P.O. Box 1007
Mt. Pleasant, SC 29465
(843) 727-6500

HENDERSON & ALLEN, LLP
T. Scott Allen Jr.
2777 Allen Parkway, 7th Floor
Houston, Texas 77019-2133
(713) 650-6600

FIBICH HAMPTON & LEEBRON
Kenneth T. Fibich
1401 McKinney, Suite 1800
Houston, Texas 77010
(713) 751-0025

Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of **Notice of Filing Unsigned Declaration of Matthew Garretson** was served by messenger on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

Barry Boise, via email (boiseb@pepperlaw.com)
Pepper Hamilton

By _____
Date 2/21/2008

FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK
99501
TEL: 907.272.3538
FAX: 907.274.0819

Declaration of Matthew Garretson

I am the attorney for the State of Alaska primarily responsible for the production of Medicaid data. The Garretson Law Firm (TGLF) works nationally with damage/healthcare data evaluation in complex litigation and settlement matters. My firm and I have considerable experience with Medicaid claims data. A copy of my CV is attached. (Exhibit A) A review of the records in my office discloses the following.

The original batch of data sent to Lilly prior to August 22, 2007 included the following by recipient identifier number.

A. All individuals receiving Alaska Medicaid included within the claims data who took Zyprexa and a diabetic drug from 1996-November 2006. This data includes the recipient ID, the dates service started and ended. It also includes the date that the medical service was paid by Medicaid. It includes the prescribing and provider identification numbers. It also provides the units of medication prescribed, billed, allowed and paid. It also provides the date of birth of the individual recipient.

B. All individuals in the Alaska Medicaid Claims databank who took an anti-diabetic drug between 1996 and November 2006. This includes both recipients who used Zyprexa and those who did not receive the drug. The data includes recipient identification, beginning and ending dates, prescribing and provider identification, and units of drugs prescribed. It also shows the amounts, billed, allowed and paid. Finally, this file also includes the recipient's date of birth.

C. All medical and hospital claims for members with a paid claim for Zyprexa, 1996-November 2006. This data included the recipient identification, dates of service. It also includes provider identification, procedures rendered, amounts billed, allowed and paid, and the presumptive diagnosis. It also includes the date of birth and gender.

D. All medical and hospital claims for members who had one of the diagnosis found by recipients who were given Zyprexa. These claims are both for Zyprexa recipients and non-recipients who had the same diagnosis. The data includes recipient identification, dates of service, payment information and provider identification. It also includes the medical procedure, diagnosis, and units provided. Finally it includes the date of birth and gender.

E. All pharmacy claims for TC07 drugs (Anti-psychotics). The data includes recipient identification, dates of service and payment, provider identification, units billed, allowed and paid. Pharmacy claims do not include diagnosis. This is true nationally, not just in Alaska. This file reflects the period from January 1996 through November 2006.

Thus, on or before September 1, 2007, the State of Alaska (SOA) provided Lilly with State Medicaid data files which were sufficient to calculate the following:

A. Number of Medicaid users from 1996 until the fourth quarter of 2006.
B. The number of Medicaid users who were prescribed Zyprexa.
C. The number of Medicaid users who took Zyprexa and contracted diabetes. This includes the number of individuals who took Zyprexa before treatment for Diabetes as well as those who received Zyprexa after treatment for diabetes.
D. The total number of Zyprexa prescriptions from 1996 until 2006.
E. The number of Zyprexa prescriptions which went to geriatric and pediatric patients.
F. The number of Zyprexa prescriptions for uses not supported by FDA regulations including compendia.
G. The average dosage for pediatric, geriatric and off label use.

Lilly was not satisfied with this information. It filed a Motion to Compel. This Motion was heard before the discovery master on September 11, 2007. The data which Lilly sought and which the State agreed to produce is discussed at pages 9-30 of the transcript of that hearing. (Exhibit B) That hearing resulted in a decision by Judge Hensley in which the discovery master ruled that Lilly was not entitled to information identifying specific patients. See Exhibit C page 8. However, Mr. Steele, on behalf of the State, had agreed to produce further information and the State went forward with production.

Gender data was provided to Lilly on September 5, 2007. Lilly was unable to merge the gender to claims data. On October 3, 2007 my office sent them the programming code to merge the data. They were still unable to merge the data. On October 8, 2007, we merged the data for them and resent all of the data.

On November 28, 2007, the court ordered the SOA to advise the court by December 7, 2007 when the Medicaid data would be produced so that phase 2 of the trial was not delayed. The order also directed the parties to meet and confer by December 21, 2007 and attempt to reach agreement on how discovery unrelated to liability shall proceed. At that time, the difficulty of producing the data was not understood. These dates reflect a date resulting from the estimate which the State made in good faith to provide to Lilly the enormous amount of additional information requested by the Vernig affidavit submitted by Lilly. Given the quantity of additional data requested, and the SOA's good faith desire to provide the information in a useable manner, the data could not be supplied on that estimated date.

David Campana the representative of the State requested the further data Lilly sought. He identified all "non-pharmacy claims" for dates of service 1-1-1994 through 11-30-06. " Please supply in the report ICN, Recipient Identifier, Status, Claim Type, Modifier, Procedure Code, units, Revenue Code, Revenue Code Units, billed amount, allowed amount, paid amount, date of service, date of payment, recipient date of birth, billing provider number, service from date,

service through date, primary diagnosis code, secondary diagnosis code." Mr. Campana also requested pharmacy claims, formulary and eligibility data at the same time.

This material has been delivered. In November, we sent Lilly the data dictionary for claims processing, recipient identifier, provider subsystem, management and administrative reporting, third party liability, surveillance, utilization review, reference subsystem and accounting interface.

At 11:30 AM, February 20, 2008, the State turned over files reflecting non-pharmacy claims, eligibility and the State formulary files. The State sent additional files including the drug formulary, eligibility files and pharmacy claims and drug formulary. These included all pharmacy claims for the years 1994-2006. This data includes the recipient identification, dates of service and payment. It also includes the provider number, units billed, allowed and paid. As noted above pharmacy claims do not include diagnosis.

Thus, the State has produced all data agreed to by Mr. Steele and requested by Lilly. This includes all material ordered produced by Judge Hensley and the Court. This data included the following.

A. Enrollment (with "start and stop" dates)
B. Gender
C. Race
D. Any additional revenue codes or diagnoses codes which may indicate either Zyprexa use or patient outcome.
E. All pharmacy claims for 1994-1996.

The State has fully complied with the Court's directions, the Discovery Master's order and its own agreement. Should Lilly designate additional data or should Lilly have difficulty reading these files, the State stands ready, willing and able to assist.

This data request was enormous, comprising virtually the entire State of Alaska data base. What the State did not and could not anticipate was the difficulty in producing this quantity of data in a readable form as specified by Lilly and Dr. Vernig. Given these difficulties, the data was produced in an expedited manner.

DATED THIS DAY OF FEBRUARY 2008

MATTHEW GARRETSON.

THE GARRETSON LAW FIRM LLC

Matthew L. Garretson

Matt Garretson is the founding partner of The Garretson Law Firm which provides mass tort / class action settlement allocation and fund administration services. The firm also handles Medicare / Medicaid reimbursement claims, government benefit preservation strategies, and probate administration for individual and mass tort plaintiffs. He received his BA from Yale University and his law degree at Kentucky's Salmon P. Chase College of Law.

Matt is a frequent speaker at Continuing Legal Education seminars about lawyers' professional responsibilities in individual or mass tort settlements. He has spoken at numerous state trial lawyer and state bar associations' annual events, The Association of Trial Lawyers of America, Mealey's as well as at Mass Torts Made Perfect.

Matt is the author of a legal text book published ATLA / West Publishing entitled Negotiating and Settling Tort Cases. In addition, he has authored several articles regarding professional responsibility in individual and mass tort settlements that have been published in *Trial Magazine*, The American Bar Association's *The Professional Lawyer*, *Ohio Trial*, Academy of Florida Trial Lawyers *Journal*, *Utah Trial Journal*, New York State Trial Lawyers Institute *Bill of Particulars*, Texas Trial Lawyers *Briefcase Online*, New Jersey Association of Trial Lawyers *In Brief*, Orange County Trial Lawyers Association *The Gavel Journal*, Florida Justice Association's *FJA Journal* and *Insurance Day* in the United Kingdom. In 2005, Loyola University Journal of Public Interest Law published an article by Matt entitled *"A Practical Approach to Avoiding Conflicts of Interest in Aggregate Settlements."*

Matt is an adjunct professor at Salmon P. Chase College of Law, where he teaches a course on law practice management with an emphasis on how to avoid professional liability claims. Matt's "form-of-settlement" client counseling model (re: impact of settlement on government benefits, liens / subrogation, structured settlements and the taxation of damages) has received national recognition and is designed to protect clients as well as help lawyers avoid "failure to inform" professional liability claims.

Matt serves as the special master and / or administrator of settlement funds throughout the country. His role in numerous high profile church-related sexual abuse and civil rights settlements (including the historic Cincinnati police brutality / racial profiling settlement) led to his selection by Lawyers Weekly as 1 of 5 "Lawyers of the Year" in Ohio for 2003. He was nominated by his peers and selected as an Ohio Super Lawyer – Rising Star in 2005 and 2006. His work was featured in the LA Times in January of 2005.

7775 Cooper Road / Cincinnati, Ohio 45242
Phone: 513-794-0400 Fax: 513-575-7200
www.garretsonfirm.com / mlg@garretsonfirm.com

Legal Ethics / Professional Responsibility Speaking Engagements

- AAJ Annual Meeting ('03, '06)
- AAJ (Hormone Therapy '04)
- AAJ (Mid Winter '05, '06)
- AAJ (Weekend With The Stars '06)
- Consumer Attorneys of California ('01, '03, '04, '06)
- Consumer Attorneys of Sonoma County ('01)
- DRI Annual Meeting ('07)
- Finkelstein & Partners (New York '02, '03)
- Hamilton Country Trial Lawyers Association ('05)
- Hormone Replacement Therapy Seminar ('07)
- Jeff Anderson & Associates/Clergy Abuse ('03)
- Kansas Trial Lawyers Association ('03, '04, '07)
- Kentucky Academy of Trial Lawyers ('06)
- Louisiana Admiralty Symposium ('06, '07)
- Louisiana Bar Mass Tort Symposium ('02, '04)
- Louisiana Trial Lawyers Association Annual ('07)
- Mass Torts Made Perfect ('03, '04, '06)
- Mealeys Lexis/Nexis Art of Negotiation ('07)
- Mealeys Lexis/Nexis Contingency Fees ('07)
- Mealeys Lexis/Nexis Ethics ('07)
- Mealeys Lexis/Nexis Client Expenses ('06)
- Mealeys Lexis/Nexis Emerging Drug and Devices ('04)
- Mealeys Lexis/Nexis Heart Device Litigation ('05)
- Mealeys Lexis/Nexis Medical Products/Heart Device ('05)
- Mississippi Trial Lawyers Association ('02)
- New York Academy of Trial Lawyers ('07)
- Norfolk and Portsmouth Bar Association ('03)
- NABIS – Medical Issues in Brain Injury ('05, '06, '07)
- Ohio Academy of Trial Lawyers Annual ('03, '04, '05, '06, '07)
- Ohio Academy of Trial Lawyers Subrogation Seminar ('06)
- Ohio Academy of Trial Lawyers Worker's Compensation ('07)
- Ohio State Bar Association Annual Convention ('06)
- Ohio Trial Advocacy Seminar ('04, '06)
- Oklahoma Trial Lawyers Association ('07)
- Plaintiff Asbestos Litigation Seminar ('07)
- Professionally Speaking Seminar ('07)
- Richardson, Patrick, Westbrook & Brickman Annual ('04, '06)
- San Antonio Trial Lawyers Association ('07)
- Society of Settlement Planners ('07)
- TBI Symposium - Brain Injury Association of Ohio ('04, '06)
- TPL-COB National Conference ('07)
- Utah Bar Association Annual Seminar ('05)
- Utah Trial Lawyers Brain Injury ('02, '03, '04, '05, '06, '07)
- Utah Trial Lawyers Association Annual Convention ('07)
- Virginia Trial Lawyers Association ('05)
- West Virginia Trial Lawyers ('03, '06, '07)
- Wyoming Trial Lawyers Association ('03, '07)

Relevant Publications

- Negotiating and Settling Tort Cases, ATLA / West Publishing (2007)
- *A Fine Line We Walk: Counseling Clients About the "Form" of Settlement*, 13 A.B.A. Prof'l Law. 4, (2002).
- *Don't Get Trapped By A Settlement Release*, Trial Magazine, September 2003.
- *Structured Settlement Factoring Transactions: New Laws Protect Clients Who Sell Their Structured Settlement Benefits*, Ohio Trial, Volume 13, Issue 2 (2004).
- *A Practical Approach to Proactive Client-Counseling and Avoiding Conflicts of Interest in Aggregate Settlements*, The Loyola University Journal of Public Interest Law, Volume 6 (2004).
- *Deferring Attorney Fees: Is There Now a Critical Mass of Enabling Legislation?* Ohio Trial, Volume 14, Issue 2 (2005)
- *Making Sense of Medicare Set-Asides*, Trial Magazine, May 2006
- *What Does the Ahlborn Decision Really Mean?*, Ohio Trial (Fall 2006).
- *Medicare's Reimbursement Claim - The Only Constant is Change*, Ohio Trial (Spring 2007).

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,
Plaintiff,
vs.
ELI LILLY AND COMPANY,
Defendant.
Case No. 3AN-06-05630 CI

MOTION ARGUMENTS BEFORE THE DISCOVERY MASTER

Pages 1 - 168
Tuesday, September 11, 2007
11:00 A.M.

at
LANE POWELL
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

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MR. SUGGS: Would you prefer that we address the issue regarding medical records first?
DISCOVERY MASTER: Early. You can do it first. Early.
MR. SUGGS: Do you want to --
MR. STEELE: Can I switch with you, David, because I'm going to talk about that?
MR. SUGGS: Oh, certainly. Absolutely.
DISCOVERY MASTER: Leave aside in your initial round of arguments the length of the 30(b)(6) motion and the newly filed motion to postpone the Taurel deposition. We'll take care of that after we've taken care of everything else.
So we'll start with -- are you going to do it, Mr. Steele?
MR. STEELE: That would be me.
DISCOVERY MASTER: Okay. Make sure everybody can hear Mr. Steele. Mr. Rothschild, Mr. Lehner, are you able to hear Mr. Steele?
MR. ROTHSCHILD: This is Eric. I can hear fine. Thank you.
MR. LEHNER: George Lehner. Yes. Thank you.
DISCOVERY MASTER: Okay. If you can't or we cut out, let us know, please.

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MR. STEELE: All right. Let me start with the things that I think we can agree on. Counsel, helpful to us and helpful to the process is the affidavit of your expert, whose name I'm going to mispronounce, Beth Veerig?
MR. BOISE: Virnig.
MR. STEELE: Virnig. The difficulty we were having was the difficulty in addressing the question of how somebody could give anybody all of the Medicaid database. It's not like a basketball where it's in our possession, wrapped up neatly and nicely, and we can just hand it to you.
So fortunately, I guess, we have this affidavit by your expert, and I think that I can address some of the things that she addresses there, because I take what she is saying to be a description by her of what else you need in addition to what we have given you thus far. So let me see if I can go through that one at a time.
Does the Court have the affidavit?
DISCOVERY MASTER: I don't think so.
MR. STEELE: It would have been part of the lengthy response that was filed.
DISCOVERY MASTER: Then I do have it. Okay. I have it. Number? Exhibit number.

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MR. BOISE: B.
MR. STEELE: Maybe get on the same page with me.
DISCOVERY MASTER: Got it.
MR. STEELE: Can you turn to page 3? Because that's what we're going to discuss.
DISCOVERY MASTER: Um-hum.
MR. STEELE: Okay. I take what is being said here to be this. Beginning at page 3, the good doctor is saying what else it is that you need in order to do what it is that you intend to do with the data. Dave Campana, who is the Medicaid person most knowledgeable about what exists and how hard it is to get it, is in a meeting out of state until the 13th. Since we just got this yesterday and I was flying, I didn't see it till this morning. So I have not been able to confer with him, but I have gotten Matt Garretson and his people on the line.
Mr. Garretson would be one of our co-counsel and also somebody who is knowledgeable in general about what kind of things exist in the Medicaid database.
To confer with him to see what of these things we think ought to be there or ought to be available and how hard it would be to get it. So I

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am prepared to go through those one at a time and say what it is that we have to say about it. I think it will probably solve some of our problems because I think we can accommodate you on some of these things.
She begins on No. 1, but No. 2 is really where we start talking about things that you want, underneath enrollment data. On No. 2, to the extent that it is available and can be de-identified - by de-identified I mean take out patient-specific information, like name and Social Security number - we're willing to produce this information.
MR. JAMIESON: Excuse me. Is that paragraph 2?
MR. STEELE: That's 2 on page 3. And again, I'm saying this on behalf of Dave Campana, who I have not been able to speak with, but speaking in general with Mr. Garretson, we believe this sort of thing is available. If it is available and it can be produced, that is, if it exists and we can get it, we will give it to you in a de-identified form.
I think we've refined our approach to de-identifying information, knowing that what you all are interested in, as are we, is being able to identify discrete patients within the database. In other words, knowing information that will be able to

say, "This is a particular patient within the database," so we don't read one person multiple times.

So I think we will de-identify it in the way that we are now currently doing with a unique identifier assigned to each individual patient.

Moving on to No. 3. We will provide the gender information. We believe that to exist. We think that we can get it for the discrete patients, and we will provide it.

What I am told about the race data, that is, what is the race of each individual recipient, we don't believe that this exists, and I offer this with one caveat. I'm a lawyer. I don't work for Medicaid in Alaska. I'm not looking at it myself. But I am told that the race data does not exist. If in fact it does exist, we will closely question the people involved, see if it can be obtained somehow. I don't know that we can infer it for something or there is other databases that we can look in or other places that we can get it.

We will make diligent inquiry to see if by hook or by crook we can give you race information if it is there. And as I say, the current information I have is that it is not, but if it can be gotten

without driving everybody crazy, we will try to do that.

Number 4. The start and stop dates is what is being asked for there. We think that this can be gotten out through the enrollment data, and if you want that, we will provide it, assuming that it is available in the database. We think that it is. So with the other caveat about talking to Dave Campana, I would say it should be there. We will give it to you if it is in fact there.

On No. 5, what is being said there is there are 124,000 people enrolled, or to be more exact, I guess 124,446 are enrolled. We've given you data from 100,000 roughly, 100,000 plus 999 others. It's claims data.

So the question that is raised in our mind is: Did the other 24,000 make a claim? If they didn't make a claim, it's not going to be in the database as claims data. So what we imagine is occurring here, in the absence of Mr. Campana, is there are 109 -- 999 people who are treaters and 124,000 people who are enrolled but not necessarily treating.

If it turns out to be otherwise, if there are other treaters that exist between 100 and

124,000, we have no objection to giving you information on treaters that may exist in addition to the ones that you've got.

What I think happened is that the number you got are the people who in fact treated, but I'm going to check on that and make sure that you have all of that.

Number 6. I don't know what to tell you on this in the absence of Dave Campana other than we don't have what we don't have. It may be the case that the people who are filling these things out didn't do their jobs right, but I do not believe that we have what it is that you are asking for in No. 6.

With respect to No. 6, we will ask yet again if more cannot be obtained somehow or somewhere. It also may be the case that First Health may have something that we don't have or have it more conveniently. If it were to exist there, of course you can have it, and I think Mr. Marcum is going to address somewhat later those things on the subpoena to First Health that we would not be objecting to.

So on No. 6, I don't know what to tell you other than, you know, we'll get what we can get, but we don't have what we don't have.

Number 7, the revenue codes. If there are

revenue codes that we have that we have not given to you and they can be feasibly extracted from the database, we will give you those revenue codes.

Number 8. We don't think we have it. We will -- I don't know how to say this other than to say, you know, we'll make double-dog sure that we don't have it. And that's a series of these questions. As I say, I'm a lawyer, and I'm not looking at it myself, but we will see what we can find out. We have inquired. We don't think we have it, and if we don't, we don't; and if we do, you're welcome to it.

Number 9 is the same thing, if we find more diagnosis codes, you'll be the first to know.

Number 10, we will give you all of the pharmacy records for all of the medicines that are in the database. So we're not going to make a distinction about which ones do or do not have something to do with things that we are interested in. You can have all of that, assuming it is available, and I have reason to believe, based on my conversation with Mr. Garretson, that it should be. I just can't guarantee it because Mr. Campana is not around.

The same answer for No. 11. You're asking

for the same thing really as No. 10, and again you can have it if it is available and if it exists.

I would suggest to you that maybe the good doctor hasn't looked at all of the things that we have given you. Maybe she's having trouble accessing it in a database, but I know, based on our statistical analysis, that some of the things that she's talking about in 10, 11, 12 and 13, all of which relate to medications, I believe that almost all of that is in there.

For example, I do believe that beta blockers are in there because that is a potential confounder, and so I believe that it is there. I believe that information is there with respect to diabetic medications because that is the measure that we are using to determine whether somebody has diabetes or not.

So maybe she's having trouble figuring out where these things are, but it is apparent to me from reading this that she doesn't know everything that is in there. But if there is more with respect to 10, 11, 12 and 13, we'll give it to you.

With respect to pre-96 data, we understand it to be corrupted for whatever reasons it is corrupted. If it can be assembled in a form that can

be transmitted to you, and I don't know how difficult that is, but barring some unreasonable amount of expense or effort that would burden the State system, you can look at the fouled-up and corrupted 1996 data and make your own judgments. And again, I haven't been able to talk to Dave Campana about how difficult it is to bundle this up and send it to you. If it does turn out to be extraordinarily difficult, I'm sure we can work something out, pay for people's time if they have it, or we'll figure something out. But if you want to look at corrupted data, you are welcome to it.

That covers the database, and I think that that pretty much covers everything that needs to be said about it unless you guys have any other questions about -- like could we have this or could we have that.

DISCOVERY MASTER: How about if you all respond to the discrete database issue.

MR. BOISE: Sure.

DISCOVERY MASTER: If you're ready to do that.

MR. BOISE: Absolutely.

DISCOVERY MASTER: Okay.

MR. BOISE: Thank you. Much of what Mr.

Steele has articulated, we certainly have had discussions about it, indeed on-the-record discussions about where similar types of, if not agreements, willingness to look for documents and look for data have been offered. And the response has largely been: If we have it, we'll try to provide it to you, and the like. Yet we still sit here without the data, and that's what prompted, in large part, our desire to go right to the source.

We don't doubt a word that Mr. Steele has said that this is complex. We don't doubt that there is more digging that needs to be done and there is experts that need to be involved in doing that digging. And that is why what we have asked for is to go to the data source itself maintained by the agent of the State, First Health, and have our experts go in and extract the data that needs to be extracted from the database.

The first example that Mr. Steele addressed was under enrollment data, and what I understood him to say was we will get all enrollment data, but in addition to that, you're going to look for additional information on race and gender. We certainly want that as well, but that was an example of data that we're seeking in a database. What we don't know is

what we don't know.

We just received at the end of last week a listing of all the fields in the database, and there is hundreds and hundreds and hundreds of fields that are attached, I think as the last exhibit to that large pleading -- it's not there. I'll get a reference for you. Exhibit F, which we received late last week, which gives hundreds of fields of additional data items which we're just learning about.

So what happened here was we got a selective cut of data instead of the whole database. We're told it's burdensome to package it like a basketball and sort of hand it to us, and we appreciate that, but we haven't understood or heard what that burden is in any way, shape or form. We've offered to have our own experts go in and extract what we need from this database, and that's what we're really asking for here.

I mean, you have, you know, the position of the State having to go back to the one person who has the information concerning this data which was unable to answer now for a period of months, and I think it's time for us to be able to see what is in that database in its totality and be able to extract

perhaps other confounding factors or other data that's in there that are listed in all of those fields.

We appreciate that the State is not in possession of all this and all this knowledge, and that's why we're asking for other experts to go in and extract what we need.

The examples by Dr. Virnig were examples of what we could obviously see and we would obviously expect to see, while we're still kept a bit in the dark as to what the whole basketball or whole database ultimately looks like.

We have not seen the medication beyond mental health medication such as beta blockers that's referenced by Mr. Steele, and we have correspondence from your colleague, Mr. Marcum, suggesting that what we have are mental health medications. So if you're -- you know, maybe you can show us, have the database here, and you can show us where the nonmental health medications are. We're happy to have that, have that data, but we just don't see it.

So we appreciate the offer for all medication but would like at this point to have the ability to go in and really extract it ourselves.

Same with the pre-96 information. I mean,

the case here, as plaintiff is going to pursue it, really goes to whether Zyprexa caused diabetes, is one certain issue here. And important to us is whether the person had diabetes long before Zyprexa was ever on the market or ever prescribed, and without pre-96 data, that becomes very challenging. If it's corrupt, it's one more reason why we need medical records, which I'll get to separately and let the State address it first. But to have Mr. Steele at this time go back to the State and figure out what would be at issue in producing pre-96 data and then get back to us at some undefined period I think is a little bit late in that process.

What we'd like to do, again, is have our expert look at the data. We have a fight, a dispute over whether we get de-identified data or not, and we'd respect what the Court's ruling is on that issue as we get to that issue, but if we have to look at it from a de-identified perspective, you know, so be it. We have reasons why we should see the whole database in its nonde-identified form.

So I mean, these are, in a nutshell, really -- I think Mr. Steele has made the argument as to why we need to see the whole database and have our own experts come in and make some judgments as to

what data we need to extract. We appreciate the concessions that were made, and we think a lot of them have been made in the past already in our meet-and-confer process, but we just are still waiting on or maybe there is some confusion about.

MR. STEELE: May I?

DISCOVERY MASTER: Are you finished, Mr. Boise?

MR. BOISE: I am. Thank you.

DISCOVERY MASTER: All right. Go ahead.

MR. STEELE: All right. Where it appears the seam must fail. With respect to the enrollment data, I've said what I've said. They say -- and I hope Beth is not -- Beth is not a guy, is she, your expert?

MR. BOISE: No.

MR. STEELE: Beth A. I thought you said it was -- it was a guy. I'm off the subject. Anyway, I've said what I've said.

With respect to No. 2, what they're saying is that they want to look at enrollment files, and they want to see the things that are listed in No. 2, and I think we can give them that information. So I didn't understand that to be all enrollment data. Obviously that includes the names. I mean, one of

the things that's interesting about Dr. Virnig's declaration is that she of course doesn't opine that she needs the names of the Medicaid recipients. You can look at it from stem to stern, and the good doctor does not suggest anywhere in there that she needs the name of the Medicaid recipient.

So they can have the enrollment data but not the names of the Medicaid recipient.

Second point. With respect to the experts extracting it, I don't really know how that would be done, but it's certainly not customary. I've been doing product liability cases for 30 years, and I have yet to have General Motors let me into their computer, and I don't think that's ever going to happen. What you do is you ask them for things, and they give it to you. And they have asked us for things, and we'll give it to them insofar as what I've said we can provide to them, with the caveats that I have offered.

I have never seen a product liability case where the defense data weasels walked into GM headquarters and started diddling on their computers, and I don't think I'm ever going to see that.

The idea that they want all is -- I think doesn't make any sense. What they've got is a

declaration from the doctor that they have chosen to use, and she has said what she wants in addition to what they already have, and we'll give it to them. And, you know, I think that that is a rational basis on which the Court can make a decision. In other words, if you're trying to be the decider here, you're trying to decide it on a rational basis. There is no rational basis offered, that I can see, as to why they need to go in and diddle on the State's computer.

If they want something, they can do what has been done here and tell us what it is, and we'll get it for them insofar as that can be done. That's about all that can be said about that.

As to '96, what I'm suggesting is whatever there is, we're going to give it to them, and they can look at it. I mean, it's not going to -- as far as I know, it exists in a discrete form because unlike what we're currently using, which is a live database, right? Where you -- it's alive and there is inputs and the inputs happen every day and it's, you know, something that's in use. The pre-96 stuff is stored. It's stored in the form so that it's like a basketball.

So if it's pre-96, it is a basketball that

you can hand to them, and we're going to give it to them. I don't know what the gripe is there, to tell you the truth. I don't even get what they're talking about. They can look at that football or basketball or whatever it is.

So setting aside the issue of patient identifying information which I think we can argue separately, I would just note that their doctor doesn't say that she needs it, nor would it be needed with respect to the database. I think that's a medical records issue, and I prefer to argue that separately.

DISCOVERY MASTER: Mr. Boise.

MR. BOISE: Just very briefly. If we're going to get the entire pre-96 database, then there is no -- there is no gripe there if we're going to get all the database.

Our main gripe is that we don't know what we don't know. We know what we've been produced is a selective portion of a database and given that selective portion to a person who is used to seeing a database, we're able to identify areas of just obvious need and issues.

What we're told here on many cases by Mr. Steele is that you don't have all procedure codes,

you may not have diagnosis codes. What we don't know is whether that data lives in a different form within the database. We don't have to go within the corridors and have our technology people go around and play with the database if you would produce the entire database, and we would be able to extract what we need on our own time and without any intrusion.

There has been no burden argument or presentation as to why that would be challenging to do other than it's not in the form of a basketball, and we're really put in the position of saying, "We're going to show you a little bit of this database, and if you ask us for specific things, we'll give it to you, but we're not going to tell you what are in all those other fields where people, nonlawyers, can go in and really look and see what is there."

Are there revenue codes that would show additional procedures? Is there data contained in eligibility files that would have more information that would go to confounding factors, that would go to issues of causation? We don't know what we don't know.

We've asked for the database. We've been told you'll look for certain items but told we're

unwilling to do the entire database because of burden. All we're suggesting is if that's the argument, we'll take on the burden and go to the source and extract what we need. So ultimately we'd like the full database. If that is too burdensome, we would offer to go and extract what we need using forensics experts to do it. So in either case, we would have the opportunity to extract and obtain what we need.

The final point that Mr. Steele made, or maybe he opened with it, was there is no reference to the need for de-identified information, and I agree we should argue for medical records separate, but what Dr. Virnig does do in here and what we do in our briefing throughout is explain we need medical records, and we can't identify which patient's medical records we need without the identified information.

We want to be able to look at -- how can we subpoena the records, unless you're willing to provide the records to us, based upon a de-identified number? So if a particular patient we believe has huge gaps, for example, in their enrollment data and we want to find out what was the full history for that patient, the only way we could possibly get that

is through medical records, and the only way we would be able to tell you which medical records we need either for you to obtain for us and provide to us in some de-identified fashion or for Lilly to go out and get them themselves is to have a patient name.

We've been able to handle 28,000 claims on behalf of plaintiffs in the underlying Zyprexa litigation, personal injury litigation. We've obtained thousands of patients' medical records. We've taken dozens of plaintiffs' depositions. We're extraordinarily sensitive to the rights of these patients to privacy and take all measures necessary not to intrude unless absolutely there is a compelling need here.

Without having this information at least in the lawyers' possession or in our expert's possession, we're unable to identify which patients we need to go out and tell a story here and be able to get the full picture, not just what limited information is contained in this database where people, as you said earlier, may not have coded something properly or may not have included the information that is key here. So that's the response.

DISCOVERY MASTER: I have a question for

Mr. Steele.

MR. STEELE: Sure.

DISCOVERY MASTER: Aside from you've never seen it done at GM, what's the burden or prejudice or risk to your client of having the defense look at the database themselves, assuming you can protect the identities of the patients?

MR. STEELE: Well, the last is the problem, and that is, of course, integral in the database, inseparable from the database, the identities of the patients. So if you're looking at the database, you are looking at the identities of the patient.

And allow me to make this point, and I haven't been able to confer with my colleagues, but if -- I'd probably be willing to let them look in our computers if they'll let us look in theirs. What do you think?

MR. SUGGS: I don't think that they would offer that.

MR. STEELE: Really? But, you know, that's something to think about is if it's sauce for the goose, it's sauce for the gander. So if this is the standard we're going to adopt, then for all of the things that Mr. Suggs wants, we want to invade their database and their records and have our experts comb

through that so -- because we don't know what we don't know, and there may be things in there that we would very much like to know that they don't want us to know.

So if that's the way it's going to be done, then let it be so. But setting that aside, what I'm telling the Court, with a reasonable degree of assurance, is that integral to those -- to this live database is the names are inseparable. There is no way to do that. So if they look, they look.

And by the way, we have given them a list of all of the fields. So if they want to make a query with respect to the list of all of the -- Mr. Boise in his argument just said we've given them hundreds of fields. We've given them hundreds of fields. If they want to make inquiries within those data fields, they can do that. They can put that by way of discovery, and we will respond to it.

The question of the need for the individual identities of the people, I mean, we're just going to have to address that, and I will do that.

But two strong points I want to make is I cannot separate the identities from the database. That's why we did it the way we did it in main measure, and if it's sauce for the goose, it's sauce

for the gander on that little deal. We can go poke around in their stuff, but that wasn't the way it was done in the MDL. We didn't go and poke through their database to get 12 million documents. They handed us what they were supposed to hand to us on the discovery order, just the way that we're doing it here. It's no different. It's no different than it's ever done.

DISCOVERY MASTER: All right. I'm going to give you the last word, Mr. Boise, briefly, and then we'll move on to the next issue.

MR. BOISE: And Mr. Suggs knows this and Mr. Steele just may not. I mean, there was extensive discussion and court involvement on his goose v. gander argument. There was discussion, disclosure of fields and what those fields meant of Lilly databases, and in certain circumstances full databases were turned over. There was a full history for each database in the disclosure, which has not happened here, so the PSC in the MDL could be fully informed as to what they were getting and not getting in making those choices.

We're asking for the piece of evidence that you are basing your entire claim on, to be informed about that piece of evidence and be fully informed,

and that's what we're asking for.
DISCOVERY MASTER: All right. Thanks. Next let's just go the patient records argument. Who's going to do that? And Mr. Boise. Okay. We'll start again with Mr. Steele.
MR. STEELE: Okay. Well, I've had this discussion with them. Is it perfectly clear to everybody that we do not have a warehouse the size of Yankee Stadium wherein from birth to death every Medicaid recipient's medical records are kept? Does everybody agree to that?
MR. BOISE: We've heard that representation. We understand that.
MR. STEELE: You don't think it's otherwise?
MR. BOISE: No, that's not our claim.
MR. STEELE: Okay. Good.
MR. BOISE: That's not our claim.
MR. STEELE: All right. So we don't have it. So now the question becomes: Where do we go from here? The first thing that needs to be said about this is that there is very little in their expert's declaration that suggests that something can be gotten from the medical records that cannot be gotten from the Medicaid database.

The fact is that Medicaid databases are used all of the time to do epidemiology studies which determine how much of a disease has been caused by a particular agent and to -- let me see if I can start with a larger metaphor that may explain better what it is that we're trying to do, but keep in mind the background here is this.
If you look at the pharmacotherapy article that is submitted with the defendant's most recent moving papers, that was a study similar to the one that we're doing that was done out of a Medicaid database from five states. No patient records were accessed in order to do that study. Lilly does Medicaid database studies and has done several on Zyprexa. In doing those Medicaid database studies, patient records, meaning charts in doctors' offices, were not used.
The way that we are approaching the problem is a valid scientific way to approach the problem. That is a large frame around this subject.
The next thing that needs to be understood is this, and excuse the crudeness of my metaphor, but this is kind of how it goes. Let's say that you've got a roulette wheel. The roulette wheel has got a whole bunch of numbers on it. Pick any number that

you like. In this case, it is the Alaska Medicaid population.
Now, we think about the roulette wheel. On the roulette wheel there is zero and double zero. Zero and double zero on the roulette wheel are the background rate of the disease. So let's say we've got the entire Medicaid population. We want to look at a particular disease, the disease will have a background rate because in this world there are very few things that are simply unique to a particular agent.
So you'll have a background rate of diabetes, you'll have a background rate of heart disease, you'll have a background rate of lung cancer, and any agent that you want to talk about that causes disease pretty much is going to have a background rate. So we talk about tobacco, we'll have a background rate of lung cancer and heart disease. If we talk about Zyprexa, we'll have a background rate of obesity, diabetes, heart disease, and so on.
So let us say that the background rate is zero and double zero within the Medicaid population. So you've got all of these numbers plus the background rate. The question becomes if you

introduce a particular agent into the Medicaid population, what do you have in addition to the background rate? So what do you have in addition to zero and double zero? Well, if you're talking about Zyprexa and diabetes, what you're talking about, according to the pharmacotherapy article and other articles, are you have zero, double zero, triple zero, quadruple zero, quintuple zero and sextuple zero. Zeroes 1 through 6. Okay?
Now, in order for us as the State to determine what our damages are, what we need to do is we need to subtract the background rate from the increase caused by the agent. So we subtract out zeroes 1 and 2, and we're left with zeroes 3 through 6, and that gives us the additional amount of disease caused by a particular agent. That's essentially how it is done in Lilly's Medicaid data studies on Zyprexa and pharmacotherapy article, Dr. Gao's study on Zyprexa.
Now, the case we are pursuing is this, and it's got to be looked at differently than a traditional PI case because a traditional PI case is: I want to give Mr. Smith money. For me to give Mr. Smith money, we've got to demonstrate that it is Mr. Smith that has been hurt and not somebody else.

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September 24, 2007

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RE: State of Alaska v. Eli Lilly & Co., 3AN-06-05630 CI

DISCOVERY MASTER ORDER
State's First Motion to Compel
Lilly's Motion to Compel
Lilly's Motion for Commission for Subpoena

Introduction

The State of Alaska seeks damages from Eli Lilly & Co. for harm allegedly caused by Lilly's marketing and sale of the drug Zyprexa. The State asserts claims in strict product liability for failure to warn and design defect, for violation of the State's Unfair Trade Practices and Consumer Protection Act, and for negligence, negligent misrepresentation and fraud.

The State has not filed a class action and is not seeking damages for individual patients. Instead, the state seeks to recover for excess expenditures allegedly incurred by

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the State's Medicaid program in paying for excess prescriptions and medical treatment for injuries caused by use of the drug.

Because it is not seeking damages for individual patients, the State does not intend to prove its case by presenting evidence regarding specific patients. Rather, the State will attempt to prove its claim solely by use of statistical and epidemiological evidence. For example, the State may argue that epidemiological data demonstrates that use of Zyprexa in a Medicaid population produces a significant increase in diabetes and that Lilly failed to warn the consumer (an ordinary doctor) of this risk and of the need to take appropriate extra precautions to prevent that risk.

The State's experts will apply existing scientific research to the State Medicaid database to reach conclusions about the injury and damages allegedly suffered by the Medicaid program. That data base, according to the State, will allow experts to identify (without naming) every Medicaid recipient who took Zyprexa, the illness for which it was prescribed, whether the patient suffers from one of the medical conditions caused by Zyprexa and information regarding other risk factors that may have caused those complications.

The trial court has imposed limits on discovery in this case. Lilly has been involved in substantial other litigation regarding Zyprexa and a considerable amount of discovery has been catalogued in a collection in Multi District Litigation in New York. Because the State has access to those documents, the Court found no good reason to allow the State to conduct direct discovery against Lilly for the same information. In addition, the court set a trial date of March 2008 in this complex case, based primarily on

the State's estimate of the amount of time necessary to prepare the case under its epidemiological theories.

In earlier proceedings Judge Rindner, although recognizing that use of epidemiological evidence is generally accepted in litigation, found that he did not have sufficient information to determine whether the State's evidence passed muster under Alaska law. The Judge ordered discovery to flesh out those claims so that he could make that determination. He also noted that Lilly was free to defend the claim in whatever ways might be appropriate, and thus did not limit Lilly's discovery solely to the defense of epidemiological evidence.

With this general background in mind I turn to the specific discovery disputes raised by pending motions. This order will address is detail the most significant dispute between the parties -- access to individual patient records. As explained below, I find that in large part Lilly has not shown how discovery of individual Zyprexa users' medical records will lead to evidence relevant to challenging the State's epidemiological evidence. To the extent that Lilly has demonstrated a theoretical possibility that this evidence may be useful, that does not outweigh the significant risk of harm posed by a wholesale invasion of mental health patients' records or the expense and considerable delay resulting from that discovery. Finally, Lilly has not explained how this discovery will aid its defense of the case in ways other than challenging the scientific evidence.

Following the general discussion of the patient records issue, this Order will address all remaining discovery disputes.

Access to Individual Patient Records

Lilly seeks discovery of medical records of State Medicaid patients receiving Zyprexa. The State opposes, claiming that the records are not relevant and asserting a number of other privacy and practical objections.

At the outset I note that Zyprexa is prescribed for patients diagnosed with mental illness or mental health concerns, including schizophrenia, certain stages of bipolar disorder and mood disorders. Thus I will not order discovery of the records containing the identity of these patients unless that discovery is vital to this litigation and unless there is no other practical way of obtaining it.

The State argues that evaluating whether and why an individual Zyprexa patient incurred adverse symptoms does not shed any light on whether the overall epidemiological evidence is valid. The State claims that its epidemiological estimate of increased risk of diabetes is based on the Medicaid population as a whole and not on specific individuals. The State supports its claims by noting that in the scientific arena, Lilly and the Federal Drug Administration rely heavily on epidemiological evidence to make major decisions concerning prescription drug regulation without needing access to specific patient records.

Lilly makes the following arguments to support its request for access to individual patient records. (1) It needs the individual records to challenge directly the State's expert epidemiological evidence; (2) The State Medicaid database is insufficient because it does not contain information about certain non–Zyprexa risk factors for diabetes, including being overweight and having a family history of diabetes; (3) Access to medical records will allow Lilly to test whether the Medicaid database entries are accurate; and (4) Lilly

is not limited to defending this case by using epidemiological evidence, and the medical records may produce relevant evidence to other forms of defense. I address these claims in order.

Lilly has not really explained why use of specific patient records is an accepted scientific method for directly challenging epidemiological evidence. Lilly's expert, Dr. Virnig, identifies the kind of general factors that might be important in evaluating an individual's claim of Zyprexa related diabetes – risk factors other than diabetes, prior history of diabetes or the fact that some diabetes patients are non-symptomatic. But Dr. Virnig does not explain how access to this specific information is useful in challenging an epidemiological study where one population is compared against another and the factors mentioned by the affidavit are controlled.

Lilly's second claim, also supported by the Virnig affidavit, is that the State's Medicaid database is not sufficiently detailed to be used as a basis for a valid epidemiological analysis because it does not contain important information. While Lilly is free to challenge to validity of the database, it is not clear to me that access to individual records is the appropriate scientific method of doing so. In fact, Dr. Virnig was able to explain in detail why the database production is inadequate without having access to patient records. If the database is inadequate, that may be cause for its exclusion from trial. If the database is admitted at trial Lilly presumably will have ample opportunity to show the jury that the State's claims are based on bad science. But nowhere in Lilly's arguments is the claim that access to individual records is necessary to show that the database is inadequate.

Lilly also asserts that access to individual patient records is necessary to challenge the validity of entries coded in the database. Lilly is technically correct. Lilly is entitled to test the accuracy of the database and the only 100% foolproof way to challenge its accuracy is to start from scratch and compare individual records to data base entries.

But, a court is obligated to impose reasonable limitations on discovery, including limitations on pursuing information that might technically lead to the discovery of relevant information. In doing so a court may balance the need for the information against the cost, burden and harm caused by obtaining the data.

Discovery of the identity of Zyprexa users would be extraordinarily intrusive. Zyprexa is used to treat mental illness, including schizophrenia, certain stages of bi-polar diseases and other mood disorders. The records of Zyprexa users are bound to contain highly personal and private information.

Discovery of these records will cause significant delay in this case. The State estimates that its case involves prescriptions to approximately 700 Zyprexa patients. To obtain these records, the State or Lilly would be required to review the Medicaid database to identify the patients and their physicians. Then, a party would be required to send an order to the physicians to produce the records. The court may be required or feel obligated to offer each patient the opportunity to object to disclosure of his or her records. Even in the absence of that requirement or courtesy, I anticipate that the court will be required to resolve assertions of physician-patient privilege by some physicians.

Discovery of the records but with information regarding the actual identity of the patient removed would be less intrusive but equally time consuming. At oral argument the parties discussed retaining a medical records gathering company to obtain the records

(under the process described above) and then redacting the records prior to distribution to the parties. But this method of discovery would still entail considerable delay through the process of patient and physician identification, potential objections made by physicians, and the record editing process. Although neither party discussed the costs of this method of discovery, neither volunteered to pay for it.

I cannot determine exactly how long gathering this data would take. But I can say with some confidence that if the discovery is ordered, the March 2008 trial date will have come and gone before anyone sees an actual patient record.

In light of these burdens associated with the gathering of records, Lilly must make a strong showing that it is likely that the discovery will produce important evidence undermining the accuracy of the Medicaid database. Lilly has not made that showing.

As to post 1996 data, Lilly makes only general assertions of potentially inaccurate database entries. For pre 1996 data, the State has conceded that some of the data is "corrupt." But I do not know what that means. That may mean that the data is so unreliable that the State may not use it to establish epidemiological proof. In that case, Lilly doesn't need actual patient records to challenge that evidence.

Finally Lilly claims that it needs specific patient information to defend the case in ways unrelated to the epidemiological proof. But, when pressed Lilly was unable to make a compelling showing as to why the court should invade a mental health patient's privacy in pursuit of that goal.

Lilly asserts that it might want to present evidence from individual patients who liked the drug and felt better using it. But its not clear to me what that type of evidence would prove. The State does not assert that Zyprexa has no benefit or that some patients

were happy with the drug. Indeed, as Lilly points out, Zyprexa is still part of the State's Medicaid formulary – Medicaid physicians are free to prescribe it and seek payment for their services. Finally, even if evidence from satisfied actual Zyprexa users is relevant, surely Lilly can find that evidence by some means other than the method proposed here.

Discovery Regarding State's Medicaid Database

Lilly has asserted a number of objections regarding the State's production of information from its Medicaid Database (aside from information regarding the identity of Zyprexa patients). The Virnig affidavit specifically identifies those deficiencies.

At oral argument the State indicated that it did not object to producing the information identified by Dr. Virnig if it was actually in the database. The State has since confirmed that it has taken steps to provide that discovery. Thus I consider Lilly's motion resolved. I am mindful that the State's case may rise or fall in large part on the database. Lilly may renew its motion regarding the database if unsatisfied with the State's supplemental discovery.

Lilly also filed a separate motion seeking a subpoena of the original database maintained for the State by First Health Services Corporation. The State opposes.

The State asserts that it took the original database, manipulated it to exclude all patient identifying information, and produced (or will produce) the rest. The State claims that if Lilly has access to the original database, it will have access to patient identifying information.

Lilly doesn't dispute the second claim -- that access to the First Health records will result in access to patient identifying information. But Lilly asserts that it should

have that access because the production from the State has been so shoddy that Lilly cannot be assured of the accuracy of the edited database information.

For the reasons stated above, Lilly is not entitled to access to patient identifying information. Because the State has committed to making additional database discovery, Lilly's claim of risk of inaccurate production is not persuasive.

Rulings on Individual Discovery Requests

Lilly's Motion to Compel (August 6, 2007)

DENIED. See discussion of Access to Patient Medical Records above.

Lilly's Motion for Application For Commission to Issue Subpoena

DENIED. See discussion of Access to patient Medical records and Discovery Regarding State's Medicaid Data Base above.

State's First Motion to Compel (July 10, 2007)

DENIED in part and GRANTED in part.

Int. # 1, RFP # 1. Lilly withdrew its objection at oral argument.

Int. # 2, RFP # 2. DENIED. The State seeks information regarding communications about Zyprexa from Lilly to public payors of medical bills in Alaska other than Medicaid. Lilly argues that the information sought will not lead to admissible evidence because the State's claims are limited to misrepresentations to Medicaid. The State argues that this information is relevant because other public payor organizations could influence the State and prescribing physicians regarding the use of Zyprexa.

The State has access to the MDL collection that likely contains a representative sample of communications about Zyprexa made by Lilly to numerous organizations. It is also likely that the communications made to other payors in Alaska are similar to

communications made to the State and evidence of communications available in the MDL collection.

The evidence sought by the State is technically discoverable – but it appears that the ability of other payors to influence the State is tenuous and the information sought is also likely redundant to information already available to the State. Given the State's interest in limiting unnecessary discovery so as to preserve the March 2008 trial date, Lilly's objection to the discovery as overbroad is sustained.

Int. # 3, RFP #3. Lilly withdrew is objection at oral argument.

Int. #6, RFP #9. DENIED. The State seeks information regarding communications about Zyprexa from Lilly to representatives of Alaska's executive or legislative branch. Lilly asserts the same objections noted above regarding Int. #2. The State does not have any evidence that other members of the Alaska executive branch or the Alaska Legislature influenced Alaska Medicaid regarding the use of Zyprexa. Lilly's objection is sustained.

Int. # 8, RFP #11; Int. #9, RFP # 12; Int. #10, RFP # 13; Int. # 11, RFP # 14. DENIED. The State seeks information regarding communications about Zyprexa from Lilly to patient advocacy groups, the American Psychiatric Association, the Texas Medication Algorithm Project, and Comprehensive NueroScience. Lilly's objections are sustained for the reasons stated above in Int. #2.

Int. #4, RFP #7. GRANTED in part. The State seeks information regarding call note references to Zyprexa generated by Lilly sales representatives in Alaska. Call notes are brief entries made by sales representatives documenting meetings with physicians. Lilly recognizes that the information may be discoverable but claims that retrieving the

information from its database is unduly burdensome. Lilly asserts that it must search approximately 40,000 entries in the call note database, a task that may take 1300 hours. The State disputes this assertion.

I do not have enough information to determine how burdensome the search for Alaska related Zyprexa call notes will be. But Lilly's proposed solution to the issue appears reasonable. Lilly proposes to produce a random sample of Zyprexa related call notes and suggests that any pattern relevant to these proceedings should reveal itself through that sample.

Lilly shall produce a random sample of 4,000 Alaska call notes referencing Zyprexa.

Int. #7, RFP # 10. Lilly withdrew its objection at oral argument.

Int. #12. GRANTED in part. The State seeks financial information regarding Lilly's worldwide revenue from Zyprexa sales, cost of products sold, gross margin, operating expenses, other expenses and income before taxes. Lilly agrees to produce publicly available information regarding sales and revenue, but objects to engaging in forensic accounting to calculate cost of products sold, gross margin, operating expenses and pre-tax income. While the more detailed financial information may help the State prove a motive for misrepresentation or corroborate the State's claim that Lilly's marketing tactics resulted in increased sales, the publicly available information offered by Lilly is relevant to the same issue. In light of the State's interest in efficient discovery to maintain the March 2008 trial date, Lilly's objections to produce other than publicly available information are sustained. Lilly must produce publicly available worldwide Zyprexa sales revenue responsive to this request.

Int. #13. Granted in part. The State seeks information regarding Lilly's Alaska Zyprexa sales revenue, and its gross margin and income before taxes. For the reasons stated regarding Int. # 12, Lilly must produce publicly available Alaska Zyprexa sales revenue responsive to this request.

Int. # 19 and 20. Lilly's 9//21/2007 letter is responsive to this request.

RFP # 4, 5 and 6. GRANTED. The State seeks documents regarding communications about Zyprexa from Lilly to Alaska physicians other than those made by Lilly sales representatives. Those include communications made by "thought leaders" – physicians or other consultants retained by Lilly to communicate about Zyprexa on Lilly's behalf. At oral argument Lilly counsel conceded that these documents may be discoverable and indicated that counsel had not made a search for them. Counsel also indicated that he would check but was not certain whether he had the capability of locating that information in Lilly's file database.

Lilly shall make a diligent search for documents responsive to these requests and produce those documents within 15 days. If unable to locate documents Lilly must explain efforts made in that regard.

Int. # 5, 15, 16, 17 and 18; RRFP # 8, 15, 17, and 18. GRANTED in part. Lilly did not object to the discoverability of the information sought by these requests but referred the State to the MDL collection to obtain that information. The State asks that Lilly at least designate the Bates ranges for that information to ease the burden of locating the documents.

At oral argument Lilly asserted that the MDL collection was so extensive, and the method of organization of documents so peculiar, that it was equally difficult for the State and Lilly to locate the information in the collection.

In my view, if Lilly knows the information sought by the State is in the MDL collection, then Lilly must have some idea as to how to locate the information. Thus, no later than September 27 Lilly must produce the information sought by the discovery, or provide some more specific means to assist the State to locate the information, or if unable to do either, explain what efforts were made to obtain the information.

Discovery Master Fees

The Discovery Master fees incurred to date for all matters submitted are $6350.00. The parties shall each pay one-half. (Invoice submitted to counsel)

Dan A. Hensley
Discovery Master

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

PLAINTIFF'S MOTION IN LIMINE TO PRECLUDE TESTIMONY OR ARGUMENT THAT ZYPREXA'S LABELING "WARNED" OF DIABETES, HYPERGLYCEMIA OR WEIGHT GAIN

Plaintiff moves this Court for an order preventing Eli Lilly's counsel and witnesses from stating or implying that Lilly "WARNED" of Zyprexa's risks of diabetes or hyperglycemia prior to the FDA-mandated label change in 2003. Further, Lilly's counsel and witnesses should be instructed to make no statements that Lilly "WARNED" of the risk of weight gain prior to the labeling change in 2007.

Federal regulations contain precise rules prescribing drug labeling. Under these regulations, serious adverse reactions are required to be listed in the "WARNINGS AND PRECAUTIONS" section of the labeling:

FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK
99501
TEL: 907.272.3538
FAX: 907.274.0819

> *Warnings and precautions*. . . .
> This section **must describe clinically significant adverse reactions** (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug), **other potential safety hazards** (including those that are expected for the pharmacological class or those resulting from drug/drug interactions), limitations in use imposed by them (e.g., avoiding certain concomitant therapy), and steps that should be taken if they occur (e.g., dosage modification). The frequency of all clinically significant adverse reactions and the approximate mortality and morbidity rates for patients experiencing the reaction, if known and necessary for the safe and effective use of the drug, must be expressed . . . [T]he labeling must be revised to include a **warning** about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established.

21 C.F.R. § 201.57(c)(6)(i) (emphasis added).[1]

Prior to 2003, there was no mention of diabetes or hyperglycemia in the "WARNINGS" section of Zyprexa's labeling.[2] Diabetes mellitus and hyperglycemia were only mentioned far down in the labeling under the section for "Adverse Reactions," where they were listed as "infrequent" and "rare" under a subheading for "Other Adverse

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[1] *Cf.* 21 C.F.R. § 201.57(e) (effective through June 29, 2006):

> **Warnings.** Under this section heading, the labeling **shall describe serious adverse reactions and potential safety hazards**, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include **a warning** as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.

(emphasis added).

[2] *See* Exhibit A (*Physicians' Desk Reference*, pp. 1649-1653 (54th ed. 2000)).

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Events Observed During the Premarketing Evaluation of [Zyprexa]."[3] This section of the labeling even emphasized, "that, although the events reported occurred during treatment with [Zyprexa], they were not necessarily caused by it."[4] Prior to 2007, the only reference to "weight gain" was also in the "Adverse Reactions" section of the required labeling, in a table of "adverse events" that reports the statistical results of premarketing trials.[5]

These mentions under the "Adverse Reactions" section of the labeling do not constitute "WARNINGS" as required and defined under 21 C.F.R. 201.57. "Adverse Reactions" are specifically defined in the federal regulations, and are distinct from "WARNINGS." *See* 21 C.F.R. 201.57(c)(7); *cf.* 21 C.F.R. 201(g) (effective through June 29, 2006).

Plaintiff does not object to statements such as "the adverse reaction section of labeling referred to diabetes" or "diabetes was reported as an adverse event from premarketing trials in the adverse reaction section of the labeling" or even that "the adverse reaction of the section noted that diabetes had been reported in post-marketing adverse event reports." But it would be false and misleading for Lilly to claim that its

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[3] *Id.* at p. 1652.

[4] *Id.*

[5] *Id.* at p. 1651.

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labeling prior to 2003 "WARNED" of the risks of diabetes and hyperglycemia, or that prior to 2007 it "WARNED" of the risk of weight gain.

DATED this 22 day of February, 2008.

FELDMAN ORLANSKY & SANDERS
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Certificate of Service

I hereby certify that a true and correct copy of **Plaintiff's Motion in Limine to Exclude Testimony or Argument that Zyprexa's Labeling "Warned" of Diabetes, Hyperglycemia and Weight Gain and (proposed) Order** were served by messenger on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
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Barry Boise, via email (boiseb@pepperlaw.com)
Pepper Hamilton

By Peggy S Crowe
Date 2/22/08

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...be encountered before leukopenic effect. When ... there is no need to increase the size of ... (see Precautions).

...—A review of published literature from ... showed that initial doses of Velban in pediatric ... varied depending on the schedule used and ... Velban was administered as a single agent or in... within a particular chemotherapeutic regimen. ... agent for Letterer-Siwe disease (histiocytosis X), ... dose of Velban was reported as 6.5 mg/m². When ... used in combination with other chemotherapeu... the treatment of Hodgkin's disease, the initial ... reported as 6 mg/m². For testicular germ cell car... initial dose of Velban was reported as 3 mg/m² ... regimen. Dose modifications should be ... hematologic tolerance.

... *Renal or Hepatic Impairment*—A reduction of ... dose of Velban is recommended for patients hav... serum bilirubin value above 3 mg/100 mL. Since ... and excretion are primarily hepatic, no modifi... recommended for patients with impaired renal ...

... of maintenance therapy varies according to ... being treated and the combination of antineo... being used. There are differences of opinion ... the duration of maintenance therapy with the ... for a particular disease; for example, various ... have been used with the MOPP program in treat... disease. Prolonged chemotherapy for main... remissions involves several risks, among which are ... infectious diseases, sterility, and possibly ... of other cancers through suppression of im... surveillance.

... disorders, survival following complete remission ... as prolonged as that achieved with shorter pe... maintenance therapy. On the other hand, failure to ... maintenance therapy in some patients may lead to ... relapse; complete remissions in patients with ... cancer, unless maintained for at least 2 years, of... early relapse.

... a solution containing 1 mg of Velban/mL, add 10 ... bacteriostatic Sodium Chloride Injection (preserved ... alcohol) or 10 mL of Sodium Chloride Injection ... to the 10 mg of Velban in the sterile vial. Do ... solutions. The drug dissolves instantly to give ...

... drug products should be inspected visually for ... matter and discoloration prior to administra... solution and container permit.

... of the remaining solutions made with nor... that do not contain preservatives should be dis... immediately. Unused preservative-containing solu... with normal saline may be stored in a refriger... use for a maximum of 28 days.

... of Velban (calculated to provide the desired ... may be injected either into the tubing of a running ... infusion or directly into a vein. The latter pro... readily adaptable to outpatient therapy. In either ... injection may be completed in about 1 minute. If ... to insure that the needle is securely within the ... that no solution containing Velban is spilled ex... cellulitis and/or phlebitis will not occur. To ... further the possibility of extravascular spillage, it ... that the syringe and needle be rinsed with ve... before withdrawal of the needle. The dose should ... in large volumes of diluent (ie, 100 to 250 mL) ... intravenously for prolonged periods (ranging from ... minutes or more), since this frequently results ... of the vein and increases the chance of ...

... the enhanced possibility of thrombosis, it is con... inadvisable to inject a solution of Velban into an ex... which the circulation is impaired or potentially ... such conditions as compressing or invading ne... or varicosity.

... proper handling and disposal of anticancer ... be considered. Several guidelines on this sub... published.[1-7] There is no general agreement ... procedures recommended in the guidelines ... appropriate.

... *Dispensing Information*—When dispensing Velban ... the original container, eg, a syringe containing ... it is imperative that it be packaged in an ... the statement: "DO NOT REMOVE COV... UNTIL MOMENT OF INJECTION. FATAL IF ... INTRATHECALLY. FOR INTRAVENOUS USE ... Warnings).

... SUPPLIED

... size (No. 687)—(1s) NDC 0002-1452-01. ... be stored in a refrigerator (2° to 8°C, or 36° ... ensure extended stability.

... Federal (USA) law prohibits dispensing with...

REFERENCES

... for the Safe Handling of Parenteral ... Drugs, NIH Publication No. 83-2621. For ... by the Superintendent of Documents, U.S. Govern... Printing Office, Washington, DC 20402.
... Council Report, Guidelines for Handling Parenteral ... JAMA, 1985;253(11):1590-1592.
... Study Commission on Cytotoxic Exposure—Rec... for Handling Cytotoxic Agents. Available ... Jeffrey P. ... Chairman, National Study Commission on Cytotoxic Exposure, Massachusetts College of Pharmacy and Allied Health Sciences, 179 Longwood Avenue, Boston, Massachusetts 02115.
4. Clinical Oncological Society of Australia, Guidelines and Recommendations for Safe Handling of Antineoplastic Agents. Med J Australia, 1983;1:426-428.
5. Jones RB, et al: Safe Handling of Chemotherapeutic Agents: A Report from the Mount Sinai Medical Center. CA—A Cancer Journal for Clinicians, 1983; (Sept/Oct) 258-263.
6. American Society of Hospital Pharmacists Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs. Am J Hosp Pharm, 1990;47:1033-1049.
7. OSHA Work-Practice Guidelines for Personnel Dealing with Cytotoxic (Antineoplastic) Drugs. Am J Hosp Pharm, 1986;43:1193-1204.

Text revised October 2, 1997

PA 2564 AMP [100297]

ZINC-INSULIN CRYSTALS OTC

See under Iletin® (insulin).

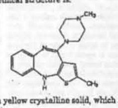
ZYPREXA® ℞

[*zī-prex-ah*]

(Olanzapine)

DESCRIPTION

ZYPREXA (olanzapine) is an antipsychotic agent that belongs to the thienobenzodiazepine class. The chemical designation is 2-methyl-4-(4-methyl-1-piperazinyl)-10*H*-thieno[2,3-*b*] [1,5]benzodiazepine. The molecular formula is $C_{17}H_{20}N_4S$, which corresponds to a molecular weight of 312.44. The chemical structure is:



Olanzapine is a yellow crystalline solid, which is practically insoluble in water.

ZYPREXA tablets are intended for oral administration only. Each tablet contains olanzapine equivalent to 2.5 mg (8 µmol), 5 mg (16 µmol), 7.5 mg (24 µmol), or 10 mg (32 µmol). Inactive ingredients are carnauba wax, color mixture white, crospovidone, F D & C Blue No. 2 Aluminum Lake, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose, magnesium stearate, microcrystalline cellulose, and other inactive ingredients.

CLINICAL PHARMACOLOGY

Pharmacodynamics:

Olanzapine is a selective monoaminergic antagonist with high affinity binding to the following receptors: serotonin $5HT_{2A/2C}$ (K_i=4 and 11 nM, respectively), dopamine D_{1-4} (K_i=11–31 nM), muscarinic M_{1-5} (K_i=1.9–25 nM), histamine H_1 (K_i=7 nM), and adrenergic α_1 receptors (K_i=19 nM). Olanzapine binds weakly to $GABA_A$, BZD, and β adrenergic receptors (K_i > 10 µM).

The mechanism of action of olanzapine, as with other antipsychotic drugs, is unknown. However, it has been proposed that this drug's antipsychotic activity is mediated through a combination of dopamine and serotonin type 2 ($5HT_2$) antagonism. Antagonism at receptors other than dopamine and $5HT_2$ with similar receptor affinities may explain some of the other therapeutic and side effects of olanzapine. Olanzapine's antagonism of muscarinic M_{1-5} receptors may explain its anticholinergic effects. Olanzapine's antagonism of histamine H_1 receptors may explain the somnolence observed with this drug. Olanzapine's antagonism of adrenergic α_1 receptors may explain the orthostatic hypotension observed with this drug.

Pharmacokinetics:

Olanzapine is well absorbed and reaches peak concentrations in approximately 6 hours following an oral dose. It is eliminated extensively by first pass metabolism, with approximately 40% of the dose metabolized before reaching the systemic circulation. Food does not affect the rate or extent of olanzapine absorption.

Olanzapine displays linear kinetics over the clinical dosing range. Its half-life ranges from 21 to 54 hours (5th to 95th percentile; mean of 30 hr), and apparent plasma clearance ranges from 12 to 47 L/hr (5th to 95th percentile; mean of 25 L/hr).

Administration of olanzapine once daily leads to steady-state concentrations in about one week that are approximately twice the concentrations after single doses. Plasma concentrations, half-life, and clearance of olanzapine may vary between individuals on the basis of smoking status, gender and age (see Special Populations).

Olanzapine is extensively distributed throughout the body, with a volume of distribution of approximately 1000 L. It is 93% bound to plasma proteins over the concentration range of 7 to 1100 ng/mL, binding primarily to albumin and α_1-acid glycoprotein.

Metabolism and Elimination—Following a single oral dose of ^{14}C labeled olanzapine, 7% of the dose of olanzapine was recovered in the urine as unchanged drug, indicating that olanzapine is highly metabolized. Approximately 57% and 30% of the dose was recovered in the urine and feces, respectively. In the plasma, olanzapine accounted for only 12% of the AUC for total radioactivity, indicating significant exposure to metabolites. After multiple dosing, the major circulating metabolites were the 10-N-glucuronide, present at steady state at 44% of the concentration of olanzapine, and 4'-N-desmethyl olanzapine, present at steady state at 31% of the concentration of olanzapine. Both metabolites lack pharmacological activity at the concentrations observed.

Direct glucuronidation and cytochrome P450 (CYP) mediated oxidation are the primary metabolic pathways for olanzapine. In vitro studies suggest that CYPs 1A2 and 2D6, and the flavin-containing monooxygenase system are involved in olanzapine oxidation. CYP2D6 mediated oxidation appears to be a minor metabolic pathway in vivo, because the clearance of olanzapine is not reduced in subjects who are deficient in this enzyme.

Special Populations—

Renal Impairment—Because olanzapine is highly metabolized before excretion and only 7% of the drug is excreted unchanged, renal dysfunction alone is unlikely to have a major impact on the pharmacokinetics of olanzapine. The pharmacokinetic characteristics of olanzapine were similar in patients with severe renal impairment and normal subjects, indicating that dosage adjustment based upon the degree of renal impairment is not required. In addition, olanzapine is not removed by dialysis. The effect of renal impairment on metabolite elimination has not been studied.

Hepatic Impairment—Although the presence of hepatic impairment may be expected to reduce the clearance of olanzapine, a study of the effect of impaired liver function in subjects (n=6) with clinically significant (Childs Pugh Classification A and B) cirrhosis revealed little effect on the pharmacokinetics of olanzapine.

Age—In a study involving 24 healthy subjects, the mean elimination half-life of olanzapine was about 1.5 times greater in elderly (>65 years) than in non-elderly subjects (≤65 years). Caution should be used in dosing the elderly, especially if there are other factors that might additively influence drug metabolism and/or pharmacodynamic sensitivity (see DOSAGE AND ADMINISTRATION).

Gender—Clearance of olanzapine is approximately 30% lower in women than in men. There were, however, no apparent differences between men and women in effectiveness or adverse effects. Dosage modifications based on gender should not be needed.

Smoking Status—Olanzapine clearance is about 40% higher in smokers than in nonsmokers, although dosage modifications are not routinely recommended.

Race—No specific pharmacokinetic study was conducted to investigate the effects of race. A cross-study comparison between data obtained in Japan and data obtained in the US suggests that exposure to olanzapine may be about 2-fold greater in the Japanese when equivalent doses are administered. Clinical trial safety and efficacy data, however, did not suggest clinically significant differences among Caucasian patients, patients of African descent, and a third pooled category including Asian and Hispanic patients. Dosage modifications for race are, therefore, not recommended.

Combined Effects—The combined effects of age, smoking, and gender could lead to substantial pharmacokinetic differences in populations. The clearance in young smoking males, for example, may be 3 times higher than that in elderly nonsmoking females. Dosing modification may be necessary in patients who exhibit a combination of factors that may result in slower metabolism of olanzapine (*see* DOSAGE AND ADMINISTRATION).

Clinical Efficacy Data:

The efficacy of olanzapine in the management of the manifestations of psychotic disorders was established in 2 short-term (6-week) controlled trials of psychotic inpatients who met DSM III-R criteria for schizophrenia. A single haloperidol arm was included as a comparative treatment in one of the two trials, but this trial did not compare these two drugs on the full range of clinically relevant doses for both.

Several instruments were used for assessing psychiatric signs and symptoms in these studies, among them the Brief Psychiatric Rating Scale (BPRS), a multi-item inventory of general psychopathology traditionally used to evaluate the effects of drug treatment in psychosis. The BPRS psychosis cluster (conceptual disorganization, hallucinatory behavior, suspiciousness, and unusual though content) is considered a particularly useful subset for assessing actively psychotic schizophrenic patients. A second traditional assessment, the Clinical Global Impression (CGI), reflects the impression of a skilled observer, fully familiar with the manifestations of schizophrenia, about the overall clinical state of the patient. In addition, two more recently developed but less well evaluated scales were employed; these included the 30-item Positive and Negative Symptoms Scale (PANSS), in which is embedded the 18 items of the BPRS, and the Scale for Assessing Negative Symptoms (SANS). The trial summaries below focus on the following outcomes: PANSS total and/or

Continued on next page

* Identi-Code® symbol. This product information was prepared in June 1999. Current information on these and other products of Eli Lilly and Company may be obtained by direct inquiry to Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, Indiana 46285, (800) 545-5979.

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Plaintiff's Motion in Limine to Preclude Testimony or Argument that Zyprexa's Labeling "Warned" of Diabetes, Hyperglycemia or Weight Gain

Case No. 3AN-06-05630 CI

002662

BPRS total; BPRS psychosis clu[illegible] PANSS negative subscale or SANS; and CGI Severity. [illegible] results of the trials follow:

(1) In a 6-week, placebo-controlled trial (n=149) involving two fixed olanzapine doses of 1 and 10 mg/day (once daily schedule), olanzapine, at 10 mg/day (but not at 1 mg/day), was superior to placebo on the PANSS total score (also on the extracted BPRS total), on the BPRS psychosis cluster, on the PANSS Negative subscale, and on CGI Severity.

(2) In a 6-week, placebo-controlled trial (n=253) involving 3 fixed dose ranges of olanzapine (5.0±2.5 mg/day, 10.0±2.5 mg/day, and 15.0±2.5 mg/day) on a once daily schedule, the two highest olanzapine dose groups (actual mean doses of 12 and 16 mg/day, respectively) were superior to placebo on BPRS total score, BPRS psychosis cluster, and CGI severity score; the highest olanzapine dose group was superior to placebo on the SANS. There was no clear advantage for the high dose group over the medium dose group.

Examination of population subsets (race and gender) did not reveal any differential responsiveness on the basis of these subgroupings.

INDICATIONS AND USAGE

ZYPREXA is indicated for the management of the manifestations of psychotic disorders.

The antipsychotic efficacy of ZYPREXA was established in short-term (6-week) controlled trials of schizophrenic inpatients (*see* CLINICAL PHARMACOLOGY).

The effectiveness of ZYPREXA in long-term use, that is, for more than 6 weeks, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use ZYPREXA for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient (*see* DOSAGE AND ADMINISTRATION).

CONTRAINDICATIONS

ZYPREXA is contraindicated in patients with a known hypersensitivity to the product.

WARNINGS

Neuroleptic Malignant Syndrome (NMS)—A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia). Additional signs may include elevated creatinine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure.

The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to exclude cases where the clinical presentation includes both serious medical illness (e.g., pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever, and primary central nervous system pathology.

The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for NMS.

If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported.

Tardive Dyskinesia—A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.

The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses.

There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and thereby may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.

Given these considerations, olanzapine should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients (1) who suffer from a chronic illness that is known to respond to antipsychotic drugs, and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or ap[illegible] smallest dose and the shortest duration of treat[illegible] producing a satisfactory clinical response should [illegible]ht. The need for continued treatment should be r[illegible]sed periodically.

If signs and symptoms of tardive dyskinesia appear in a patient on olanzapine, drug discontinuation should be considered. However, some patients may require treatment with olanzapine despite the presence of the syndrome.

PRECAUTIONS

General

Orthostatic Hypotension—Olanzapine may induce orthostatic hypotension associated with dizziness, tachycardia, and in some patients, syncope, especially during the initial dose-titration period, probably reflecting its α_1-adrenergic antagonistic properties. Syncope was reported in 0.6% (15/2500) of olanzapine-treated patients in phase 2-3 studies. The risk of orthostatic hypotension and syncope may be minimized by initiating therapy with 5 mg QD (*see* DOSAGE AND ADMINISTRATION). A more gradual titration to the target dose should be considered if hypotension occurs. Olanzapine should be used with particular caution in patients with known cardiovascular disease (history of myocardial infarction or ischemia, heart failure, or conduction abnormalities), cerebrovascular disease, and conditions which would predispose patients to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications).

Seizures—During premarketing testing, seizures occurred in 0.9% (22/2500) of olanzapine-treated patients. There were confounding factors that may have contributed to the occurrence of seizures in many of these cases. Olanzapine should be used cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold, e.g., Alzheimer's dementia. Conditions that lower the seizure threshold may be more prevalent in a population of 65 years or older.

Hyperprolactinemia—As with other drugs that antagonize dopamine D_2 receptors, olanzapine elevates prolactin levels, and a modest elevation persists during chronic administration. Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer of this type. Although disturbances such as galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating compounds, the clinical significance of elevated serum prolactin levels is unknown for most patients. As is common with compounds which increase prolactin release, an increase in mammary gland neoplasia was observed in the olanzapine carcinogenicity studies conducted in mice and rats (*see* Carcinogenesis). However, neither clinical studies nor epidemiologic studies have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive.

Transaminase Elevations—In placebo-controlled studies, clinically significant ALT (SGPT) elevations (≥3 times the upper limit of the normal range) were observed in 2% (6/243) of patients exposed to olanzapine compared to none (0/115) of the placebo patients. None of these patients experienced jaundice. In two of these patients, liver enzymes decreased toward normal despite continued treatment and in two others, enzymes decreased upon discontinuation of olanzapine. In the remaining two patients, one, seropositive for hepatitis C, had persistent enzyme elevation for four months after discontinuation, and the other had insufficient follow-up to determine if enzymes normalized.

Within the larger premarketing database of about 2400 patients with baseline SGPT ≤90 IU/L, the incidence of SGPT elevation to >200 IU/L was 2% (50/2381). Again, none of these patients experienced jaundice or other symptoms attributable to liver impairment and most had transient changes that tended to normalize while olanzapine treatment was continued.

Among all 2500 patients in clinical trials, about 1% (23/2500) discontinued treatment due to transaminase increases.

Caution should be exercised in patients with signs and symptoms of hepatic impairment, in patients with pre-existing conditions associated with limited hepatic functional reserve, and in patients who are being treated with potentially hepatotoxic drugs. Periodic assessment of transaminases is recommended in patients with significant hepatic disease (*see* Laboratory Tests).

Potential for Cognitive and Motor Impairment—Somnolence was a commonly reported adverse event associated with olanzapine treatment, occurring at an incidence of 26% in olanzapine patients compared to 15% in placebo patients. This adverse event was also dose related. Somnolence led to discontinuation in 0.4% (9/2500) of patients in the premarketing database.

Since olanzapine has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that olanzapine therapy does not affect them adversely.

Body Temperature Regulation—Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Appropriate care is advised when prescribing olanzapine for patients who will be experiencing conditions which may contribute to an elevation in core body temperature, e.g., exercising strenuously, exposure to [illegible] cholinergic activity, or being subject to dehydration.

Dysphagia—Esophageal dysmotility and [illegible] have been associated with antipsychotic drug use. [illegible]zapine-treated patients in a study of olanzapine in [illegible]imer's dementia died from aspiration pneumonia. [illegible] these patients had experienced dysphagia prior to [illegible]velopment of aspiration pneumonia. Aspiration pn[illegible] is a common cause of morbidity and mortality in [illegible] with advanced Alzheimer's dementia. Olanzapine [illegible] antipsychotic drugs should be used cautiously in patients [illegible] risk for aspiration pneumonia.

Suicide—The possibility of a suicide attempt is inher[illegible] schizophrenia, and close supervision of high-risk pa[illegible] should accompany drug therapy. Prescriptions for ola[illegible]ine should be written for the smallest quantity of [illegible] consistent with good patient management, in order [illegible]duce the risk of overdose.

Use in Patients with Concomitant Illness—Clinical [illegible]ence with olanzapine in patients with certain con[illegible] systemic illnesses (*see* Renal Impairment and Hepa[illegible]pairment *under* CLINICAL PHARMACOLOGY, S[illegible] Populations) is limited.

Olanzapine exhibits in vitro muscarinic receptor affi[illegible] premarketing clinical trials with olanzapine, olan[illegible] was associated with constipation, dry mouth, and ta[illegible]dia, all adverse events possibly related to cholinergic an[illegible]onism. Such adverse events were not often the basis [illegible]continuations from olanzapine, but olanzapine should [illegible] used with caution in patients with clinically signi[illegible] prostatic hypertrophy, narrow angle glaucoma, or a [illegible] of paralytic ileus.

Olanzapine has not been evaluated or used to any appre[illegible]ble extent in patients with a recent history of myoca[illegible] infarction or unstable heart disease. Patients with these [illegible]agnoses were excluded from premarketing clinical st[illegible] Because of the risk of orthostatic hypotension with ola[illegible]pine, caution should be observed in cardiac patients (*se*[illegible]thostatic Hypotension).

Information for Patients—Physicians are advised to dis[illegible] the following issues with patients for whom they prescribe olanzapine:

Orthostatic Hypotension—Patients should be advised of [illegible] risk of orthostatic hypotension, especially during the period of initial dose titration and in association with the use of concomitant drugs that may potentiate the orthostatic ef[illegible]fect of olanzapine, e.g., diazepam or alcohol (*see* Drug Interactions).

Interference with Cognitive and Motor Performance—Be[illegible]cause olanzapine has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that olanzapine therapy does not affect them adversely.

Pregnancy—Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy with olanzapine.

Nursing—Patients should be advised not to breast-feed [illegible] infant if they are taking olanzapine.

Concomitant Medication—Patients should be advised to in[illegible]form their physicians if they are taking, or plan to take, [illegible] prescription or over-the-counter drugs, since there is a po[illegible]tential for interactions.

Alcohol—Patients should be advised to avoid alcohol while taking olanzapine.

Heat Exposure and Dehydration—Patients should be ad[illegible]vised regarding appropriate care in avoiding overheating and dehydration.

Laboratory Tests—Periodic assessment of transaminases [illegible] recommended in patients with significant hepatic disease (*see* Transaminase Elevations).

Drug Interactions—The risks of using olanzapine in combi[illegible]nation with other drugs have not been extensively evalu[illegible]ated in systematic studies. Given the primary CNS effects [illegible] olanzapine, caution should be used when olanzapine [illegible] taken in combination with other centrally acting drugs [illegible] alcohol.

Because of its potential for inducing hypotension, [illegible]ine may enhance the effects of certain antihypertensive agents.

Olanzapine may antagonize the effects of levodopa and [illegible]pamine agonists.

The Effect of Other Drugs on Olanzapine—Agents that [illegible]duce CYP1A2 or glucuronyl transferase enzymes, such [illegible] omeprazole and rifampin, may cause an increase in [illegible]pine clearance. Inhibitors of CYP1A2 (e.g., fluvo[illegible]) could potentially inhibit olanzapine elimination. Because olanzapine is metabolized by multiple enzyme systems, [illegible]hibition of a single enzyme may not appreciably decrease olanzapine clearance.

Charcoal—The administration of activated charcoal (1 g) [illegible]duced the C_{max} and AUC of olanzapine by about [illegible] peak olanzapine levels are not typically obtained [illegible] about 6 hours after dosing, charcoal may be a useful [illegible]ment for olanzapine overdose.

Cimetidine and Antacids—Single doses of cimetidine [illegible] mg) or aluminum- and magnesium-containing antacids [illegible] not affect the oral bioavailability of olanzapine.

Carbamazepine—Carbamazepine therapy (200 mg [illegible]) causes an approximately 50% increase in the clearance [illegible] olanzapine. This increase is likely due to the fact that [illegible]bamazepine is a potent inducer of CYP1A2 activity. Higher daily doses of carbamazepine may cause an even greater [illegible]crease in olanzapine clearance.

A B C D

[illegible]—Ethanol (45 mg/70 kg single dose) did not have an [illegible] on olanzapine pharmacokinetics.

[illegible]—Warfarin (20 mg single dose) did not affect olanzapine pharmacokinetics.

[illegible] of Olanzapine on Other Drugs—In vitro studies utilizing human liver microsomes suggest that olanzapine has [illegible] potential to inhibit CYP1A2, CYP2C9, CYP2C19, [illegible], and CYP3A. Thus, olanzapine is unlikely to cause [illegible] important drug interactions mediated by these [illegible].

[illegible] doses of olanzapine did not affect the pharmacokinetics of imipramine or its active metabolite desipramine, and [illegible]. Multiple doses of olanzapine did not influence the [illegible] of diazepam and its active metabolite N-desmethyldiazepam, lithium, ethanol, or biperiden. However, the coadministration of either diazepam or ethanol with olanzapine potentiated the orthostatic hypotension observed with olanzapine. Multiple doses of olanzapine did not affect the pharmacokinetics of theophylline or its metabolites.

[illegible]genesis, *Mutagenesis, Impairment of Fertility*—

[illegible]genesis—Oral carcinogenicity studies were conducted in mice and rats. Olanzapine was administered to [illegible] two 78-week studies at doses of 3, 10, 30/20 mg/kg/ [illegible] equivalent to 0.8-5 times the maximum recommended [illegible] daily dose on a mg/m² basis) and 0.25, 2, 8 mg/kg/ [illegible] equivalent to 0.06-2 times the maximum recommended [illegible] daily dose on a mg/m² basis). Rats were dosed for 2 [illegible] at doses of 0.25, 1, 2.5, 4 mg/kg/day (males) and 0.25, [illegible] mg/kg/day (females) (equivalent to 0.13-2 and 0.13-4 [illegible] the maximum recommended human daily dose on a [illegible] basis, respectively). The incidence of liver hemangiomas and hemangiosarcomas was significantly increased in [illegible] study in female mice dosed at 8 mg/kg/day (2 [illegible] the maximum recommended human daily dose on a [illegible] basis). These tumors were not increased in another [illegible] study in females dosed at 10 or 30/20 mg/kg/day (2-5 [illegible] the maximum recommended human daily dose on a [illegible] basis); in this study, there was a high incidence of [illegible] mortalities in males of the 30/20 mg/kg/day group. The [illegible] of mammary gland adenomas and adenocarcinomas was significantly increased in female mice dosed at ≥2 [illegible]/day and in female rats dosed at ≥4 mg/kg/day (0.5 [illegible] times the maximum recommended human daily dose [illegible] mg/m² basis, respectively). Antipsychotic drugs have [illegible] shown to chronically elevate prolactin levels in rodents. Serum prolactin levels were not measured during the [illegible] carcinogenicity studies; however, measurements [illegible] subchronic toxicity studies showed that olanzapine [illegible] serum prolactin levels up to 4-fold in rats at the [illegible] doses used in the carcinogenicity study. An increase in [illegible] gland neoplasms has been found in rodents after [illegible] administration of other antipsychotic drugs and is [illegible] to be prolactin mediated. The relevance for human risk of the finding of prolactin mediated endocrine tumors in rodents is unknown (see Hyperprolactinemia *under* [illegible]UTIONS, General).

[illegible]—No evidence of mutagenic potential for olanzapine was found in the Ames reverse mutation test, in vivo [illegible] test in mice, the chromosomal aberration test [illegible] hamster ovary cells, unscheduled DNA synthesis [illegible] rat hepatocytes, induction of forward mutation test [illegible] lymphoma cells, or in vivo sister chromatid exchange test in bone marrow of Chinese hamsters.

[illegible] of Fertility—In a fertility and reproductive performance study in rats, male mating performance, but not [illegible], was impaired at a dose of 22.4 mg/kg/day and female fertility was decreased at a dose of 3 mg/kg/day (11 [illegible] times the maximum recommended human daily [illegible] mg/m² basis, respectively). Discontinuance of [illegible] treatment reversed the effects on male mating [illegible]. In female rats, the precoital period was increased and the mating index reduced at 5 mg/kg/day (2.5 [illegible] the maximum recommended human daily dose on a [illegible] basis). Diestrous was prolonged and estrous delayed [illegible] mg/kg/day (0.6 times the maximum recommended human daily dose on a mg/m² basis); therefore olanzapine may [illegible] delay in ovulation.

[illegible] Category C—In reproduction studies in rats at [illegible] up to 18 mg/kg/day and in rabbits at doses up to 30 [illegible]/day (9 and 30 times the maximum recommended human daily dose on a mg/m² basis, respectively) no evidence [illegible] teratogenicity was observed. In a rat teratology study, [illegible] resorptions and increased numbers of nonviable fetuses were observed at a dose of 18 mg/kg/day (9 times the [illegible] recommended human daily dose on a mg/m² basis). [illegible] was prolonged at 10 mg/kg/day (5 times the [illegible] recommended human daily dose on a mg/m² basis). [illegible] rabbit teratology study, fetal toxicity (manifested [illegible] increased resorptions and decreased fetal weight) occurred at a maternally toxic dose of 30 mg/kg/day (30 times [illegible] maximum recommended human daily dose on a mg/m² [illegible].

[illegible] transfer of olanzapine occurs in rat pups. [illegible] no adequate and well-controlled trials with olanzapine in pregnant females. Seven pregnancies were observed during clinical trials with olanzapine, including 2 resulting in normal births, 1 resulting in neonatal death due [illegible] cardiovascular defect, 3 therapeutic abortions, and 1 [illegible] abortion. Because animal reproduction studies [illegible] always predictive of human response, this drug [illegible] used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

[illegible] Delivery—Parturition in rats was not affected by [illegible]. The effect of olanzapine on labor and delivery in [illegible] unknown.

Nursing Mothers—Olanzapine was excreted in milk of treated rats during lactation. It is not known if olanzapine is excreted in human milk. It is recommended that women receiving olanzapine should not breast-feed.

Pediatric Use—Safety and effectiveness in pediatric patients have not been established.

Geriatric Use—Of the 2500 patients in clinical studies with olanzapine, 11% (263) were 65 years of age or over. In general, there was no indication of any different tolerability of olanzapine in the elderly compared to younger adults. Nevertheless, the presence of factors that might decrease pharmacokinetic clearance or increase the pharmacodynamic response to olanzapine should lead to consideration of a lower starting dose (*see* PRECAUTIONS and DOSAGE AND ADMINISTRATION).

ADVERSE REACTIONS

The premarketing development program for olanzapine included over 3100 patients and/or normal subjects exposed to 1 or more doses of olanzapine. Of these 3100 subjects, 2500 were patients who participated in multiple-dose effectiveness trials, and their experience corresponded to approximately 1122 patient-years. The conditions and duration of treatment with olanzapine varied greatly and included (in overlapping categories) open-label and double-blind phases of studies, inpatients and outpatients, fixed-dose and dose-titration studies, and short-term or longer-term exposure. Adverse reactions were assessed by collecting adverse events, results of physical examinations, vital signs, weights, laboratory analytes, ECGs, chest-x-rays, and results of ophthalmologic examinations.

Adverse events during exposure were obtained by spontaneous report and recorded by clinical investigators using terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping similar types of events into a smaller number of standardized event categories. In the tables and tabulations that follow, standard COSTART dictionary terminology has been used to classify reported adverse events.

The stated frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed. An event was considered treatment emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation.

Adverse Findings Observed in Short-Term, Placebo-Controlled Trials—The following findings are based on a pool of two 6-week, placebo-controlled trials in which mean olanzapine doses ranged from 7-16 mg/day.

Adverse Events Associated with Discontinuation of Treatment in Short-Term, Placebo-Controlled Trials—Overall, there was no difference in the incidence of discontinuation due to adverse events (5% for olanzapine vs 5% for placebo). However, discontinuations due to increases in SGPT were considered to be drug related (2% for olanzapine vs 0% for placebo) (*see* PRECAUTIONS).

Adverse Events Occurring at an Incidence of 1% or More Among Olanzapine-Treated Patients in Short-Term, Placebo-Controlled Trials—Table 1 enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred during acute therapy (up to 6 weeks) of schizophrenia in 1% or more of patients treated with olanzapine (doses ≥2.5 mg/day) where the incidence in patients treated with olanzapine was greater than the incidence in placebo-treated patients.

The prescriber should be aware that the figures in the tables and tabulations cannot be used to predict the incidence of side effects in the course of usual medical practice where patient characteristics and other factors differ from those that prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and nondrug factors to the side effect incidence in the population studied.

Table 1
Treatment-Emergent Adverse Event Incidence in 6-Week Placebo-Controlled Clinical Trials[1]

Body System/Adverse Event	Percentage of Patients Reporting Event: Olanzapine (N=248)	Placebo (N=118)
Body as a Whole		
Headache	17	15
Fever	5	3
Abdominal pain	4	2
Back pain	4	3
Chest pain	4	2
Neck rigidity	2	1
Intentional injury	1	0
Cardiovascular System		
Postural hypotension	5	2
Tachycardia	4	1
Hypotension	2	1
Digestive System		
Constipation	9	3
Dry mouth	7	4
Increased appetite	2	1
Metabolic and Nutritional Disorders		
Weight gain	6	1
Peripheral edema	2	0
Lower extremity edema	1	0
Musculoskeletal System		
Joint pain	5	3
Extremity pain (other than joint)	4	3
Twitching	2	1
Nervous System		
Somnolence	26	15
Agitation	23	17
Insomnia	20	19
Nervousness	16	14
Hostility	15	14
Dizziness	11	4
Anxiety	9	8
Personality disorder[2]	8	4
Akathisia	5	1
Hypertonia	4	3
Tremor	4	3
Amnesia	2	0
Articulation impairment	2	0
Euphoria	2	0
Stuttering	2	0
Respiratory System		
Rhinitis	10	6
Cough increased	5	3
Pharyngitis	5	3
Skin and Appendages		
Vesiculobullous rash	2	1
Special Senses		
Amblyopia	5	4
Blepharitis	2	1
Corneal lesion	1	0
Urogenital System		
Premenstrual syndrome[3]	2	0

[1] Events reported by at least 1% of patients treated with olanzapine, except the following events which had an incidence equal to or less than placebo: abnormal dreams, accidental injury, anorexia, apathy, asthenia, cogwheel rigidity, confusion, conjunctivitis, dental pain, diarrhea, depression, dysmenorrhea[3], dyspepsia, ecchymosis, emotional lability, hallucinations, hyperkinesia, hypertension, hypokinesia, joint stiffness, libido increased, myalgia, nausea, paranoid reaction, paresthesia, pruritus, rash, schizophrenic reaction, sweating, thinking abnormal, tooth caries, vaginitis[3], vomiting.

[2] Personality disorder is the COSTART term for designating non-aggressive objectionable behavior.

[3] Denominator used was for females only (olanzapine, N=41; placebo, N=23).

Commonly Observed Adverse Events in Short-Term, Placebo-Controlled Trials—The most commonly observed adverse events associated with the use of olanzapine (incidence of 5% or greater) and not observed at an equivalent incidence among placebo-treated patients (olanzapine incidence at least twice that for placebo) were:

Common Treatment-Emergent Adverse Events Associated with the Use of Olanzapine in 6-Week Trials

Adverse Event	Percentage of Patients Reporting Event: Olanzapine (N=248)	Placebo (N=118)
Postural hypotension	5	2
Constipation	9	3
Weight gain	6	1
Dizziness	11	4
Personality disorder[1]	8	4
Akathisia	5	1

[1] Personality disorder is the COSTART term for designating non-aggressive objectionable behavior.

Dose Dependency of Adverse Events in Short-Term, Placebo-Controlled Trials—

Extrapyramidal Symptoms: The following table enumerates the percentage of patients with treatment-emergent extra-

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* Identi-Code® symbol. This product information was prepared [illegible]. Current package [illegible] and other products of Eli Lilly and Company may be obtained by direct inquiry to Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, Indiana 46285, (800) 545-5979.

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pyramidal symptoms as assessed by categorical analyses of formal rating scales during acute therapy in a controlled clinical trial comparing olanzapine at 3 fixed doses with placebo in the treatment of schizophrenia.

TREATMENT-EMERGENT EXTRAPYRAMIDAL SYMPTOMS ASSESSED BY RATING SCALES INCIDENCE IN A FIXED DOSAGE RANGE, PLACEBO-CONTROLLED CLINICAL TRIAL—ACUTE PHASE*

	Percentage of Patients			
	Placebo	Olanzapine 5 ± 2.5 mg/day	Olanzapine 10 ± 2.5 mg/day	Olanzapine 15 ± 2.5 mg/day
Parkinsonism[1]	15	14	12	14
Akathisia[2]	23	16	19	27

*No statistically significant differences.
[1] Percentage of patients with a Simpson-Angus Scale total score >3.
[2] Percentage of patients with a Barnes Akathisia Scale global score ≥2.

The following table enumerates the percentage of patients with treatment-emergent extrapyramidal symptoms as assessed by spontaneously reported adverse events during acute therapy in the same controlled clinical trial comparing olanzapine at 3 fixed doses with placebo in the treatment of schizophrenia.

TREATMENT-EMERGENT EXTRAPYRAMIDAL SYMPTOMS ASSESSED BY ADVERSE EVENTS INCIDENCE IN A FIXED DOSAGE RANGE, PLACEBO-CONTROLLED CLINICAL TRIAL—ACUTE PHASE

	Percentage of Patients Reporting Event			
	Placebo (N=68)	Olanzapine 5±2.5 mg/day (N=65)	Olanzapine 10±2.5 mg/day (N=64)	Olanzapine 15±2.5 mg/day (N=69)
Dystonic events[1]	1	3	2	3
Parkinsonism events[2]	10	8	14	20
Akathisia events[3]	1	5	11*	10*
Dyskinetic events[4]	4	0	2	1
Residual events[5]	1	2	5	1
Any extrapyramidal event	16	15	25	32*

*Statistically significantly different from placebo.
[1] Patients with the following COSTART terms were counted in this category: dystonia, generalized spasm, neck rigidity, oculogyric crisis, opisthotonos, torticollis.
[2] Patients with the following COSTART terms were counted in this category: akinesia, cogwheel rigidity, extrapyramidal syndrome, hypertonia, hypokinesia, masked facies, tremor.
[3] Patients with the following COSTART terms were counted in this category: akathisia, hyperkinesia.
[4] Patients with the following COSTART terms were counted in this category: buccoglossal syndrome, choreoathetosis, dyskinesia, tardive dyskinesia.
[5] Patients with the following COSTART terms were counted in this category: movement disorder, myoclonus, twitching.

Other Adverse Events: The following table addresses dose relatedness for other adverse events using data from a trial involving fixed dosage ranges. It enumerates the percentage of patients with treatment-emergent adverse events for the three fixed-dose range groups and placebo. The data were analyzed using the Cochran-Armitage test, excluding the placebo group, and the table includes only those adverse events for which there was a statistically significant trend.

	Percentage of Patients Reporting Event			
Adverse Event	Placebo (N=68)	Olanzapine 5±2.5 mg/day (N=65)	Olanzapine 10±2.5 mg/day (N=64)	Olanzapine 15±2.5 mg/day (N=69)
Asthenia	15	8	9	20
Dry mouth	4	3	5	[illegible]
Nausea	9	0	2	9
Somnolence	16	20	30	39
Tremor	3	0	5	7

Vital Sign Changes—Olanzapine is associated with orthostatic hypotension and tachycardia (*see* PRECAUTIONS).
Weight Gain—In placebo-controlled, 6-week studies, weight gain was reported in 5.6% of olanzapine patients compared to 0.8% of placebo patients. Olanzapine patients gained an average of 2.8 kg, compared to an average 0.4 kg weight loss in placebo patients; 29% of olanzapine patients gained greater than 7% of their baseline weight, compared to 3% of placebo patients. A categorization of patients at baseline on the basis of body mass index (BMI) revealed a significantly greater effect in patients with low BMI compared to normal or overweight patients; nevertheless, weight gain was greater in all 3 olanzapine groups compared to the placebo group. During long-term continuation therapy with olanzapine (238 median days of exposure), 56% of olanzapine patients met the criterion for having gained greater than 7% of their baseline weight. Average weight gain during long-term therapy was 5.4 kg.
Laboratory Changes—An assessment of the premarketing experience for olanzapine revealed an association with asymptomatic increases in SGPT, SGOT, and GGT (*see* PRECAUTIONS). Olanzapine administration was also associated with increases in serum prolactin (*see* PRECAUTIONS), with an asymptomatic elevation of the eosinophil count in 0.3% of patients, and with an increase in CPK.
Given the concern about neutropenia associated with other psychotropic compounds and the finding of leukopenia associated with the administration of olanzapine in several animal models (*see* ANIMAL TOXICOLOGY), careful attention was given to examination of hematologic parameters in premarketing studies with olanzapine. There was no indication of a risk of clinically significant neutropenia associated with olanzapine treatment in the premarketing database for this drug.
ECG Changes—Between-group comparisons for pooled placebo-controlled trials revealed no statistically significant olanzapine/placebo differences in the proportions of patients experiencing potentially important changes in ECG parameters, including QT, QTc, and PR intervals. Olanzapine use was associated with a mean increase in heart rate of 2.4 beats per minute compared to no change among placebo patients. This slight tendency to tachycardia may be related to olanzapine's potential for inducing orthostatic changes (*see* PRECAUTIONS).
Other Adverse Events Observed During the Premarketing Evaluation of Olanzapine—Following is a list of COSTART terms that reflect treatment-emergent adverse events as defined in the introduction to the ADVERSE REACTIONS section reported by patients treated with olanzapine at multiple doses ≥1 mg/day during any phase of a trial within the database of 2500 patients. All reported events are included except those already listed in Table 1 or elsewhere in labeling, those events for which a drug cause was remote, those event terms which were so general as to be uninformative, and events reported only once and which did not have a substantial probability of being acutely life-threatening. It is important to emphasize that, although the events reported occurred during treatment with olanzapine, they were not necessarily caused by it.
Events are further categorized by body system and listed in order of decreasing frequency according to the following definitions: frequent adverse events are those occurring in at least 1/100 patients (only those not already listed in the tabulated results from placebo-controlled trials appear in this listing); infrequent adverse events are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients.
Body as a Whole—*Frequent:* flu syndrome and suicide attempt; *Infrequent:* chills, chills and fever, face edema, hangover effect, malaise, moniliasis, neck pain, pelvic pain, and photosensitivity reaction; *Rare:* abdomen enlarged and sudden death.
Cardiovascular System—*Infrequent:* cerebrovascular accident, hemorrhage, migraine, palpitation, vasodilatation, and ventricular extrasystoles; *Rare:* heart arrest.
Digestive System—*Frequent:* increased salivation, nausea and vomiting, and thirst; *Infrequent:* aphthous stomatitis, dysphagia, eructation, esophagitis, fecal incontinence, flatulence, gastritis, gastroenteritis, gingivitis, glossitis, hepatitis, melena, mouth ulceration, oral moniliasis, peridontal abscess, rectal hemorrhage, stomatitis, and tongue edema; *Rare:* enteritis, esophageal ulcer, and tongue discoloration.
Endocrine System—*Infrequent:* diabetes mellitus and goiter; *Rare:* diabetic acidosis.
Hemic and Lymphatic System—*Infrequent:* cyanosis, leukocytosis, lymphadenopathy, and thrombocythemia.
Metabolic and Nutritional Disorders—*Frequent:* weight loss; *Infrequent:* alkaline phosphatase increased, bilirubinemia, dehydration, hyperglycemia, hyperkalemia, hyperuricemia, hypoglycemia, hypokalemia, hyponatremia, ketosis, and water intoxication; *Rare:* hypercholesteremia and hyperlipemia.
Musculoskeletal System—*Infrequent:* arthritis, back and hip pain, bursitis, leg cramps, myasthenia, and rheumatoid [illegible]

Nervous System—*Frequent:* tardive dyskinesia; *Inf*[illegible] abnormal gait, alcohol misuse, antisocial reaction, [illegible] CNS stimulation, coma, delirium, depersonalizatio[illegible] thesia, hypotonia, incoordination, libido decreased, [illegible] sive compulsive symptoms, phobias, somatization, [illegible] lant misuse, stupor, vertigo, and withdrawal syn[illegible] *Rare:* facial paralysis, neuralgia, nystagmus, and suba[illegible] noid hemorrhage.
Respiratory System—*Frequent:* dyspnea; *Infrequent:* [illegible] asthma, epistaxis, hemoptysis, hyperventilation, and [illegible] alteration; *Rare:* laryngitis.
Skin and Appendages—*Infrequent:* alopecia, conta[illegible] matitis, dry skin, eczema, hirsutism, seborrhea, skin [illegible] and urticaria; *Rare:* maculopapular rash and [illegible] discoloration.
Special Senses—*Infrequent:* cataract, deafness, dip[illegible] dry eyes, ear pain, eye hemorrhage, eye inflamma[illegible] pain, ocular muscle abnormality, taste perversion, and [illegible] nitus; *Rare:* abnormality of accommodation, glaucoma, [illegible] atoconjunctivitis, macular hypopigmentation, mydriasis, and pigment deposits lens.
Urogenital System—*Frequent:* hematuria, metrorrha[illegible] urinary incontinence, and urinary tract infection; *Infre*[illegible] *quent:* abnormal ejaculation*, amenorrhea*, breast [illegible] cystitis, decreased menstruation*, dysuria, increased [illegible] struation*, female lactation, impotence*, menorrha[illegible] polyuria, pyuria, urinary retention, urinary frequency, [illegible] nation impaired, and uterine fibroids enlarged*; *R*[illegible] albuminuria.
*Adjusted for gender.
Postintroduction Reports—Adverse events reported [illegible] market introduction which were temporally (but not nece[illegible] sarily causally) related to ZYPREXA therapy include [illegible] following: priapism.

DRUG ABUSE AND DEPENDENCE

Controlled Substance Class—Olanzapine is not a contr[illegible] substance.
Physical and Psychological Dependence—In studies [illegible] spectively designed to assess abuse and dependence poten[illegible] tial, olanzapine was shown to have acute depressive [illegible] effects but little or no potential of abuse or physical depen[illegible] dence in rats administered oral doses up to 15 times [illegible] maximum recommended human daily dose (20 mg) and [illegible] sus monkeys administered oral doses up to 8 times the max[illegible] imum recommended human daily dose on a mg/m^2 basis. Olanzapine has not been systematically studied in humans for its potential for abuse, tolerance, or physical depend[illegible] ence. While the clinical trials did not reveal any tendency for any drug-seeking behavior, these observations were not systematic, and it is not possible to predict on the basis of this limited experience the extent to which a CNS-active drug will be misused, diverted, and/or abused once mar[illegible] keted. Consequently, patients should be evaluated carefully for a history of drug abuse, and such patients should be ob[illegible] served closely for signs of misuse or abuse of olanzapine (e.g., development of tolerance, increases in dose, drug-seeking behavior).

OVERDOSAGE

Human Experience—In premarketing trials involving more than 3100 patients and/or normal subjects, accidental or in[illegible] tentional acute overdosage of olanzapine was identified in 67 patients. In the patient taking the largest identified amount, 300 mg, the only symptoms reported were drowsi[illegible] ness and slurred speech. In the limited number of patients who were evaluated in hospitals, including the patient tak[illegible] ing 300 mg, there were no observations indicating an ad[illegible] verse change in laboratory analytes or ECG. Vital signs were usually within normal limits following overdose[illegible]
Overdosage Management—The possibility of multiple [illegible] involvement should be considered. In case of acute overdos[illegible] age, establish and maintain an airway and ensure adequate oxygenation and ventilation. Gastric lavage (after intuba[illegible] tion, if patient is unconscious) and administration of acti[illegible] vated charcoal together with a laxative should be consid[illegible] ered. The possibility of obtundation, seizures, or dystonic re[illegible] action of the head and neck following overdose may create a risk of aspiration with induced emesis. Cardiovascular mon[illegible] itoring should commence immediately and should include continuous electrocardiographic monitoring to detect possi[illegible] ble arrhythmias.
There is no specific antidote to olanzapine. Therefore, ap[illegible] propriate supportive measures should be initiated. Hypo[illegible] tension and circulatory collapse should be treated with ap[illegible] propriate measures such as intravenous fluids and/or sym[illegible] pathomimetic agents. (Do not use epinephrine, dopamine, or other sympathomimetics with beta-agonist activity, since beta stimulation may worsen hypotension in the setting of olanzapine-induced alpha blockade.) Close medical supervi[illegible] sion and monitoring should continue until the patient recovers.

DOSAGE AND ADMINISTRATION

Usual Dose—Olanzapine should be administered on a once-a-day schedule without regard to meals, generally begin[illegible] ning with 5 to 10 mg initially, with a target dose of 10 mg/day within several days. Further dosage adjustments, if in[illegible] dicated, should generally occur at intervals of not less than 1 week, since steady state for olanzapine would not be achieved for approximately 1 week in the typical patient. When dosage adjustments are necessary, dose increments/decrements of 5 mg QD are recommended.
Antipsychotic efficacy was demonstrated in a dose range of 10 to 15 mg/day in clinical trials. However, doses above 10 mg/day were not demonstrated to be more efficacious [illegible]

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... mg/day dose. An increase to a dose greater than the ... dose of 10 mg/day (i.e., to a dose of 15 mg/day or ...) is recommended only after clinical assessment. The ... of doses above 20 mg/day has not been evaluated in ... trials.

... in Special Populations—The recommended starting ... is 5 mg in patients who are debilitated, who have a ... to hypotensive reactions, who otherwise ex... combination of factors that may result in slower me... of olanzapine (e.g., nonsmoking female patients ... years of age), or who may be more pharmacodynami... sensitive to olanzapine (see CLINICAL PHARMACOL... also see Use in Patients with Concomitant Illness and ... Interactions under PRECAUTIONS). When indicated, ... escalation should be performed with caution in these patients.

... Treatment—While there is no body of evidence ... to answer the question of how long the patient ... with olanzapine should remain on it, the effective... maintenance treatment is well established for many ... antipsychotic drugs. It is recommended that respond... patients be continued on olanzapine, but at the lowest ... needed to maintain remission. Patients should be pe... reassessed to determine the need for maintenance treatment.

... SUPPLIED

... tablets are white, round, film-coated, and imprinted in ... with LILLY and the tablet number. They are available as:

[illegible]	TABLET STRENGTH			
	2.5 mg	5 mg	7.5 mg	10 mg
[illegible]	4112	4115	4116	4117
[illegible]	LILLY 4112	LILLY 4115	LILLY 4116	LILLY 4117
... Codes: ... 60	NDC-0002-4112-60	NDC-0002-4115-60	NDC-0002-4116-60	NDC-0002-4117-60
... ID*	—	NDC-0002-4115-33	NDC-0002-4116-33	NDC-0002-4117-33

... Dose® (unit dose medication, Lilly)

... at controlled room temperature, 20° to 25°C (68° to ...F) [see USP]. The USP defines controlled room tempera... a temperature maintained thermostatically that en... the usual and customary working environment ... to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that ... excursions between 15° and 30°C (59° and 86°F) ... experienced in pharmacies, hospitals, and ...

... from light and moisture.

ANIMAL TOXICOLOGY

... studies with olanzapine, the principal hemato... findings were reversible peripheral cytopenias in indi... dogs dosed at 10 mg/kg (17 times the maximum rec... human daily dose on a mg/m^2 basis), dose-... decreases in lymphocytes and neutrophils in mice, ... lymphopenia in rats. A few dogs treated with 10 mg/kg ... reversible neutropenia and/or reversible hemo... between 1 and 10 months of treatment. Dose-... decreases in lymphocytes and neutrophils were seen ... doses of 10 mg/kg (equal to 2 times the max... recommended human daily dose on a mg/m^2 basis) in ... months' duration. Nonspecific lymphopenia, ... decreased body weight gain, occurred in rats ... mg/kg (11 times the maximum recommended ... daily dose on a mg/m^2 basis) for 3 months or 16 ... times the maximum recommended human daily ... mg/m^2 basis) for 6 or 12 months. No evidence of ... cytotoxicity was found in any of the species ... Bone marrows were normocellular or hypercellu... suggesting that the reductions in circulating blood cells ... probably due to peripheral (non-marrow) factors).

... revised November 19, 1998

... by Eli Lilly Industries, Inc.
... Puerto Rico 00985, a subsidiary of
... Company, Indianapolis, IN, USA

[111998]

... in Product Identification Guide, page 321

EDUCATIONAL MATERIALS

... Patient Education Materials
... Your Diabetes™ Patient Education System
... English and Spanish)
... workbook on diabetes self-care and basic ...
... on selected topics (e.g., meal planning, exer... gestational, injecting insulin)
... series
... planning guides
... diaries
... Education Materials and Services
...

◊ Professional slide series

For information on these and other educational materials, see your Lilly sales representative.

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(609) 452-7060 or
(800) 335-5476
FAX: (609) 452-8512

ABELCET® ℞
['ā-bəl- "set]
(Amphotericin B Lipid Complex Injection)

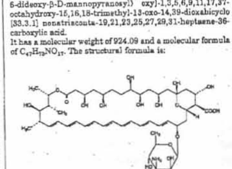
DESCRIPTION

ABELCET® is a sterile, pyrogen-free suspension for intravenous infusion. ABELCET® consists of amphotericin B complexed with two phospholipids in a 1:1 drug-to-lipid molar ratio. The two phospholipids, L-α-dimyristoylphosphatidylcholine (DMPC) and L-α-dimyristoylphosphatidylglycerol (DMPG), are present in a 7:3 molar ratio. ABELCET® is yellow and opaque in appearance, with a pH of 5–7.

NOTE: Liposomal encapsulation or incorporation in a lipid complex can substantially affect a drug's functional properties relative to those of the unencapsulated or nonlipid-associated drug. In addition, different liposomal or lipid-complexed products with a common active ingredient may vary from one another in the chemical composition and physical form of the lipid component. Such differences may affect functional properties of these drug products.

Amphotericin B is a polyene, antifungal antibiotic produced from a strain of *Streptomyces nodosus*. Amphotericin B is designated chemically as [1R-(1R*, 3S*, 5R*, 6R*, 9R*, 11R*, 15S*, 16R*, 17R*, 18S*, 19E, 21E, 23E, 25E, 27E, 29E, 31E, 33R*, 35S*, 36R*, 37S*)]-33-[(3-Amino-3, 6-dideoxy-β-D-mannopyranosyl) oxy]-1,3,5,6,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxabicyclo [33.3.1] nonatriaconta-19,21,23,25,27,29,31-heptaene-36-carboxylic acid.

It has a molecular weight of 924.09 and a molecular formula of $C_{47}H_{73}NO_{17}$. The structural formula is:



ABELCET® is provided as a sterile, opaque suspension in 20 mL glass, single-use vials. Each vial of ABELCET® contains 100 mg of amphotericin B (see DOSAGE AND ADMINISTRATION), and each mL of ABELCET® contains:

Amphotericin B USP	5 mg
L-α-dimyristoylphosphatidylcholine (DMPC)	3.4 mg
L-α-dimyristoylphosphatidylglycerol (DMPG)	1.5 mg
Sodium Chloride USP	9 mg
Water for Injection USP, q.s. 1 mL	

MICROBIOLOGY

Mechanism of Action

The active component of ABELCET®, amphotericin B, acts by binding to sterols in the cell membrane of susceptible fungi, with a resultant change in the permeability of the membrane. Mammalian cell membranes also contain sterols, and damage to human cells is believed to occur through the same mechanism of action.

Activity *in vitro* and *in vivo*

ABELCET® shows *in vitro* activity against *Aspergillus* sp. (n=3) and *Candida* sp. (n=10), with MICs generally <1 μg/mL. Depending upon the species and strain of *Aspergillus* and *Candida* tested, significant *in vitro* differences in susceptibility to amphotericin B have been reported (MICs ranging from 0.1 to >10 μg/mL). However, standardized techniques for susceptibility testing for antifungal agents have not been established, and results of susceptibility studies do not necessarily correlate with clinical outcome. ABELCET® is active in animal models against *Aspergillus fumigatus*, *Candida albicans*, *C. guilliermondii*, *C. stellatoidea*, and *C. tropicalis*, *Cryptococcus sp.*, *Coccidioidomyces sp.*, *Histoplasma sp.*, and *Blastomyces sp.* in which end-points were clearance of microorganisms from target or...

Drug Resistance

Fungal species with decreased susceptibility to amphotericin B have been isolated after serial passage in culture media containing the drug, and from some patients receiving prolonged therapy. Although the relevance of drug resistance to clinical outcome has not been established, fungal species which are resistant to amphotericin B may also be resistant to ABELCET®.

CLINICAL PHARMACOLOGY

Pharmacokinetics

The assay used to measure amphotericin B in the blood after the administration of ABELCET® does not distinguish amphotericin B that is complexed with the phospholipids of ABELCET® from amphotericin B that is uncomplexed.

The pharmacokinetics of amphotericin B after the administration of ABELCET® are nonlinear. Volume of distribution and clearance from blood increase with increasing dose of ABELCET®, resulting in less than proportional increases in blood concentrations of amphotericin B over a dose range of 0.6–5 mg/kg/day. The pharmacokinetics of amphotericin B in whole blood after the administration of ABELCET® and amphotericin B desoxycholate are:

[See table at top of next page]

The large volume of distribution and high clearance from blood of amphotericin B after the administration of ABELCET® probably reflect uptake by tissues. The long terminal elimination half-life probably reflects a slow redistribution from tissues. Although amphotericin B is excreted slowly, there is little accumulation in the blood after repeated dosing. AUC of amphotericin B increased approximately 34% from day 1 after the administration of ABELCET® 5 mg/kg/day for 7 days. The effect of gender or ethnicity on the pharmacokinetics of ABELCET® has not been studied.

Tissue concentrations of amphotericin B have been obtained at autopsy from one heart transplant patient who received three doses of ABELCET® at 5.3 mg/kg/day:

Concentration In Human Tissues

Organ	Amphotericin B Tissue Concentration (μg/g)
Spleen	290
Lung	222
Liver	196
Lymph Node	7.6
Kidney	6.9
Heart	5
Brain	1.6

This pattern of distribution is consistent with that observed in preclinical studies in dogs in which greatest concentrations of amphotericin B after ABELCET® administration were observed in the liver, spleen, and lung; however, the relationship of tissue concentrations of amphotericin B to its biological activity when administered as ABELCET® is unknown.

Special Populations

Hepatic Impairment: The effect of hepatic impairment on the disposition of ABELCET® is not known.

Renal Impairment: The effect of renal impairment on the disposition of ABELCET® is not known. The effect of dialysis on the elimination of ABELCET® has not been studied; however, amphotericin B is not removed by hemodialysis when administered as amphotericin B desoxycholate.

Pediatric and Elderly Patients: The pharmacokinetics and pharmacodynamics of pediatric patients (≤16 years of age) and elderly patients (≥65 years of age) have not been studied.

INDICATIONS AND USAGE

ABELCET® is indicated for the treatment of invasive fungal infections in patients who are refractory to or intolerant of conventional amphotericin B therapy. This is based on open-label treatment of patients judged by their physicians to be intolerant to or failing conventional amphotericin B therapy (See DESCRIPTION OF CLINICAL STUDIES).

DESCRIPTION OF CLINICAL STUDIES

Fungal Infections

Data from 473 patients were pooled from three open-label studies in which ABELCET® was provided for the treatment of patients with invasive fungal infections who were judged by their physicians to be refractory to or intolerant of conventional amphotericin B, or who had preexisting nephrotoxicity. Results of these studies demonstrated effectiveness of ABELCET® in the treatment of invasive fungal infections as a second line therapy.

Patients were defined by their individual physician as being refractory to or failing conventional amphotericin B therapy based on overall clinical judgement after receiving a minimum total dose of 500 mg of amphotericin B. Nephrotoxicity was defined as a serum creatinine that had increased to >2.5 mg/dL in adults and >1.5 mg/dL in pediatric patients, or a creatinine clearance of <25 mL/min while receiving conventional amphotericin B therapy.

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21 C.F.R. § 201.57

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Effective: June 30, 2006

Code of Federal Regulations Currentness
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter C. Drugs: General
Part 201. Labeling (Refs & Annos)
Subpart B. Labeling Requirements for Prescription Drugs and/or Insulin

→§ 201.57 Specific requirements on content and format of labeling for human prescription drug and biological products described in § 201.56(b)(1).

The requirements in this section apply only to prescription drug products described in § 201.56(b)(1) and must be implemented according to the schedule specified in § 201.56(c), except for the requirement in paragraph (c)(18) of this section to reprint any FDA-approved patient labeling at the end of prescription drug labeling or accompany the prescription drug labeling, which must be implemented no later than June 30, 2007.

(a) Highlights of prescribing information. The following information must appear in all prescription drug labeling:

(1) Highlights limitation statement. The verbatim statement "These highlights do not include all the information needed to use (insert name of drug product) safely and effectively. See full prescribing information for (insert name of drug product)."

(2) Drug names, dosage form, route of administration, and controlled substance symbol. The proprietary name and the established name of the drug, if any, as defined in section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act (the act) or, for biological products, the proper name (as defined in § 600.3 of this chapter) including any appropriate descriptors. This information must be followed by the drug's dosage form and route of administration. For controlled substances, the controlled substance symbol designating the schedule in which the controlled substance is listed must be included as required by § 1302.04 of this chapter.

(3) Initial U.S. approval. The verbatim statement "Initial U.S. Approval" followed by the four-digit year in which FDA initially approved a new molecular entity, new biological product, or new combination of active ingredients. The statement must be placed on the line immediately beneath the established name or, for biological products, proper name of the product.

(4) Boxed warning. A concise summary of any boxed warning required by paragraph (c)(1) of this section, not to exceed a length of 20 lines. The summary must be preceded by a heading, in upper-case letters, containing the word "WARNING" and other words that are appropriate to identify the subject of the warning. The heading and the summary must be contained within a box and bolded. The following verbatim statement must be placed immediately following the heading of the boxed warning: "See full prescribing information for complete boxed warning."

(5) Recent major changes. A list of the section(s) of the full prescribing information, limited to the labeling sections described in paragraphs (c)(1), (c)(2), (c)(3), (c)(5), and (c)(6) of this section, that contain(s) substantive labeling changes that have been approved by FDA or authorized under § 314.70(c)(6) or (d)(2), or § 601.12(f)(1) through (f)(3) of this chapter. The heading(s) and, if appropriate, the subheading(s) of the labeling section(s) af-

fected by the change must be listed together with each section's identifying number and the date (month/year) on which the change was incorporated in labeling. These labeling sections must be listed in the order in which they appear in the full prescribing information. A changed section must be listed under this heading in Highlights for at least 1 year after the date of the labeling change and must be removed at the first printing subsequent to the 1 year period.

(6) Indications and usage. A concise statement of each of the product's indications, as required under paragraph (c)(2) of this section, with any appropriate subheadings. Major limitations of use (e.g., lack of effect in particular subsets of the population, or second line therapy status) must be briefly noted. If the product is a member of an established pharmacologic class, the concise statement under this heading in Highlights must identify the class in the following manner: "(Drug) is a (name of class) indicated for (indication(s))."

(7) Dosage and administration. A concise summary of the information required under paragraph (c)(3) of this section, with any appropriate subheadings, including the recommended dosage regimen, starting dose, dose range, critical differences among population subsets, monitoring recommendations, and other clinically significant clinical pharmacologic information.

(8) Dosage forms and strengths. A concise summary of the information required under paragraph (c)(4) of this section, with any appropriate subheadings (e.g., tablets, capsules, injectable, suspension), including the strength or potency of the dosage form in metric system (e.g., 10-milligram tablets) and whether the product is scored.

(9) Contraindications. A concise statement of each of the product's contraindications, as required under paragraph (c)(5) of this section, with any appropriate subheadings.

(10) Warnings and precautions. A concise summary of the most clinically significant information required under paragraph (c)(6) of this section, with any appropriate subheadings, including information that would affect decisions about whether to prescribe a drug, recommendations for patient monitoring that are critical to safe use of the drug, and measures that can be taken to prevent or mitigate harm.

(11) Adverse reactions.

(i) A list of the most frequently occurring adverse reactions, as described in paragraph (c)(7) of this section, along with the criteria used to determine inclusion (e.g., incidence rate). Adverse reactions important for other reasons (e.g., because they are serious or frequently lead to discontinuation or dosage adjustment) must not be repeated under this heading in Highlights if they are included elsewhere in Highlights (e.g., Warnings and Precautions, Contraindications).

(ii) For drug products other than vaccines, the verbatim statement "To report SUSPECTED ADVERSE REACTIONS, contact (insert name of manufacturer) at (insert manufacturer's phone number) or FDA at (insert current FDA phone number and Web address for voluntary reporting of adverse reactions)."

(iii) For vaccines, the verbatim statement "To report SUSPECTED ADVERSE REACTIONS, contact (insert name of manufacturer) at (insert manufacturer's phone number) or VAERS at (insert the current VAERS phone number and Web address for voluntary reporting of adverse reactions)."

(iv) For manufacturers with a Web site for voluntary reporting of adverse reactions, the Web address of the direct link to the site.

(12) Drug interactions. A concise summary of

the information required under paragraph (c)(8) of this section, with any appropriate subheadings.

(13) Use in specific populations. A concise summary of the information required under paragraph (c)(9) of this section, with any appropriate subheadings.

(14) Patient counseling information statement. The verbatim statement "See 17 for Patient Counseling Information" or, if the product has FDA-approved patient labeling, the verbatim statement "See 17 for Patient Counseling Information and (insert either FDA-approved patient labeling or Medication Guide)."

(15) Revision date. The date of the most recent revision of the labeling, identified as such, placed at the end of Highlights.

(b) Full prescribing information: Contents. Contents must contain a list of each heading and subheading required in the full prescribing information under § 201.56(d)(1), if not omitted under § 201.56(d)(4), preceded by the identifying number required under § 201.56(d)(1). Contents must also contain any additional subheading(s) included in the full prescribing information preceded by the identifying number assigned in accordance with § 201.56(d)(2).

(c) Full prescribing information. The full prescribing information must contain the information in the order required under paragraphs (c)(1) through (c)(18) of this section, together with the headings, subheadings, and identifying numbers required under § 201.56(d)(1), unless omitted under § 201.56(d)(4). If additional subheadings are used within a labeling section, they must be preceded by the identifying number assigned in accordance with § 201.56(d)(2).

(1) Boxed warning. Certain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box. The boxed warning ordinarily must be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. The box must contain, in uppercase letters, a heading inside the box that includes the word "WARNING" and conveys the general focus of the information in the box. The box must briefly explain the risk and refer to more detailed information in the "Contraindications" or "Warnings and Precautions" section, accompanied by the identifying number for the section or subsection containing the detailed information.

(2) Indications and usage. This section must state that the drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a recognized disease or condition.

(i) This section must include the following information when the conditions listed are applicable:

(A) If the drug is used for an indication only in conjunction with a primary mode of therapy (e.g., diet, surgery, behavior changes, or some other drug), a statement that the drug is indicated as an adjunct to that mode of therapy.

(B) If evidence is available to support the safety and effectiveness of the drug or biological product only in selected subgroups of the larger population (e.g., patients with mild disease or patients in a special age group), or if the indication is approved based on a surrogate endpoint under § 314.510 or § 601.41 of this chapter, a succinct description of the limitations of usefulness of the drug and any uncertainty about anticipated clinical benefits, with reference to the "Clinical Studies" section

for a discussion of the available evidence.

(C) If specific tests are necessary for selection or monitoring of the patients who need the drug (e.g., microbe susceptibility tests), the identity of such tests.

(D) If information on limitations of use or uncertainty about anticipated clinical benefits is relevant to the recommended intervals between doses, to the appropriate duration of treatment when such treatment should be limited, or to any modification of dosage, a concise description of the information with reference to the more detailed information in the "Dosage and Administration" section.

(E) If safety considerations are such that the drug should be reserved for specific situations (e.g., cases refractory to other drugs), a statement of the information.

(F) If there are specific conditions that should be met before the drug is used on a long term basis (e.g., demonstration of responsiveness to the drug in a short term trial in a given patient), a statement of the conditions; or, if the indications for long term use are different from those for short term use, a statement of the specific indications for each use.

(ii) If there is a common belief that the drug may be effective for a certain use or if there is a common use of the drug for a condition, but the preponderance of evidence related to the use or condition shows that the drug is ineffective or that the therapeutic benefits of the product do not generally outweigh its risks, FDA may require that this section state that there is a lack of evidence that the drug is effective or safe for that use or condition.

(iii) Any statements comparing the safety or effectiveness of the drug with other agents for the same indication must, except for biological products, be supported by substantial evidence derived from adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless this requirement is waived under § 201.58 or § 314.126(c) of this chapter. For biological products, such statements must be supported by substantial evidence.

(iv) For drug products other than biological products, all indications listed in this section must be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless the requirement is waived under § 201.58 or § 314.126(c) of this chapter. Indications or uses must not be implied or suggested in other sections of the labeling if not included in this section.

(v) For biological products, all indications listed in this section must be supported by substantial evidence of effectiveness. Indications or uses must not be implied or suggested in other sections of the labeling if not included in this section.

(3) 2 Dosage and administration.

(i) This section must state the recommended dose and, as appropriate:

(A) The dosage range,

(B) An upper limit beyond which safety and effectiveness have not been established, or beyond which increasing the dose does not result in increasing effectiveness,

(C) Dosages for each indication and subpopulation,

(D) The intervals recommended between doses,

(E) The optimal method of titrating

dosage,

(F) The usual duration of treatment when treatment duration should be limited,

(G) Dosing recommendations based on clinical pharmacologic data (e.g., clinically significant food effects),

(H) Modification of dosage needed because of drug interactions or in special patient populations (e.g., in children, in geriatric age groups, in groups defined by genetic characteristics, or in patients with renal or hepatic disease),

(I) Important considerations concerning compliance with the dosage regimen,

(J) Efficacious or toxic concentration ranges and therapeutic concentration windows of the drug or its metabolites, if established and clinically significant. Information on therapeutic drug concentration monitoring (TDM) must also be included in this section when TDM is necessary.

(ii) Dosing regimens must not be implied or suggested in other sections of the labeling if not included in this section.

(iii) Radiation dosimetry information must be stated for both the patient receiving a radioactive drug and the person administering it.

(iv) This section must also contain specific direction on dilution, preparation (including the strength of the final dosage solution, when prepared according to instructions, in terms of milligrams of active ingredient per milliliter of reconstituted solution, unless another measure of the strength is more appropriate), and administration of the dosage form, if needed (e.g., the rate of administration of parenteral drug in milligrams per minute; storage conditions for stability of the reconstituted drug, when important; essential information on drug incompatibilities if the drug is mixed in vitro with other drugs or diluents; and the following verbatim statement for parenterals: "Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.")

(4) 3 Dosage forms and strengths. This section must contain information on the available dosage forms to which the labeling applies and for which the manufacturer or distributor is responsible, including:

(i) The strength or potency of the dosage form in metric system (e.g., 10 milligram tablets), and, if the apothecary system is used, a statement of the strength in parentheses after the metric designation; and

(ii) A description of the identifying characteristics of the dosage forms, including shape, color, coating, scoring, and imprinting, when applicable. The National Drug Code number(s) for the drug product must not be included in this section.

(5) 4 Contraindications. This section must describe any situations in which the drug should not be used because the risk of use (e.g., certain potentially fatal adverse reactions) clearly outweighs any possible therapeutic benefit. Those situations include use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by the drug and for whom no potential benefit makes the risk acceptable. Known hazards and not theoretical possibilities must be listed (e.g., if severe hypersensitivity to the drug has not been demonstrated, it should not be listed as a contraindication). If no contraindications are known, this section must state "None."

(6) 5 Warnings and precautions.

(i) General. This section must describe clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug), other potential safety hazards (including those that are expected for the pharmacological class or those resulting from drug/drug interactions), limitations in use imposed by them (e.g., avoiding certain concomitant therapy), and steps that should be taken if they occur (e.g., dosage modification). The frequency of all clinically significant adverse reactions and the approximate mortality and morbidity rates for patients experiencing the reaction, if known and necessary for the safe and effective use of the drug, must be expressed as provided under paragraph (c)(7) of this section. In accordance with §§ 314.70 and 601.12 of this chapter, the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established. A specific warning relating to a use not provided for under the "Indications and Usage" section may be required by FDA in accordance with sections 201(n) and 502(a) of the act if the drug is commonly prescribed for a disease or condition and such usage is associated with a clinically significant risk or hazard.

(ii) Other special care precautions. This section must contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug (e.g., precautions not required under any other specific section or subsection).

(iii) Monitoring: Laboratory tests. This section must identify any laboratory tests helpful in following the patient's response or in identifying possible adverse reactions. If appropriate, information must be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be performed before, during, and after therapy.

(iv) Interference with laboratory tests. This section must briefly note information on any known interference by the product with laboratory tests and reference the section where the detailed information is presented (e.g., "Drug Interactions" section).

(7) 6 Adverse reactions. This section must describe the overall adverse reaction profile of the drug based on the entire safety database. For purposes of prescription drug labeling, an adverse reaction is an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence. This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.

(i) Listing of adverse reactions. This section must list the adverse reactions that occur with the drug and with drugs in the same pharmacologically active and chemically related class, if applicable. The list or lists must be preceded by the information necessary to interpret the adverse reactions (e.g., for clinical trials, total number exposed, extent and nature of exposure).

(ii) Categorization of adverse reactions. Within a listing, adverse reactions must be categorized by body system, by severity of the reaction, or in order of decreasing frequency, or by a combination of these, as appropriate. Within a category, adverse reactions must be listed in decreasing order of frequency. If frequency information cannot be reliably determined, adverse reactions must be listed in decreasing order of severity.

(A) Clinical trials experience. This section must list the adverse reactions identified in clinical trials that occurred at or above a specified rate appropriate to the safety database. The rate of occurrence of an adverse reaction for the drug and comparators (e.g., placebo) must be presented, unless such data cannot be determined or presentation of comparator rates would be misleading. If adverse reactions that occurred below the specified rate are included, they must be included in a separate listing. If comparative rates of occurrence cannot be reliably determined (e.g., adverse reactions were observed only in the uncontrolled trial portion of the overall safety database), adverse reactions must be grouped within specified frequency ranges as appropriate to the safety database for the drug (e.g., adverse reactions occurring at a rate of less than 1/100, adverse reactions occurring at a rate of less than 1/500) or descriptively identified, if frequency ranges cannot be determined. For adverse reactions with significant clinical implications, the listings must be supplemented with additional detail about the nature, frequency, and severity of the adverse reaction and the relationship of the adverse reaction to drug dose and demographic characteristics, if data are available and important.

(B) Postmarketing experience. This section of the labeling must list the adverse reactions, as defined in paragraph (c)(7) of this section, that are identified from domestic and foreign spontaneous reports. This listing must be separate from the listing of adverse reactions identified in clinical trials.

(iii) Comparisons of adverse reactions between drugs. For drug products other than biological products, any claim comparing the drug to which the labeling applies with other drugs in terms of frequency, severity, or character of adverse reactions must be based on adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless this requirement is waived under § 201.58 or § 314.126(c) of this chapter. For biological products, any such claim must be based on substantial evidence.

(8) 7 Drug interactions.

(i) This section must contain a description of clinically significant interactions, either observed or predicted, with other prescription or over-the-counter drugs, classes of drugs, or foods (e.g., dietary supplements, grapefruit juice), and specific practical instructions for preventing or managing them. The mechanism(s) of the interaction, if known, must be briefly described. Interactions that are described in the "Contraindications" or "Warnings and Precautions" sections must be discussed in more detail under this section. Details of drug interaction pharmacokinetic studies that are included in the "Clinical Pharmacology" section that are pertinent to clinical use of the drug must not be repeated in this section.

(ii) This section must also contain practical guidance on known interference of the drug with laboratory tests.

(9) 8 Use in specific populations. This section must contain the following subsections:

(i) 8.1 Pregnancy. This subsection may be omitted only if the drug is not absorbed systemically and the drug is not known to have a potential for indirect harm to the fetus. For all other drugs, this subsection must contain the following information:

(A) Teratogenic effects. Under this subheading, the labeling must identify one of the following categories that applies to the drug, and the labeling must bear the state-

ment required under the category:

(1) Pregnancy category A. If adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of a risk in later trimesters), the labeling must state: "Pregnancy Category A. Studies in pregnant women have not shown that (name of drug) increases the risk of fetal abnormalities if administered during the first (second, third, or all) trimester(s) of pregnancy. If this drug is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, however, (name of drug) should be used during pregnancy only if clearly needed." The labeling must also contain a description of the human studies. If animal reproduction studies are also available and they fail to demonstrate a risk to the fetus, the labeling must also state: "Reproduction studies have been performed in (kinds of animal(s)) at doses up to (x) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to (name of drug)." The labeling must also contain a description of available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(2) Pregnancy category B. If animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women, the labeling must state: "Pregnancy Category B. Reproduction studies have been performed in (kind(s) of animal(s)) at doses up to (x) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to (name of drug). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed." If animal reproduction studies have shown an adverse effect (other than decrease in fertility), but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus during the first trimester of pregnancy (and there is no evidence of a risk in later trimesters), the labeling must state: "Pregnancy Category B. Reproduction studies in (kind(s) of animal(s)) have shown (describe findings) at (x) times the human dose. Studies in pregnant women, however, have not shown that (name of drug) increases the risk of abnormalities when administered during the first (second, third, or all) trimester(s) of pregnancy. Despite the animal findings, it would appear that the possibility of fetal harm is remote, if the drug is used during pregnancy. Nevertheless, because the studies in humans cannot rule out the possibility of harm, (name of drug) should be used during pregnancy only if clearly needed." The labeling must also contain a description of the human studies and a description of available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(3) Pregnancy category C. If animal reproduction studies have shown an adverse effect on the fetus, if there are no adequate and well-controlled stud-

ies in humans, and if the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks, the labeling must state: "Pregnancy Category C. (Name of drug) has been shown to be teratogenic (or to have an embryocidal effect or other adverse effect) in (name(s) of species) when given in doses (x) times the human dose. There are no adequate and well-controlled studies in pregnant women. (Name of drug) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus." The labeling must contain a description of the animal studies. If there are no animal reproduction studies and no adequate and well-controlled studies in humans, the labeling must state: "Pregnancy Category C. Animal reproduction studies have not been conducted with (name of drug). It is also not known whether (name of drug) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. (Name of drug) should be given to a pregnant woman only if clearly needed." The labeling must contain a description of any available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(4) Pregnancy category D. If there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective), the labeling must state: "Pregnancy Category D. See 'Warnings and Precautions' section." Under the "Warnings and Precautions" section, the labeling must state: "(Name of drug) can cause fetal harm when administered to a pregnant woman. (Describe the human data and any pertinent animal data.) If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus."

(5) Pregnancy category X. If studies in animals or humans have demonstrated fetal abnormalities or if there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available), the labeling must state: "Pregnancy Category X. See 'Contraindications' section." Under "Contraindications," the labeling must state: "(Name of drug) may (can) cause fetal harm when administered to a pregnant woman. (Describe the human data and any pertinent animal data.) (Name of drug) is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus."

(B) Nonteratogenic effects. Under this subheading the labeling must contain other information on the drug's effects on reproduction and the drug's use during preg-

nancy that is not required specifically by one of the pregnancy categories, if the information is relevant to the safe and effective use of the drug. Information required under this heading must include nonteratogenic effects in the fetus or newborn infant (for example, withdrawal symptoms or hypoglycemia) that may occur because of a pregnant woman's chronic use of the drug for a preexisting condition or disease.

(ii) 8.2 Labor and delivery. If the drug has a recognized use during labor or delivery (vaginal or abdominal delivery), whether or not the use is stated in the Indications and Usage section, this subsection must describe the available information about the effect of the drug on the mother and the fetus, on the duration of labor or delivery, on the possibility that forceps delivery or other intervention or resuscitation of the newborn will be necessary, and the effect of the drug on the later growth, development, and functional maturation of the child. If any information required under this subsection is unknown, it must state that the information is unknown.

(iii) 8.3 Nursing mothers.

(A) If a drug is absorbed systemically, this subsection must contain, if known, information about excretion of the drug in human milk and effects on the nursing infant. Pertinent adverse effects observed in animal offspring must be described.

(B) If a drug is absorbed systemically and is known to be excreted in human milk, this subsection must contain one of the following statements, as appropriate. If the drug is associated with serious adverse reactions or if the drug has a known tumorigenic potential, the labeling must state: "Because of the potential for serious adverse reactions in nursing infants from (name of drug) (or, "Because of the potential for tumorigenicity shown for (name of drug) in (animal or human) studies), a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother." If the drug is not associated with serious adverse reactions and does not have a known tumorigenic potential, the labeling must state: "Caution should be exercised when (name of drug) is administered to a nursing woman."

(C) If a drug is absorbed systemically and information on excretion in human milk is unknown, this subsection must contain one of the following statements, as appropriate. If the drug is associated with serious adverse reactions or has a known tumorigenic potential, the labeling must state: "It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from (name of drug) (or, "Because of the potential for tumorigenicity shown for (name of drug) in (animal or human) studies), a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother." If the drug is not associated with serious adverse reactions and does not have a known tumorigenic potential, the labeling must state: "It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when (name of drug) is administered to a nursing woman."

(iv) 8.4 Pediatric use.

(A) Pediatric population(s)/pediatric patient(s): For the purposes of paragraphs (c)(9)(iv)(B) through (c)(9)(iv)(H) of this section, the terms pediatric population(s) and pediatric patient(s) are defined as the

pediatric age group, from birth to 16 years, including age groups often called neonates, infants, children, and adolescents.

(B) If there is a specific pediatric indication different from those approved for adults that is supported by adequate and well-controlled studies in the pediatric population, it must be described under the "Indications and Usage" section, and appropriate pediatric dosage information must be given under the "Dosage and Administration" section. The "Pediatric use" subsection must cite any limitations on the pediatric indication, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug. Data summarized in this subsection should be discussed in more detail, if appropriate, under the "Clinical Pharmacology" or "Clinical Studies" section. As appropriate, this information must also be contained in the "Contraindications" and/or "Warnings and Precautions" section(s).

(C) If there are specific statements on pediatric use of the drug for an indication also approved for adults that are based on adequate and well-controlled studies in the pediatric population, they must be summarized in the "Pediatric use" subsection and discussed in more detail, if appropriate, under the "Clinical Pharmacology" and "Clinical Studies" sections. Appropriate pediatric dosage must be given under the "Dosage and Administration" section. The "Pediatric use" subsection of the labeling must also cite any limitations on the pediatric use statement, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug. As appropriate, this information must also be contained in the "Contraindications" and/or "Warnings and Precautions" section(s).

(D)(1) When a drug is approved for pediatric use based on adequate and well-controlled studies in adults with other information supporting pediatric use, the "Pediatric use" subsection of the labeling must contain either the following statement or a reasonable alternative:

The safety and effectiveness of (drug name) have been established in the age groups ____ to ____ (note any limitations, e.g., no data for pediatric patients under 2, or only applicable to certain indications approved in adults). Use of (drug name) in these age groups is supported by evidence from adequate and well-controlled studies of (drug name) in adults with additional data (insert wording that accurately describes the data submitted to support a finding of substantial evidence of effectiveness in the pediatric population).

(2) Data summarized in the preceding prescribed statement in this subsection must be discussed in more detail, if appropriate, under the "Clinical Pharmacology" or the "Clinical Studies" section. For example, pediatric pharmacokinetic or pharmacodynamic studies and dose response information should be described in the "Clinical Pharmacology" section. Pediatric dosing instructions must be included in the "Dosage and Administration" section. Any differences between pediatric and adult responses, need for spe-

cific monitoring, dosing adjustments, and any other information related to safe and effective use of the drug in pediatric patients must be cited briefly in the "Pediatric use" subsection and, as appropriate, in the "Contraindications," "Warnings and Precautions," and "Dosage and Administration" sections.

(E) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for a particular pediatric population, the "Pediatric use" subsection must contain an appropriate statement such as "Safety and effectiveness in pediatric patients below the age of (____) have not been established." If use of the drug in this pediatric population is associated with a specific hazard, the hazard must be described in this subsection, or, if appropriate, the hazard must be stated in the "Contraindications" or "Warnings and Precautions" section and this subsection must refer to it.

(F) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for any pediatric population, this subsection must contain the following statement: "Safety and effectiveness in pediatric patients have not been established." If use of the drug in premature or neonatal infants, or other pediatric subgroups, is associated with a specific hazard, the hazard must be described in this subsection, or, if appropriate, the hazard must be stated in the "Contraindications" or "Warnings and Precautions" section and this subsection must refer to it.

(G) If the sponsor believes that none of the statements described in paragraphs (c)(9)(iv)(B) through (c)(9)(iv)(F) of this section are appropriate or relevant to the labeling of a particular drug, the sponsor must provide reasons for omission of the statements and may propose alternative statement(s). FDA may permit use of an alternative statement if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug's labeling and that the alternative statement is accurate and appropriate.

(H) If the drug product contains one or more inactive ingredients that present an increased risk of toxic effects to neonates or other pediatric subgroups, a special note of this risk must be made, generally in the "Contraindications" or "Warnings and Precautions" section.

(v) 8.5 Geriatric use.

(A) A specific geriatric indication, if any, that is supported by adequate and well-controlled studies in the geriatric population must be described under the "Indications and Usage" section, and appropriate geriatric dosage must be stated under the "Dosage and Administration" section. The "Geriatric use" subsection must cite any limitations on the geriatric indication, need for specific monitoring, specific hazards associated with the geriatric indication, and other information related to the safe and effective use of the drug in the geriatric population. Unless otherwise noted, information contained in the "Geriatric use" subsection must pertain to use of the drug in persons 65 years of age and older. Data summarized in this subsection must be discussed in more detail, if appropriate, under "Clinical Pharmacology" or the "Clinical Studies" section. As appropriate, this information must also be contained in the "Warnings and Precautions" and/or "Contraindications" section(s).

(B) Specific statements on geriatric use of the drug for an indication approved for adults generally, as distinguished from a specific geriatric indication, must be contained in the "Geriatric use" subsection and must reflect all information available to the sponsor that is relevant to the appropriate use of the drug in elderly patients. This information includes detailed results from controlled studies that are available to the sponsor and pertinent information from well-documented studies obtained from a literature search. Controlled studies include those that are part of the marketing application and other relevant studies available to the sponsor that have not been previously submitted in the investigational new drug application, new drug application, biologics license application, or a supplement or amendment to one of these applications (e.g., postmarketing studies or adverse drug reaction reports). The "Geriatric use" subsection must contain the following statement(s) or reasonable alternative, as applicable, taking into account available information:

(1) If clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects, and other reported clinical experience has not identified such differences, the "Geriatric use" subsection must include the following statement:

Clinical studies of (name of drug) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

(2) If clinical studies (including studies that are part of marketing applications and other relevant studies available to the sponsor that have not been submitted in the sponsor's applications) included enough elderly subjects to make it likely that differences in safety or effectiveness between elderly and younger subjects would have been detected, but no such differences (in safety or effectiveness) were observed, and other reported clinical experience has not identified such differences, the "Geriatric use" subsection must contain the following statement:

Of the total number of subjects in clinical studies of (name of drug), ____ percent were 65 and over, while ____ percent were 75 and over. (Alternatively, the labeling may state the total number of subjects included in the studies who were 65 and over and 75 and over.) No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

(3) If evidence from clinical studies and other reported clinical experience available to the sponsor indicates that use of the drug in elderly patients is associated with differences in safety or

effectiveness, or requires specific monitoring or dosage adjustment, the "Geriatric use" subsection must contain a brief description of observed differences or specific monitoring or dosage requirements and, as appropriate, must refer to more detailed discussions in the "Contraindications," "Warnings and Precautions," "Dosage and Administration," or other sections.

(C)(1) If specific pharmacokinetic or pharmacodynamic studies have been carried out in the elderly, they must be described briefly in the "Geriatric use" subsection and in detail under the "Clinical Pharmacology" section. The "Clinical Pharmacology" and "Drug Interactions" sections ordinarily contain information on drug/disease and drug/drug interactions that is particularly relevant to the elderly, who are more likely to have concomitant illness and to use concomitant drugs.

(2) If a drug is known to be substantially excreted by the kidney, the "Geriatric use" subsection must include the statement:

This drug is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

(D) If use of the drug in the elderly appears to cause a specific hazard, the hazard must be described in the "Geriatric use" subsection, or, if appropriate, the hazard must be stated in the "Contraindications" or "Warnings and Precautions" section, and the "Geriatric use" subsection must refer to those sections.

(E) Labeling under paragraphs (c)(9)(v)(A) through (c)(9)(v)(C) of this section may include statements, if they are necessary for safe and effective use of the drug, and reflect good clinical practice or past experience in a particular situation, e.g., for a sedating drug, it could be stated that:

Sedating drugs may cause confusion and over-sedation in the elderly; elderly patients generally should be started on low doses of (name of drug) and observed closely.

(F) If the sponsor believes that none of the requirements described in paragraphs (c)(9)(v)(A) through (c)(9)(v)(E) of this section are appropriate or relevant to the labeling of a particular drug, the sponsor must provide reasons for omission of the statements and may propose an alternative statement. FDA may permit omission of the statements if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug's labeling. FDA may permit use of an alternative statement if the agency determines that such statement is accurate and appropriate.

(vi) Additional subsections. Additional subsections may be included, as appropriate, if sufficient data are available concerning the use of the drug in other specified subpopulations (e.g., renal or hepatic impairment).

(10) 9 Drug abuse and dependence. This section must contain the following information, as appropriate:

(i) 9.1 Controlled substance. If the drug is controlled by the Drug Enforcement Administration, the schedule in which it is controlled must be stated.

(ii) 9.2 Abuse. This subsection must state the

types of abuse that can occur with the drug and the adverse reactions pertinent to them, and must identify particularly susceptible patient populations. This subsection must be based primarily on human data and human experience, but pertinent animal data may also be used.

(iii) 9.3 Dependence. This subsection must describe characteristic effects resulting from both psychological and physical dependence that occur with the drug and must identify the quantity of the drug over a period of time that may lead to tolerance or dependence, or both. Details must be provided on the adverse effects of chronic abuse and the effects of abrupt withdrawal. Procedures necessary to diagnose the dependent state and the principles of treating the effects of abrupt withdrawal must be described.

(11) 10 Overdosage. This section must be based on human data. If human data are unavailable, appropriate animal and in vitro data may be used. The following specific information must be provided:

(i) Signs, symptoms, and laboratory findings associated with an overdosage of the drug;

(ii) Complications that can occur with the drug (for example, organ toxicity or delayed acidosis);

(iii) Concentrations of the drug in biologic fluids associated with toxicity or death; physiologic variables influencing excretion of the drug, such as urine pH; and factors that influence the dose response relationship of the drug, such as tolerance. The pharmacokinetic data given in the "Clinical Pharmacology" section also may be referenced here, if applicable to overdoses;

(iv) The amount of the drug in a single dose that is ordinarily associated with symptoms of overdosage and the amount of the drug in a single dose that is likely to be life threatening;

(v) Whether the drug is dialyzable; and

(vi) Recommended general treatment procedures and specific measures for support of vital functions (e.g., proven antidotes, gastric lavage, forced diuresis, or as per Poison Control Center). Such recommendations must be based on data available for the specific drug or experience with pharmacologically related drugs. Unqualified recommendations for which data are lacking for the specific drug or class of drugs must not be stated.

(12) 11 Description.

(i) This section must contain:

(A) The proprietary name and the established name, if any, as defined in section 502(e)(2) of the act, of the drug or, for biological products, the proper name (as defined in § 600.3 of this chapter) and any appropriate descriptors;

(B) The type of dosage form(s) and the route(s) of administration to which the labeling applies;

(C) The same qualitative and/or quantitative ingredient information as required under § 201.100(b) for drug labels or §§ 610.60 and 610.61 of this chapter for biological product labels;

(D) If the product is sterile, a statement of that fact;

(E) The pharmacological or therapeutic class of the drug;

(F) For drug products other than biological products, the chemical name and structural formula of the drug; and

(G) If the product is radioactive, a statement of the important nuclear physical

characteristics, such as the principal radiation emission data, external radiation, and physical decay characteristics.

(ii) If appropriate, other important chemical or physical information, such as physical constants or pH, must be stated.

(13) 12 Clinical pharmacology.

(i) This section must contain information relating to the human clinical pharmacology and actions of the drug in humans. Pharmacologic information based on in vitro data using human biomaterials or pharmacologic animal models, or relevant details about in vivo study designs or results (e.g., drug interaction studies), may be included in this section if essential to understand dosing or drug interaction information presented in other sections of the labeling. This section must include the following subsections:

(A) 12.1 Mechanism of action. This subsection must summarize what is known about the established mechanism(s) of the drug's action in humans at various levels (e.g., receptor, membrane, tissue, organ, whole body). If the mechanism of action is not known, this subsection must contain a statement about the lack of information.

(B) 12.2 Pharmacodynamics. This subsection must include a description of any biochemical or physiologic pharmacologic effects of the drug or active metabolites related to the drug's clinical effect in preventing, diagnosing, mitigating, curing, or treating disease, or those related to adverse effects or toxicity. Exposure-response relationships (e.g., concentration-response, dose-response) and time course of pharmacodynamic response (including short-term clinical response) must be included if known. If this information is unknown, this subsection must contain a statement about the lack of information. Detailed dosing or monitoring recommendations based on pharmacodynamic information that appear in other sections (e.g., "Warnings and Precautions" or "Dosage and Administration") must not be repeated in this subsection, but the location of such recommendations must be referenced.

(C) 12.3 Pharmacokinetics. This subsection must describe the clinically significant pharmacokinetics of a drug or active metabolites, (i.e., pertinent absorption, distribution, metabolism, and excretion parameters). Information regarding bioavailability, the effect of food, minimum concentration (Cmin), maximum concentration (Cmax), time to maximum concentration (Tmax), area under the curve (AUC), pertinent half-lives (t1/2), time to reach steady state, extent of accumulation, route(s) of elimination, clearance (renal, hepatic, total), mechanisms of clearance (e.g., specific enzyme systems), drug/drug and drug/food (e.g., dietary supplements, grapefruit juice) pharmacokinetic interactions (including inhibition, induction, and genetic characteristics), and volume of distribution (Vd) must be presented if clinically significant. Information regarding nonlinearity in pharmacokinetic parameters, changes in pharmacokinetics over time, and binding (plasma protein, erythrocyte) parameters must also be presented if clinically significant. This section must also include the results of pharmacokinetic studies (e.g., of metabolism or interaction) that establish the absence of an effect, including pertinent human studies and in vitro data. Dosing recommendations based on clinically significant factors that change the product's pharmacokinetics (e.g., age, gender, race, hepatic or renal dysfunction, concomitant therapy) that appear in other sections (e.g., "Warnings and Precautions," "Dosage and Administration" or "Use in Specific Popu-

lations") must not be repeated in this subsection, but the location of such recommendations must be referenced.

(ii) Data that demonstrate activity or effectiveness in in vitro or animal tests and that have not been shown by adequate and well-controlled clinical studies to be pertinent to clinical use may be included under this section only under the following circumstances:

(A) In vitro data for anti-infective drugs may be included if the data are immediately preceded by the statement "The following in vitro data are available but their clinical significance is unknown."

(B) For other classes of drugs, in vitro and animal data that have not been shown by adequate and well-controlled studies, as defined in § 314.126(b) of this chapter, to be necessary for the safe and effective use may be included in this section only if a waiver is granted under § 201.58 or § 314.126(c) of this chapter.

(14) 13 Nonclinical toxicology. This section must contain the following subsections as appropriate:

(i) 13.1 Carcinogenesis, mutagenesis, impairment of fertility. This subsection must state whether long term studies in animals have been performed to evaluate carcinogenic potential and, if so, the species and results. If results from reproduction studies or other data in animals raise concern about mutagenesis or impairment of fertility in either males or females, this must be described. Any precautionary statement on these topics must include practical, relevant advice to the prescriber on the significance of these animal findings. Human data suggesting that the drug may be carcinogenic or mutagenic, or suggesting that it impairs fertility, as described in the "Warnings and Precautions" section, must not be included in this subsection of the labeling.

(ii) 13.2 Animal toxicology and/or pharmacology. Significant animal data necessary for safe and effective use of the drug in humans that is not incorporated in other sections of labeling must be included in this section (e.g., specifics about studies used to support approval under § 314.600 or § 601.90 of this chapter, the absence of chronic animal toxicity data for a drug that is administered over prolonged periods or is implanted in the body).

(15) 14 Clinical studies. This section must discuss those clinical studies that facilitate an understanding of how to use the drug safely and effectively. Ordinarily, this section will describe the studies that support effectiveness for the labeled indication(s), including discussion of study design, population, endpoints, and results, but must not include an encyclopedic listing of all, or even most, studies performed as part of the product's clinical development program. If a specific important clinical study is mentioned in any section of the labeling required under §§ 201.56 and 201.57 because the study is essential to an understandable presentation of the information in that section of the labeling, any detailed discussion of the study must appear in this section.

(i) For drug products other than biological products, any clinical study that is discussed in prescription drug labeling that relates to an indication for or use of the drug must be adequate and well-controlled as described in § 314.126(b) of this chapter and must not imply or suggest indications or uses or dosing regimens not stated in the "Indications and Usage" or "Dosage and Administration" section. For biological products, any clinical study that is discussed that relates to an indication for or use of the biological product must constitute or contribute to substantial evidence and must not imply or suggest indications or uses or dosing regimens not stated in the "Indications and Us-

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age" or "Dosage and Administration" section.

(ii) Any discussion of a clinical study that relates to a risk from the use of the drug must also refer to the other sections of the labeling where the risk is identified or discussed.

(16) 15 References. When prescription drug labeling must summarize or otherwise rely on a recommendation by an authoritative scientific body, or on a standardized methodology, scale, or technique, because the information is important to prescribing decisions, the labeling may include a reference to the source of the information.

(17) 16 How supplied/storage and handling. This section must contain information on the available dosage forms to which the labeling applies and for which the manufacturer or distributor is responsible. The information must include, as appropriate:

(i) The strength or potency of the dosage form in metric system (e.g., 10 milligram tablets) and, if the apothecary system is used, a statement of the strength in parentheses after the metric designation;

(ii) The units in which the dosage form is ordinarily available for prescribing by practitioners (e.g., bottles of 100);

(iii) Appropriate information to facilitate identification of the dosage forms, such as shape, color, coating, scoring, imprinting, and National Drug Code number; and

(iv) Special handling and storage conditions.

(18) 17 Patient counseling information. This section must contain information necessary for patients to use the drug safely and effectively (e.g., precautions concerning driving or the concomitant use of other substances that may have harmful additive effects). Any FDA-approved patient labeling must be referenced in this section and the full text of such patient labeling must be reprinted immediately following this section or, alternatively, accompany the prescription drug labeling. Any FDA-approved patient labeling printed immediately following this section or accompanying the labeling is subject to the type size requirements in paragraph (d)(6) of this section, except for a Medication Guide to be detached and distributed to patients in compliance with § 208.24 of this chapter. Medication Guides for distribution to patients are subject to the type size requirements set forth in § 208.20 of this chapter.

(d) Format requirements. All labeling information required under paragraphs (a), (b), and (c) of this section must be printed in accordance with the following specifications:

(1) All headings and subheadings required by paragraphs (a) and (c) of this section must be highlighted by bold type that prominently distinguishes the headings and subheadings from other labeling information. Reverse type is not permitted as a form of highlighting.

(2) A horizontal line must separate the information required by paragraphs (a), (b), and (c) of this section.

(3) The headings listed in paragraphs (a)(5) through (a)(13) of this section must be presented in the center of a horizontal line.

(4) If there are multiple subheadings listed under paragraphs (a)(4) through (a)(13) of this section, each subheading must be preceded by a bullet point.

(5) The labeling information required by paragraphs (a)(1) through (a)(4), (a)(11)(ii) through (a)(11)(iv), and (a)(14) of this section must be in bold print.

(6) The letter height or type size for all labeling information, headings, and subheadings set forth in paragraphs (a), (b), and (c) of this sec-

tion must be a minimum of 8 points, except for labeling information that is on or within the package from which the drug is to be dispensed, which must be a minimum of 6 points.

(7) The identifying numbers required by § 201.56(d) and paragraphs (c)(1) through (c)(18) of this section must be presented in bold print and must precede the heading or subheading by at least two square em's (i.e., two squares of the size of the letter "m" in 8 point type).

(8) The information required by paragraph (a) of this section, not including the information required under paragraph (a)(4) of this section, must be limited in length to an amount that, if printed in 2 columns on a standard sized piece of typing paper (8 1/2 by 11 inches), single spaced, in 8 point type with 1/2-inch margins on all sides and between columns, would fit on one-half of the page.

(9) Sections or subsections of labeling that are identified as containing recent major changes under paragraph (a)(5) of this section must be highlighted in the full prescribing information by the inclusion of a vertical line on the left edge of the new or modified text.

(10) For the information required by paragraph (b) of this section, each section heading must be in bold print. Each subheading within a section must be indented and not bolded.

[71 FR 3988, Jan. 24, 2006]

SOURCE: 40 FR 13998, March 27, 1975; 51 FR 8182, March 7, 1986; 51 FR 43904, Dec. 5, 1986; 52 FR 2111, Jan. 20, 1987; 53 FR 4135, Feb. 12, 1988; 54 FR 39635, Sept. 27, 1989, 57 FR 54300, Nov. 18, 1992; 58 FR 45201, Aug. 26, 1993; 62 FR 51515, Oct. 1, 1997; 63 FR 26698, May 13, 1998; 64 FR 400, Jan. 5, 1999, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg-360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

21 C. F. R. § 201.57, **21 CFR § 201.57**

Current through February 14, 2008; 73 FR 8785

END OF DOCUMENT

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21 C.F.R. § 201.57

Effective: [See Text Amendments] to June 29, 2006

Code of Federal Regulations
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services
Subchapter C. Drugs: General
Part 201. Labeling
Subpart B. Labeling Requirements for Prescription Drugs and/or Insulin

→§ 201.57 Specific requirements on content and format of labeling for human prescription drugs.

<Text of section effective until June 30, 2006.>
Each section heading listed in § 201.56(d), if not omitted under § 201.56(d)(3), shall contain the following information in the following order:

(a) Description.

(1) Under this section heading, the labeling shall contain:

(i) The proprietary name and the established name, if any, as defined in section 502(e)(2) of the act, of the drug;

(ii) The type of dosage form and the route of administration to which the labeling applies;

(iii) The same qualitative and/or quantitative ingredient information as required under § 201.100(b) for la- bels;

(iv) If the product is sterile, a statement of that fact;

(v) The pharmacological or therapeutic class of the drug;

(vi) The chemical name and structural formula of the drug;

(vii) If the product is radioactive, a statement of the important nuclear physical characteristics, such as the principal radiation emission data, external radiation, and physical decay characteristics.

(2) If appropriate, other important chemical or physical information, such as physical constants, or pH, shall be stated.

(b) Clinical Pharmacology.

(1) Under this section heading, the labeling shall contain a concise factual summary of the clinical pharmacology and actions of the drug in humans. The summary may include information based on in vitro and/or animal data if the information is essential to a description of the biochemical and/or physiological mode of action of the drug or is otherwise pertinent to human therapeutics. Pharmacokinetic information that is important to safe and effective use of the drug is required, if known, e.g., degree and rate of absorption, path-

ways of biotransformation, percentage of dose as unchanged drug and metabolites, rate or half-time of elimination, concentration in body fluids associated with therapeutic and/or toxic effects, degree of binding to plasma proteins, degree of uptake by a particular organ or in the fetus, and passage across the blood brain barrier. Inclusion of pharmacokinetic information is restricted to that which relates to clinical use of the drug. If the pharmacological mode of action of the drug is unknown or if important metabolic or pharmacokinetic data in humans are unavailable, the labeling shall contain a statement about the lack of informa- tion.

(2) Data that demonstrate activity or effectiveness in in vitro or animal tests and that have not been shown by adequate and well-controlled clinical studies to be pertinent to clinical use may be included under this section of the labeling only under the following circumstances:

(i) In vitro data for anti-infective drugs may be included if the data are immediately preceded by the statement "The following in vitro data are available but their clinical significance is unknown."

(ii) For other classes of drugs, in vitro and animal data that have not been shown by adequate and well-controlled clinical studies, as defined in § 314.126(b) of this chapter, to be pertinent to clinical use may be used only if a waiver is granted under § 201.58 or § 314.126(b) of this chapter.

(c) Indications and Usage.

(1) Under this section heading, the labeling shall state that:

(i) The drug is indicated in the treatment, prevention, or diagnosis of a recognized disease or condition, e.g., penicillin is indicated for the treatment of pneumonia due to susceptible pneumococci; and/or

(ii) The drug is indicated for the treatment, prevention, or diagnosis of an important manifestation of a disease or condition, e.g., chlorothiazide is indicated for the treatment of edema in patients with congestive heart failure; and/or

(iii) The drug is indicated for the relief of symptoms associated with a disease or syndrome, e.g., chlorpheniramine is indicated for the symptomatic relief of nasal congestion in patients with vasomotor rhinitis; and/or

(iv) The drug, if used for a particular indication only in conjunction with a primary mode of therapy, e.g., diet, surgery, or some other drug, is an adjunct to the mode of therapy.

(2) All indications shall be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless the requirement is waived under § 201.58 or § 314.126(b) of this chapter.

(3) This section of the labeling shall also contain the following additional information:

(i) If evidence is available to support the safety and effectiveness of the drug only in selected subgroups of the larger population with a disease, syndrome, or symptom under consideration, e.g., patients with mild disease or patients in a special age group, the labeling shall describe the available evidence and state the limitations of usefulness of the drug. The labeling shall also identify specific tests needed for selection or monitoring of the patients who need the drug, e.g., microbe susceptibility tests. Information on the approx-

imate kind, degree, and duration of improvement to be anticipated shall be stated if available and shall be based on substantial evidence derived from adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless the requirement is waived under § 201.58 or § 314.126(b) of this chapter. If the information is relevant to the recommended intervals between doses, the usual duration of treatment, or any modification of dosage, it shall be stated in the "Dosage and Administration" section of the labeling and referenced in this section.

(ii) If safety considerations are such that the drug should be reserved for certain situations, e.g., cases refractory to other drugs, this information shall be stated in this section.

(iii) If there are specific conditions that should be met before the drug is used on a long-term basis, e.g., demonstration of responsiveness to the drug in a short-term trial, the labeling shall identify the conditions; or, if the indications for long-term use are different from those for short-term use, the labeling shall identify the specific indications for each use.

(iv) If there is a common belief that the drug may be effective for a certain use or if there is a common use of the drug for a condition, but the preponderance of evidence related to the use or condition shows that the drug is ineffective, the Food and Drug Administration may require that the labeling state that there is a lack of evidence that the drug is effective for that use or condition.

(v) Any statements comparing the safety or effectiveness, either greater or less, of the drug with other agents for the same indication shall be supported by adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless this requirement is waived under § 201.58 or § 314.126(b) of this chapter.

(d) Contraindications. Under this section heading, the labeling shall describe those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit. These situations include administration of the drug to patients known to have a hypersensitivity to it; use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by it; or continued use of the drug in the face of an unacceptably hazardous adverse reaction. Known hazards and not theoretical possibilities shall be listed, e.g., if hypersensitivity to the drug has not been demonstrated, it should not be listed as a contraindication. If no contraindications are known, this section of the labeling shall state "None known."

(e) Warnings. Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved. A specific warning relating to a use not provided for under the "Indications and Usage" section of the labeling may be required by the Food and Drug Administration if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with serious risk or hazard. Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. The boxed warning ordinarily shall be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. If a boxed warning is required, its location will be specified by the Food and Drug Administration. The frequency of these serious adverse reactions and, if known, the approximate mortality and morbidity rates for patients sustaining the reaction, which are important to safe and effective use of the drug, shall be expressed as

provided under the "Adverse Reactions" section of the labeling.

(f) Precautions. Under this section heading, the labeling shall contain the following subsections as appropriate for the drug:

(1) General. This subsection of the labeling shall contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug, e.g., precautions not required under any other specific section or subsection of the labeling.

(2) Information for patients. This subsection of the labeling shall contain information to be given to patients for safe and effective use of the drug, e.g., precautions concerning driving or the concomitant use of other substances that may have harmful additive effects. Any printed patient information or Medication Guide required under this chapter to be distributed to the patient shall be referred to under the "Precautions" section of the labeling and the full text of such patient information or Medication Guide shall be reprinted at the end of the labeling. The print size requirements for the Medication Guide set forth in § 208.20 of this chapter, however, do not apply to the Medication Guide that is reprinted in the professional labeling.

(3) Laboratory tests. This subsection of the labeling shall identify any laboratory tests that may be helpful in following the patient's response or in identifying possible adverse reactions. If appropriate, information shall be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be done before, during, and after therapy.

(4)(i) Drug interactions. This subsection of the labeling shall contain specific practical guidance for the physician on preventing clinically significant drug/drug and drug/food interactions that may occur in vivo in patients taking the drug. Specific drugs or classes of drugs with which the drug to which the labeling applies may interact in vivo shall be identified, and the mechanism(s) of the interaction shall be briefly described. Information in this subsection of the labeling shall be limited to that pertaining to clinical use of the drug in patients. Drug interactions supported only by animal or in vitro experiments may not ordinarily be included, but animal or in vitro data may be used if shown to be clinically relevant. Drug incompatibilities, i.e., drug interactions that may occur when drugs are mixed in vitro, as in a solution for intravenous administration, shall be discussed under the "Dosage and Administration" section of the labeling rather than under this subsection of the labeling.

(ii) Drug/laboratory test interactions. This subsection of the labeling shall contain practical guidance on known interference of the drug with laboratory tests.

(5) Carcinogenesis, mutagenesis, impairment of fertility. This subsection of the labeling shall state whether long-term studies in animals have been performed to evaluate carcinogenic potential and, if so, the species and results. If reproduction studies or other data in animals reveal a problem or potential problem concerning mutagenesis or impairment of fertility in either males or females, the information shall be described. Any precautionary statement on these topics shall include practical, relevant advice to the physician on the significance of these animal findings. If there is evidence from human data that the drug may be carcinogenic or mutagenic or that it impairs fertility, this information shall be included under the "Warnings" section of the labeling. Also, under "Precautions," the labeling shall state: "See 'Warnings' section for information on carcinogenesis, mutagenesis, and impairment of fertility."

(6) Pregnancy. This subsection of the labeling may be omitted only if the drug is not absorbed systemically

and the drug is not known to have a potential for indirect harm to the fetus. For all other drugs, this subsection of the labeling shall contain the following information:

(i) Teratogenic effects. Under this heading the labeling shall identify one of the following categories that applies to the drug, and the labeling shall bear the statement required under the category:

(a) Pregnancy category A. If adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of a risk in later trimesters), the labeling shall state: "Pregnancy Category A. Studies in pregnant women have not shown that (name of drug) increases the risk of fetal abnormalities if administered during the first (second, third, or all) trimester(s) of pregnancy. If this drug is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, however, (name of drug) should be used during pregnancy only if clearly needed." The labeling shall also contain a description of the human studies. If animal reproduction studies are available and they fail to demonstrate a risk to the fetus, the labeling shall also state: "Reproduction studies have been performed in (kinds of animal(s)) at doses up to (x) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to (name of drug)." The labeling shall also contain a description of available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(b) Pregnancy category B. If animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women, the labeling shall state: "Pregnancy Category B. Reproduction studies have been performed in (kind(s) of animal(s)) at doses up to (x) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to (name of drug). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed." If animal reproduction studies have shown an adverse effect (other than decrease in fertility), but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus during the first trimester of pregnancy (and there is no evidence of a risk in later trimesters), the labeling shall state: "Pregnancy Category B. Reproduction studies in (kind(s) of animal(s)) have shown (describe findings) at (x) times the human dose. Studies in pregnant women, however, have not shown that (name of drug) increases the risk of abnormalities when administered during the first (second, third, or all) trimester(s) of pregnancy. Despite the animal findings, it would appear that the possibility of fetal harm is remote, if the drug is used during pregnancy. Nevertheless, because the studies in humans cannot rule out the possibility of harm, (name of drug) should be used during pregnancy only if clearly needed." The labeling shall also contain a description of the human studies and a description of available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(c) Pregnancy category C. If animal reproduction studies have shown an adverse effect on the fetus, if there are no adequate and well-controlled studies in humans, and if the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks, the labeling shall state: "Pregnancy Category C. (Name of drug) has been shown to be teratogenic (or to have an embryocidal effect or other adverse effect) in (name(s) of species) when given in doses (x) times the human dose. There are no adequate and well-controlled studies in pregnant women. (Name of drug) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus." The labeling shall contain a description of the animal studies. If there are no animal reproduction studies and no adequate and well-

controlled studies in humans, the labeling shall state: "Pregnancy Category C. Animal reproduction studies have not been conducted with (name of drug). It is also not known whether (name of drug) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. (Name of drug) should be given to a pregnant woman only if clearly needed." The labeling shall contain a description of any available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(d) Pregnancy category D. If there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective), the labeling shall state: "Pregnancy Category D. See 'Warnings' section." Under the "Warnings" section, the labeling states: "(Name of drug) can cause fetal harm when administered to a pregnant woman. (Describe the human data and any pertinent animal data.) If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus."

(e) Pregnancy category X. If studies in animals or humans have demonstrated fetal abnormalities or if there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available), the labeling shall state: "Pregnancy Category X. See 'Contraindications' section." Under "Contraindications," the labeling shall state: "(Name of drug) may (can) cause fetal harm when administered to a pregnant woman. (Describe the human data and any pertinent animal data.) (Name of drug) is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus."

(ii) Nonteratogenic effects. Under this heading the labeling shall contain other information on the drug's effects on reproduction and the drug's use during pregnancy that is not required specifically by one of the pregnancy categories, if the information is relevant to the safe and effective use of the drug. Information required under this heading shall include nonteratogenic effects in the fetus or newborn infant (for example, withdrawal symptoms or hypoglycemia) that may occur because of a pregnant woman's chronic use of the drug for a preexisting condition or disease.

(7) Labor and delivery. If the drug has a recognized use during labor or delivery (vaginal or abdominal delivery), whether or not the use is stated in the indications section of the labeling, this subsection of the labeling shall describe the available information about the effect of the drug on the mother and the fetus, on the duration of labor or delivery, on the possibility that forceps delivery or other intervention or resuscitation of the newborn will be necessary, and the effect of the drug on the later growth, development, and functional maturation of the child. If any information required under this subsection is unknown, this subsection of the labeling shall state that the information is unknown.

(8) Nursing mothers.

(i) If a drug is absorbed systemically, this subsection of the labeling shall contain, if known, information about excretion of the drug in human milk and effects on the nursing infant. Pertinent adverse effects ob-

served in animal offspring shall be described.

(ii) If a drug is absorbed systemically and is known to be excreted in human milk, this subsection of the labeling shall contain one of the following statements, as appropriate. If the drug is associated with serious adverse reactions or if the drug has a known tumorigenic potential, the labeling shall state: "Because of the potential for serious adverse reactions in nursing infants from (name of drug)(or, "Because of the potential for tumorigenicity shown for (name of drug) in (animal or human) studies), a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother." If the drug is not associated with serious adverse reactions and does not have a known tumorigenic potential, the labeling shall state: "Caution should be exercised when (name of drug) is administered to a nursing woman."

(iii) If a drug is absorbed systemically and information on excretion in human milk is unknown, this subsection of the labeling shall contain one of the following statements, as appropriate. If the drug is associated with serious adverse reactions or has a known tumorigenic potential, the labeling shall state: "It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from (name of drug)(or, "Because of the potential for tumorigenicity shown for (name of drug) in (animal or human) studies), a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother." If the drug is not associated with serious adverse reactions and does not have a known tumorigenic potential, the labeling shall state: "It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when (name of drug) is administered to a nursing woman."

(9) Pediatric use.

(i) Pediatric population(s)/pediatric patient(s): For the purposes of paragraphs (f)(9)(ii) through (f)(9)(viii) of this section, the terms pediatric population(s) and pediatric patient(s) are defined as the pediatric age group, from birth to 16 years, including age groups often called neonates, infants, children, and adolescents.

(ii) If there is a specific pediatric indication (i.e., an indication different from those approved for adults) that is supported by adequate and well-controlled studies in the pediatric population, it shall be described under the "Indications and Usage" section of the labeling, and appropriate pediatric dosage information shall be given under the "Dosage and Administration" section of the labeling. The "Pediatric use" subsection shall cite any limitations on the pediatric indication, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug. Data summarized in this subsection of the labeling should be discussed in more detail, if appropriate, under the "Clinical Pharmacology" or "Clinical Studies" section. As appropriate, this information shall also be contained in the "Contraindications," "Warnings," and elsewhere in the "Precautions" sections.

(iii) If there are specific statements on pediatric use of the drug for an indication also approved for adults that are based on adequate and well-controlled studies in the pediatric population, they shall be summarized in the "Pediatric use" subsection of the labeling and discussed in more detail, if appropriate, under the "Clinical Pharmacology" and "Clinical Studies" sections. Appropriate pediatric dosage shall be given under the "Dosage and Administration" section of the labeling. The "Pediatric use" subsection of the labeling shall

also cite any limitations on the pediatric use statement, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug. As appropriate, this information shall also be contained in the "Contraindications," "Warnings," and elsewhere in the "Precautions" sections.

(iv) FDA may approve a drug for pediatric use based on adequate and well-controlled studies in adults, with other information supporting pediatric use. In such cases, the agency will have concluded that the course of the disease and the effects of the drug, both beneficial and adverse, are sufficiently similar in the pediatric and adult populations to permit extrapolation from the adult efficacy data to pediatric patients. The additional information supporting pediatric use must ordinarily include data on the pharmacokinetics of the drug in the pediatric population for determination of appropriate dosage. Other information, such as data from pharmacodynamic studies of the drug in the pediatric population, data from other studies supporting the safety or effectiveness of the drug in pediatric patients, pertinent premarketing or postmarketing studies or experience, may be necessary to show that the drug can be used safely and effectively in pediatric patients. When a drug is approved for pediatric use based on adequate and well-controlled studies in adults with other information supporting pediatric use, the "Pediatric use" subsection of the labeling shall contain either the following statement, or a reasonable alternative: "The safety and effectiveness of (drug name) have been established in the age groups ___ to ___ (note any limitations, e.g., no data for pediatric patients under 2, or only applicable to certain indications approved in adults). Use of (drug name) in these age groups is supported by evidence from adequate and well-controlled studies of (drug name) in adults with additional data (insert wording that accurately describes the data submitted to support a finding of substantial evidence of effectiveness in the pediatric population)." Data summarized in the preceding prescribed statement in this subsection of the labeling shall be discussed in more detail, if appropriate, under the "Clinical Pharmacology" or the "Clinical Studies" section. For example, pediatric pharmacokinetic or pharmacodynamic studies and dose-response information should be described in the "Clinical Pharmacology" section. Pediatric dosing instructions shall be included in the "Dosage and Administration" section of the labeling. Any differences between pediatric and adult responses, need for specific monitoring, dosing adjustments, and any other information related to safe and effective use of the drug in pediatric patients shall be cited briefly in the "Pediatric use" subsection and, as appropriate, in the "Contraindications," "Warnings," "Precautions," and "Dosage and Administration" sections.

(v) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for a particular pediatric population, the "Pediatric use" subsection of the labeling shall contain an appropriate statement such as "Safety and effectiveness in pediatric patients below the age of (___) have not been established." If use of the drug in this pediatric population is associated with a specific hazard, the hazard shall be described in this subsection of the labeling, or, if appropriate, the hazard shall be stated in the "Contraindications" or "Warnings" section of the labeling and this subsection shall refer to it.

(vi) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for any pediatric population, this subsection of the labeling shall contain the following statement: "Safety and effectiveness in pediatric patients have not been established." If use of the drug in premature or neonatal infants, or other pediatric subgroups, is associated with a specific hazard, the hazard shall be described in this subsection of the labeling, or, if appropriate, the hazard shall be stated in the "Contraindications" or "Warnings" section of the labeling and this subsection shall refer to it.

also cite any limitations on the pediatric use statement, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug. As appropriate, this information shall also be contained in the "Contraindications," "Warnings," and elsewhere in the "Precautions" sections.

(iv) FDA may approve a drug for pediatric use based on adequate and well-controlled studies in adults, with other information supporting pediatric use. In such cases, the agency will have concluded that the course of the disease and the effects of the drug, both beneficial and adverse, are sufficiently similar in the pediatric and adult populations to permit extrapolation from the adult efficacy data to pediatric patients. The additional information supporting pediatric use must ordinarily include data on the pharmacokinetics of the drug in the pediatric population for determination of appropriate dosage. Other information, such as data from pharmacodynamic studies of the drug in the pediatric population, data from other studies supporting the safety or effectiveness of the drug in pediatric patients, pertinent premarketing or postmarketing studies or experience, may be necessary to show that the drug can be used safely and effectively in pediatric patients. When a drug is approved for pediatric use based on adequate and well-controlled studies in adults with other information supporting pediatric use, the "Pediatric use" subsection of the labeling shall contain either the following statement, or a reasonable alternative: "The safety and effectiveness of (drug name) have been established in the age groups ___ to ___ (note any limitations, e.g., no data for pediatric patients under 2, or only applicable to certain indications approved in adults). Use of (drug name) in these age groups is supported by evidence from adequate and well-controlled studies of (drug name) in adults with additional data (insert wording that accurately describes the data submitted to support a finding of substantial evidence of effectiveness in the pediatric population)." Data summarized in the preceding prescribed statement in this subsection of the labeling shall be discussed in more detail, if appropriate, under the "Clinical Pharmacology" or the "Clinical Studies" section. For example, pediatric pharmacokinetic or pharmacodynamic studies and dose-response information should be described in the "Clinical Pharmacology" section. Pediatric dosing instructions shall be included in the "Dosage and Administration" section of the labeling. Any differences between pediatric and adult responses, need for specific monitoring, dosing adjustments, and any other information related to safe and effective use of the drug in pediatric patients shall be cited briefly in the "Pediatric use" subsection and, as appropriate, in the "Contraindications," "Warnings," "Precautions," and "Dosage and Administration" sections.

(v) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for a particular pediatric population, the "Pediatric use" subsection of the labeling shall contain an appropriate statement such as "Safety and effectiveness in pediatric patients below the age of (___) have not been established." If use of the drug in this pediatric population is associated with a specific hazard, the hazard shall be described in this subsection of the labeling, or, if appropriate, the hazard shall be stated in the "Contraindications" or "Warnings" section of the labeling and this subsection shall refer to it.

(vi) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for any pediatric population, this subsection of the labeling shall contain the following statement: "Safety and effectiveness in pediatric patients have not been established." If use of the drug in premature or neonatal infants, or other pediatric subgroups, is associated with a specific hazard, the hazard shall be described in this subsection of the labeling, or, if appropriate, the hazard shall be stated in the "Contraindications" or "Warnings" section of the labeling and this subsection shall refer to it.

(vii) If the sponsor believes that none of the statements described in paragraphs (f)(9)(ii) through (f)(9)(vi) of this section is appropriate or relevant to the labeling of a particular drug, the sponsor shall provide reasons for omission of the statements and may propose alternative statement(s). FDA may permit use of an alternative statement if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug's labeling and that the alternative statement is accurate and appropriate.

(viii) If the drug product contains one or more inactive ingredients that present an increased risk of toxic effects to neonates or other pediatric subgroups, a special note of this risk shall be made, generally in the "Contraindications," "Warnings," or "Precautions" section.

(10) Geriatric use.

(i) A specific geriatric indication, if any, that is supported by adequate and well-controlled studies in the geriatric population shall be described under the "Indications and Usage" section of the labeling, and appropriate geriatric dosage shall be stated under the "Dosage and Administration" section of the labeling. The "Geriatric use" subsection shall cite any limitations on the geriatric indication, need for specific monitoring, specific hazards associated with the geriatric indication, and other information related to the safe and effective use of the drug in the geriatric population. Unless otherwise noted, information contained in the "Geriatric use" subsection of the labeling shall pertain to use of the drug in persons 65 years of age and older. Data summarized in this subsection of the labeling shall be discussed in more detail, if appropriate, under "Clinical Pharmacology" or the "Clinical Studies" section. As appropriate, this information shall also be contained in "Contraindications," "Warnings," and elsewhere in "Precautions."

(ii) Specific statements on geriatric use of the drug for an indication approved for adults generally, as distinguished from a specific geriatric indication, shall be contained in the "Geriatric use" subsection and shall reflect all information available to the sponsor that is relevant to the appropriate use of the drug in elderly patients. This information includes detailed results from controlled studies that are available to the sponsor and pertinent information from well-documented studies obtained from a literature search. Controlled studies include those that are part of the marketing application and other relevant studies available to the sponsor that have not been previously submitted in the investigational new drug application, new drug application, biological license application, or a supplement or amendment to one of these applications (e.g., postmarketing studies or adverse drug reaction reports). The "Geriatric use" subsection shall contain the following statement(s) or reasonable alternative, as applicable, taking into account available information:

(A) If clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects, and other reported clinical experience has not identified such differences, the "Geriatric use" subsection shall include the following statement:

"Clinical studies of (name of drug) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy."

(B) If clinical studies (including studies that are part of marketing applications and other relevant stud-

ies available to the sponsor that have not been submitted in the sponsor's applications) included enough elderly subjects to make it likely that differences in safety or effectiveness between elderly and younger subjects would have been detected, but no such differences (in safety or effectiveness) were observed, and other reported clinical experience has not identified such differences, the "Geriatric use" subsection shall contain the following statement:

Of the total number of subjects in clinical studies of (name of drug), ___ percent were 65 and over, while ___ percent were 75 and over. (Alternatively, the labeling may state the total number of subjects included in the studies who were 65 and over and 75 and over.) No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

(C) If evidence from clinical studies and other reported clinical experience available to the sponsor indicates that use of the drug in elderly patients is associated with differences in safety or effectiveness, or requires specific monitoring or dosage adjustment, the "Geriatric use" subsection of the labeling shall contain a brief description of observed differences or specific monitoring or dosage requirements and, as appropriate, shall refer to more detailed discussions in the "Contraindications," "Warnings," "Dosage and Administration," or other sections of the labeling.

(iii)(A) If specific pharmacokinetic or pharmacodynamic studies have been carried out in the elderly, they shall be described briefly in the "Geriatric use" subsection of the labeling and in detail under the "Clinical Pharmacology" section. The "Clinical Pharmacology" section and "Drug interactions" subsection of the "Precautions" section ordinarily contain information on drug-disease and drug-drug interactions that is particularly relevant to the elderly, who are more likely to have concomitant illness and to utilize concomitant drugs.

(B) If a drug is known to be substantially excreted by the kidney, the "Geriatric use" subsection shall include the statement:

"This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function."

(iv) If use of the drug in the elderly appears to cause a specific hazard, the hazard shall be described in the "Geriatric use" subsection of the labeling, or, if appropriate, the hazard shall be stated in the "Contraindications," "Warnings," or "Precautions" section of the labeling, and the "Geriatric use" subsection shall refer to those sections.

(v) Labeling under paragraphs (f)(10)(i) through (f)(10)(iii) of this section may include statements, if they would be useful in enhancing safe use of the drug, that reflect good clinical practice or past experience in a particular situation, e.g., for a sedating drug, it could be stated that:

"Sedating drugs may cause confusion and over-sedation in the elderly; elderly patients generally should be started on low doses of (name of drug) and observed closely."

(vi) If the sponsor believes that none of the requirements described in paragraphs (f)(10)(i) through (f)(10)(v) of this section is appropriate or relevant to the labeling of a particular drug, the sponsor shall provide reasons for omission of the statements and may propose an alternative statement. FDA may permit omission of the statements if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug's labeling. FDA may permit use of an alternative statement if the agency determines that such statement is accurate and appropriate.

(g) Adverse Reactions. An adverse reaction is an undesirable effect, reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence.

(1) This section of the labeling shall list the adverse reactions that occur with the drug and with drugs in the same pharmacologically active and chemically related class, if applicable.

(2) In this listing, adverse reactions may be categorized by organ system, by severity of the reaction, by frequency, or by toxicological mechanism, or by a combination of these, as appropriate. If frequency information from adequate clinical studies is available, the categories and the adverse reactions within each category shall be listed in decreasing order of frequency. An adverse reaction that is significantly more severe than the other reactions listed in a category, however, shall be listed before those reactions, regardless of its frequency. If frequency information from adequate clinical studies is not available, the categories and adverse reactions within each category shall be listed in decreasing order of severity. The approximate frequency of each adverse reaction shall be expressed in rough estimates or orders of magnitude essentially as follows: "The most frequent adverse reaction(s) to (name of drug) is (are)(list reactions). This (these) occur(s) in about (e.g., one-third of patients; one in 30 patients; less than one-tenth of patients). Less frequent adverse reactions are (list reactions), which occur in approximately (e.g., one in 100 patients). Other adverse reactions, which occur rarely, in approximately (e.g., one in 1,000 patients), are (list reactions)." Percent figures may not ordinarily be used unless they are documented by adequate and well-controlled studies as defined in § 314.126(b) of this chapter, they are shown to reflect general experience, and they do not falsely imply a greater degree of accuracy than actually exists.

(3) The "Warnings" section of the labeling or, if appropriate, the "Contraindications" section of the labeling shall identify any potentially fatal adverse reaction.

(4) Any claim comparing the drug to which the labeling applies with other drugs in terms of frequency, severity, or character of adverse reactions shall be based on adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless this requirement is waived under § 201.58 or § 314.126(b) of this chapter.

(h) Drug Abuse and Dependence. Under this section heading, the labeling shall contain the following subsections, as appropriate for the drug:

(1) Controlled Substance. If the drug is controlled by the Drug Enforcement Administration, the schedule in which it is controlled shall be stated.

(2) Abuse. This subsection of the labeling shall be based primarily on human data and human experience, but pertinent animal data may also be used. This subsection shall state the types of abuse that can occur with the drug and the adverse reactions pertinent to them. Particularly susceptible patient populations shall be identified.

(3) Dependence. This subsection of the labeling shall describe characteristic effects resulting from both psychological and physical dependence that occur with the drug and shall identify the quantity of the drug over a period of time that may lead to tolerance or dependence, or both. Details shall be provided on the adverse effects of chronic abuse and the effects of abrupt withdrawal. Procedures necessary to diagnose the dependent state shall be provided, and the principles of treating the effects of abrupt withdrawal shall be described.

(i) Overdosage. Under this section heading, the labeling shall describe the signs, symptoms, and laboratory findings of acute overdosage and the general principles of treatment. This section shall be based on human data, when available. If human data are unavailable, appropriate animal and in vitro data may be used. Specific information shall be provided about the following:

(1) Signs, symptoms, and laboratory findings associated with an overdosage of the drug.

(2) Complications that can occur with the drug (for example, organ toxicity or delayed acidosis).

(3) Oral LD50 of the drug in animals; concentrations of the drug in biologic fluids associated with toxicity and/or death; physiologic variables influencing excretion of the drug, such as urine pH; and factors that influence the dose response relationship of the drug, such as tolerance. The pharmacokinetic data given in the "Clinical Pharmacology" section also may be referenced here, if applicable to overdoses.

(4) The amount of the drug in a single dose that is ordinarily associated with symptoms of overdosage and the amount of the drug in a single dose that is likely to be life-threatening.

(5) Whether the drug is dialyzable.

(6) Recommended general treatment procedures and specific measures for support of vital functions, such as proven antidotes, induced emesis, gastric lavage, and forced diuresis. Unqualified recommendations for which data are lacking with the specific drug or class of drugs, especially treatment using another drug (for example, central nervous system stimulants, respiratory stimulants) may not be stated unless specific data or scientific rationale exists to support safe and effective use.

(j) Dosage and Administration. This section of the labeling shall state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established; dosages shall be stated for each indication when appropriate. This section shall also state the intervals recommended between doses, the optimal method of titrating dosage, the usual duration of treatment, and any modification of dosage needed in special patient populations, e.g., in children, in geriatric age groups, or in patients with renal or hepatic disease. Specific tables or monographs may be included to clarify dosage schedules. Radiation dosimetry information shall be stated for both the patient receiving a radioactive drug and the person administering it. This section shall also contain specific direction on dilution, preparation (including the strength of the final dosage solution, when prepared according to instructions, in terms of milligrams active ingredient per milliliter of reconstituted solution, unless another measure of the strength is more appropriate), and administration of the dosage form, if needed, e.g., the rate of administration of parenteral drug in milligrams per minute; storage conditions for stability of the drug or reconstituted drug, when important; essential information on drug incompatibilities if the drug is mixed in vitro with other drugs; and the following statement for parenterals: "Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit."

(k) How Supplied. This section of the labeling shall contain information on the available dosage forms to which the labeling applies and for which the manufacturer or distributor is responsible. The information shall ordinarily include:

(1) The strength of the dosage form, e.g., 10-milligram tablets, in metric system and, if the apothecary system is used, a statement of the strength is placed in parentheses after the metric designation;

(2) The units in which the dosage form is ordinarily available for prescribing by practitioners, e.g., bottles of 100;

(3) Appropriate information to facilitate identification of the dosage forms, such as shape, color, coating, scoring, and National Drug Code; and

(4) Special handling and storage conditions.

(l) Animal Pharmacology and/or Animal Toxicology. In most cases, the labeling need not include this section. Significant animal data necessary for safe and effective use of the drug in humans shall ordinarily be included in one or more of the other sections of the labeling, as appropriate. Commonly for a drug that has been marketed for a long time, and in rare cases for a new drug, chronic animal toxicity studies have not been performed or completed for a drug that is administered over prolonged periods or is implanted in the body. The unavailability of such data shall be stated in the appropriate section of the labeling for the drug. If the pertinent animal data cannot be appropriately incorporated into other sections of the labeling, this section may be used.

(m) "Clinical Studies" and "References". These sections may appear in labeling in the place of a detailed discussion of a subject that is of limited interest but nonetheless important. A reference to a specific important clinical study may be made in any section of the format required under §§ 201.56 and 201.57 if the study is essential to an understandable presentation of the available information. References may appear in sections of the labeling format, other than the "Clinical Studies" or "References" section, in rare circumstances only. A clinical study or reference may be cited in prescription drug labeling only under the following conditions:

(1) If the clinical study or reference is cited in the labeling in the place of a detailed discussion of data and information concerning an indication for use of the drug, the reference shall be based upon, or the clinical study shall constitute, an adequate and well-controlled clinical investigation under § 314.126(b) of this chapter.

(2) If the clinical study or reference is cited in the labeling in the place of a detailed discussion of data and information concerning a risk or risks from the use of the drug, the risk or risks shall also be identified or discussed in the appropriate section of the labeling for the drug.

[44 FR 37462, June 26, 1979; 55 FR 11576, March 29, 1990; 59 FR 64249, Dec. 13, 1994; 62 FR 45325, Aug. 27, 1997; 63 FR 66396, Dec. 1, 1998]

SOURCE: 40 FR 13998, March 27, 1975; 51 FR 8182, March 7, 1986; 51 FR 43904, Dec. 5, 1986; 52 FR 2111, Jan. 20, 1987; 53 FR 4135, Feb. 12, 1988; 54 FR 39635, Sept. 27, 1989, 57 FR 54300, Nov. 18, 1992; 58 FR 45201, Aug. 26, 1993; 62 FR 51515, Oct. 1, 1997; 63 FR 26698, May 13, 1998; 64 FR 400, Jan. 5, 1999, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg-360ss, 371, 374, 379e; 42 U.S.C.

21 C.F.R. § 201.57

216, 241, 262, 264.

21 C. F. R. § 201.57, 21 CFR § 201.57

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February 20, 2008

The Honorable Mark Rindner
Superior Court Judge
Alaska Court System
825 West Fourth Avenue, Room 432
Anchorage, Alaska 99501-2004

Re: *State of Alaska v. Eli Lilly and Company,* Case No. 3AN-06-05630 CI
Our File No. 9867.38

Dear Judge Rindner:

In advance of the pretrial conference in this case on Friday, February 22, 2008, we thought it would be helpful to set out in a letter the following list of issues that the Court may wish to address at this conference. By copy of this letter to Mr. Eric Sanders, we invite counsel for the State of Alaska to submit additional items for consideration at the pretrial conference.

1. Pending Motions

As of the date of this letter, the following motions are pending before the Court, and their resolution may affect the parties' trial strategies and presentations:

Dispositive Motions

- Lilly's Motion for Summary Judgment (filed December 10, 2007)
- Lilly's Supplemental Brief Seeking Dismissal of the State's Claims Pursuant to the UTPCPA Exemption and Federal Preeemption (filed February 5, 2008).
- Lilly's Motion in Response to Court's On-Record Comments During the January 29, 2008 Hearing (filed February 12, 2008).

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Plaintiff's Motions in Limine

- Motion in Limine to Exclude Testimony or Argument Regarding Efficacy or Benefits of Zyprexa for Non-indicated or "Off-label" Uses.
- Motion in Limine to Exclude Testimony or Argument Regarding the Lack of Restrictions on the Availability of Zyprexa or Lack of an Injunction Against Certain Conduct by Defendant.
- Motion in Limine to Exclude Testimony or Argument Regarding Other Drugs Manufactured by Defendant Eli Lilly and Company.
- Motion in Limine to Exclude Testimony or Argument Regarding Efficacy or Benefits of Zyprexa for Indicated Uses.

Lilly's Motions In Limine

- Motion in Limine to Exclude Evidence Relating to the State of Alaska's Alleged Damages or Economic Injury. (*Not opposed.*)
- Motion in Limine to Exclude Certain Testimony of the State's Experts Under Seal.
- Motion in Limine to Exclude References to Foreign Regulatory Action.
- Motion in Limine to Exclude Evidence Relating to New York Times Articles Under Seal.
- Motion in Limine to Exclude Evidence Relating to Other Litigation Involving the Defendant.
- Motion in Limine to Exclude Evidence Relating to Defendant's Profits, Net Worth and the Price of Zyprexa.
- Motion in Limine to Exclude References to Recent Regulatory Communications and Developments.
- Motion in Limine to Exclude Testimony and Call Notes of Non-Alaska Based Sales Representatives.

2. **Voir Dire**

- Guidelines for how the parties may describe the case to potential jurors.
- Time limits, if any, for voir dire.
- Number of peremptory challenges each side will have and whether parties can stipulate to increase that number.

3. **Juror Questionnaire**

- Contents of proposed juror questionnaire.

4. **Opening Statements**

- Time limits, if any. 2 hrs
- Number of lawyers allowed to open (and close) for each party.
- Guidelines for use of demonstratives and exhibit excerpts in opening statements.

5. **Witnesses**

- Out-of-order witnesses and special witness scheduling issues.
- Reciprocal agreement between parties to give notice of next witnesses to be called.
- Notification of order of witnesses.

6. **Deposition Designations**

- Resolution of remaining objections to deposition designations.

- Guidelines whether Lilly can "re-call" deposition witnesses during its case in chief to play testimony from the witness beyond what was played during plaintiff's case in chief.

7. Exhibits

- Reciprocal agreement between parties to give specified amount of notice before introducing demonstratives and other categories of exhibits.

8. Logistical/Procedural Trial Issues

- Use of courtroom technology, including logistics and sharing between parties.
- Overall timing limits.
- Length of trial and days off.

9. Jury Instructions/Verdict Form

- Opening jury instructions.
- Closing jury instructions and verdict form.

Very truly yours,

LANE POWELL LLC

Brewster H. Jamieson

nlb
cc: Eric T. Sanders, Esq. (via email)
009867.0038/163534.1

A B C D

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	Case No. 3AN-06-5630 CIV
Defendant.	)	
	)	

ORDER GRANTING PLAINTIFF'S MOTION IN LIMINE TO PRECLUDE TESTIMONY OR ARGUMENT THAT ZYPREXA'S LABELING "WARNED" OF DIABETES, HYPERGLYCEMIA AND WEIGHT GAIN

IT IS HEREBY ORDERED that Plaintiff's Motion in Limine to Preclude Testimony or Argument that Zyprexa's Labeling "Warned" of Diabetes, Hyperglycemia and Weight Gain is GRANTED. Lilly's counsel and witnesses are precluded from stating or implying that Lilly "warned" of Zyprexa's risks of diabetes and hyperglycemia prior to the FDA-mandated label change in 2003. Further, it is ordered that Lilly's counsel and witnesses will be instructed to make no statements that Lilly "warned" of the risk of weight gain prior to the labeling change in 2007.

DATED this ____ day of _____, 2008.

BY THE COURT

_____
Mark Rindner
Superior Court Judge

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A B C D

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

DEFENDANT ELI LILLY AND COMPANY'S REPLY IN SUPPORT OF ITS MOTION IN LIMINE TO EXCLUDE EVIDENCE RELATING TO OTHER LITIGATION INVOLVING THE DEFENDANT

Despite its admission that evidence of other Lilly litigation is irrelevant, the State has asked the Court to carve out an exception for a hypothetical guilty plea that it read about in the *The New York Times*. Lilly is not a party to any plea agreement with the federal or state governments relating to Zyprexa®. The State's assertions about the admissibility of a future plea agreement lack any of the specifics required for the Court to even begin an analysis of relevance, such as the conduct covered by the plea or the applicable time period of the alleged offenses. These specifics are lacking for one reason – there is no plea agreement. The State's response is purely speculative and the Court should grant Lilly's unopposed motion.

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A B C D

DATED this 20th day of February, 2008.

PEPPER HAMILTON LLP
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George A. Lehner, admitted pro hac vice
John F. Brenner, *admitted pro hac vice*
Andrew R. Rogoff, admitted *pro hac vice*
Eric J. Rothschild, admitted *pro hac vice*
and
LANE POWELL LLC
Attorneys for Defendant

By _____
Brewster H. Jamieson, ASBA No. 8411122
Andrea E. Girolamo-Welp, ASBA No. 0211044

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

DEFENDANT ELI LILLY AND COMPANY'S NOTICE OF FILING REPLY IN FURTHER SUPPORT OF ITS MOTION IN LIMINE TO EXCLUDE REFERENCES TO RECENT REGULATORY COMMUNICATIONS AND DEVELOPMENTS UNDER SEAL

COMES NOW Defendant Eli Lilly and Company ("Lilly") and files its Reply in Further Support of Its Motion in Limine to Exclude References to Recent Regulatory Communications and Developments, under seal, attached to this notice. The subject and contents of the Reply may fall under prior confidentiality rulings.

DATED this 20th day of February, 2008.

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A B C D

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

DEFENDANT ELI LILLY AND COMPANY'S REPLY IN SUPPORT OF ITS MOTION IN LIMINE TO EXCLUDE EVIDENCE RELATING TO DEFENDANT'S PROFITS, NET WORTH AND THE PRICE OF ZYPREXA®

Eli Lilly and Company ("Lilly") made three arguments in its motion to exclude evidence of Lilly's profits, net worth or the price of Zyprexa: (a) Alaska law bars evidence of a defendant's financial condition; (b) the State conceded that evidence of Zyprexa's price is irrelevant to the issues of this case, and (c) admission of evidence of profits, net worth or price has little probative value, but substantial potential for prejudice. The State's response to Lilly's motion fails to address any of these arguments, instead focusing on the purported relevance of this evidence to Lilly's motive and intent. Because Alaska law prohibits financial evidence, and Lilly's motive and intent are irrelevant to the issues in this case, the Court should grant Lilly's motion.

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I. THE STATE FAILS TO ADDRESS LILLY'S LEGAL ARGUMENT.

In its motion to exclude evidence of profits, net worth and the price of Zyprexa, Lilly cited Alaska law that absent a claim for punitive damages, evidence of a defendant's financial condition is irrelevant.[1] The State presents no case law to refute this position. Regardless of the relevance arguments that comprise the State's response, the State has failed to address controlling Alaska case law that evidence of corporate net worth is irrelevant to this portion of the Court's bifurcated trial plan.

The State also has not addressed Lilly's motion with respect to pricing evidence. As noted in Lilly's Motion, the State has already commented that "it is not contending that Lilly's [alleged] misrepresentations and concealments artificially inflated the price of Zyprexa."[2] Moreover, the State's chosen causes of action "do not include claims that it overpaid for each Zyprexa prescription that is purchased."[3] The State has failed to respond to these direct concessions from its own pleadings and has provided no argument, other than a vague notion of motive, for the relevance of pricing evidence.

---

[1] *Fleegel v. Estate of Boyles*, 61 P.3d 1267, 1271 (Alaska, 2002).

[2] State's Opp. to Summ. J. at 12.

[3] *Id.*

II. LILLY'S MOTIVE AND INTENT ARE IRRELEVANT TO THE STATE'S CASE.

The State claims that evidence of Lilly's profits, net worth and the price of Zyprexa is relevant to the motive and intent behind Lilly's marketing. However, neither motive nor intent is an element of any cause of action in this case – a point emphasized by the State in its Memorandum Describing Its Proofs and Claims. For example, with regard to its Unfair Trade Practices claim, the State noted that "neither intent to deceive nor actual injury is required . . .".[4] By the State's own admission, evidence of motive and intent is irrelevant to its case and the Court should reject the State's attempt to use intent as a means to admit otherwise irrelevant evidence.

III. THE STATE'S EXAMPLES FAIL TO OPEN THE DOOR TO PROFIT AND PRICING EVIDENCE.

The State argues that evidence of Lilly's profits and pricing is relevant to demonstrate Lilly's motivation for its marketing to primary care physicians (PCP's) and desire to achieve "open access" formulary status for Lilly medications.[5] The State has mischaracterized Lilly's argument as one of motive. The fact that bipolar patients are helped by Zyprexa, and that some patients' bipolar disorders are diagnosed and treated by PCP's, is not an issue of "good" or "bad" motive. The State's reference to Lilly's alleged profit motive

[4] Pl. Mem. Proofs and Claims at 21.

[5] State's Resp. at 2.

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is remote, at best, from the actual marketing practices at issue and will lead to irrelevant collateral issues concerning pharmaceutical accounting and finance. The prejudice of introducing company profit information outweighs any marginal relevance of this "profit motive".[6]

IV. CONCLUSION

For the foregoing reasons, the Court should grant Lilly's motion and bar the State from introducing evidence relating to Lilly's profits, net worth or the price of Zyprexa.

DATED this 20th day of February, 2008.

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Attorneys for Defendant

By _____
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000867.0038/163546.1

[6] The State's reference to Lilly's need to respond to the loss of its Prozac patent is itself inadmissible. As the Court is aware, the State has filed a motion to exclude evidence regarding other drugs manufactured by Lilly, a motion that Lilly has agreed with provided that both parties are prohibited from referencing any medication other than Zyprexa. Because the parties have already agreed that references to other Lilly medications should be excluded from this trial, the State cannot use the expiration of the Prozac patent as a basis to discuss Lilly's corporate finances.

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Annotate

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

PLAINTIFF'S OBJECTIONS TO DEFENDANT'S PAGE/LINE COUNTER DESIGNATIONS

Plaintiff respectfully submits its specific objections to Defendant's Counter Designations of deposition testimony on the grounds set forth below:

Exhibit 1; Deposition of Michael Bandick

START (PAGE:LINE)	END (PAGE:LINE)	OBJECTION
211:6	211:7	Not necessary for fairness; non-responsive
322:19	322:21	Non-responsive
522:14	523:2	Not necessary for fairness; non-responsive

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Exhibit 2; Deposition of Jack E. Jordan

START (PAGE:LINE)	END (PAGE:LINE)	OBJECTION
423:7	423:11	Not necessary for fairness; non-responsive

Exhibit 3; Deposition of Bruce Kinon, M.D.

START (PAGE:LINE)	END (PAGE:LINE)	OBJECTION
52:9	52:16	Non-responsive
72:16	72:17	Non-responsive
73:17	73:18	Non-responsive
92:10	92:15	Non-responsive
93:7	93:17	Non-responsive; not preceded by question
237:17	237:24	Non-responsive
241:2	241:21	Non-responsive
412:14	412:23	Not necessary for fairness; non-responsive

Exhibit 4; Deposition of Denice M. Torres

START (PAGE:LINE)	END (PAGE:LINE)	OBJECTION
244:11	246:10	Not necessary for fairness; non-responsive
257:6	257:13	Not necessary for fairness
402:1	403:4	Non-responsive
561:6	562:13	Non-responsive

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DATED this 20 day of February, 2008.

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Certificate of Service
I hereby certify that a true and correct copy of **Plaintiff's Objections to Defendant's Page/Line Counter Designations** was served by messenger on:

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Barry Boise, via email (boiseb@pepperlaw.com)
Pepper Hamilton

By Peggy S Crowe
Date 2/20/08

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Bandick, Mike - Vol. I
211:6-7
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Not necessary for fairness; non-responsive

211: 6 thing, Lilly wasn't involved in the content
7 of CME.

Bandick, Mike - Vol. I
322:19-21
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: non-responsive

322:19 A. There are many mechanisms to
20 provide that and we did follow clear
21 guidelines and policies on how to do that.

Bandick, Mike - Vol. I
522:14-523:3
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Not necessary for fairness; non-responsive

522:14 Q. Was Zyprexa indicated for the
15 treatment of agitation associated with
16 dementia?
17 A. I'd like to make a comment
18 that on an earlier page, it was Page 7, the
19 last line says "see Pages XX for additional
20 safety information." So this clearly was a
21 draft. There was in the Zyprexa
22 IntraMuscular trials pursuit treat potential
23 agitation indications of which agitation in
24 dementia was one of those indications. If
523: 1 that indication was not approved by FDA, then
2 that would render this draft document moot.
3 MR. ALLEN: Objection.

Jordan, Jack - Vol. I
423:7-11
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Not necessary for fairness; non-responsive

423: 7 Q. Is there a diagnosis of
8 schizophrenia or bipolar mania on Donna?
9 A. The Donna profile was
10 approved by our medical folks to represent
11 bipolar mania.

Kinon, Bruce - Vol. I

52:9-16
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Non-responsive

52: 9 My recollection of the role
10 of this group was to understand from a
11 medical point of view the hyperglycemia and
12 diabetes issues involved with Zyprexa, and
13 try to deliver that information to clinicians
14 in a way that they would have the answers
15 they needed to the questions that they were
16 posing.

Kinon, Bruce - Vol. I

72:16-17
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Non-responsive

72:16 I have published extensively on the weight
17 gain associated with Zyprexa.

Kinon, Bruce - Vol. I

73:17-18
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Non-responsive

73:17 recollect, these were never key messages in
18 terms of our interpretation of the data.

Kinon, Bruce - Vol. I

92:10-15
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Non-responsive

92:10 A. I've never seen this
11 No. 24 pounds the way it's stated here. We
12 have clearly stated the weight gain in
13 patients on Zyprexa in long-term studies as
14 part of our original label and it remains in
15 our label to date.

Kinon, Bruce - Vol. I

93:7-17
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Non-responsive

93: 7 A. The sentence following the
8 one you asked me to read clearly indicates
9 that analyses were still being done at the
10 time of this report. I can only come to the

conclusion that this is a preliminary draft report.
The final conclusions regarding data were clearly stated in our label and have clearly been published in the articles that I and my colleagues have reported.

Kinon, Bruce - Vol. I
237:17-24
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Non-responsive

237:17 Q. And when did you first learn that physicians believed that Lilly was minimizing weight gain?
A. It wasn't that Lilly was minimizing weight gain, there was the perception that Lilly was minimizing weight gain. From my understanding we were never minimizing weight gain as a side effect.

Kinon, Bruce - Vol. I
241:2-21
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Non-responsive

241: 2 Q. Didn't the company instruct its sales people that weight gain was manageable?
A. Around this time we were clearly telling clinicians that if weight gain was a problem with their patients they should consider other interventions if not switching the patient off of Zyprexa.
We also provided them with psychoeducational materials to help them with their patients who were gaining weight. This is our Healthy Lifestyle programs, our Solutions For Wellness.
We were doing a lot of things. In addition, we were doing prospective clinical trials to try to show that perhaps there was a treatment that could be added to antipsychotic drugs to reduce the weight gain. That's what we meant by weight gain is manageable.

Kinon, Bruce - Vol. I
412:14-23
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Not necessary for fairness;Non-responsive

412:14 Q. Did Lilly tell doctors that
15 Zyprexa caused weight gain of clinical
16 significance greater than the other second
17 generation antipsychotics?
18 A. We try to very clearly
19 indicate the comparative risks associated
20 with weight gain on olanzapine versus the
21 other compounds. And we have clearly
22 presented that at numerous scientific
23 congresses.

Torres, Denice - Vol. I
244:11-246:10
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Not necessary for fairness;Non-responsive

244:11 Q. So, if Eli Lilly at any time
12 during marketing of Zyprexa attempted to
13 capitalize on this knowledge, that
14 off-label usage defined the market, if
15 they attempted to capitalize on that,
16 they would be in violation of the
17 regulations as you know them?
18 MR. WASSON: Object to form.
19 THE WITNESS: I think, sir,
20 what you're talking about in the
21 first sentence, I think it would
22 be helpful to read the second
23 sentence. "Off-label usage is
24 commonplace with atypicals due to
245: 1 the medical necessity of
2 addressing complicated
3 symptomatology. What is deemed a
4 depression diagnosis for one
5 physician may be viewed as bipolar
6 depression for another," hence,
7 looking at the market in a way of
8 looking at its total usage. And
9 so I think it's -- you know,
10 unfortunately, in these
11 therapeutic areas, sometimes it's
12 very, very difficult to put a
13 diagnosis on a patient of
14 schizophrenia/bipolar. In fact,
15 I've been in situations with world
16 thought leaders where there was a
17 very popular case which a lot of
18 people saw on TV about a woman
19 that drowned her children. And
20 there was great debate on whether
21 or not the woman suffered from
22 bipolar or whether she suffered
23 from schizophrenia. So, basically
24 what this is looking at, if you
246: 1 asked the bipolar experts, they
2 would say her diagnosis was
3 bipolar. If you answer -- asked
4 the schizophrenia experts, they
5 would talk about her diagnosis as
6 schizophrenia. So all this
7 paragraph is talking about is it's
8 very difficult to ascertain with
9 any great preciseness what a usage
10 is for.

Torres, Denice - Vol. I
257:6-13
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Not necessary for fairness

257: 6 Q. What was the result of the
7 CATIE study? Do you know what the
8 results on the CATIE study on
9 effectiveness has been?
10 A. You know what, I left my
11 position prior to the CATIE results, but
12 my understanding is they were quite
13 positive for Zyprexa.

Torres, Denice - Vol. I

402:1-4
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Non-responsive

402: 1 the sum total of the benefits of the
2 product and --
3 Q. Well, I don't see that
4 listed. You just said the goal was to

Torres, Denice - Vol. I

561:6-562:13
Issues: [redacted] 02 Defendant's counter designations
Comment: Objection: Non-responsive

561: 6 Q. "Discuss the efficacy and
7 safety of atypical antipsychotics in
8 child and adolescent psychiatry." You
9 weren't even supposed to be detailing
10 child and adolescent psychiatrists, were
11 you, on Zyprexa?
12 A. Detailing, no.
13 Q. Why was Eli Lilly providing
14 an educational grant to train physicians
15 on how to use second generation
16 antipsychotics in children and
17 adolescents?
18 A. One, I don't know about this
19 program, but why would Lilly provide an
20 unrestricted grant? There was a huge
21 market need. Would physicians want to
22 know or psychiatrists want to know about
23 antipsychotic use in children? Of course
24 they would. Why? Huge unmet need. Huge
562: 1 unmet need. In fact, I think it was
2 Risperdal just recently after all of
3 these years received an indication for
4 the use of Risperdal in children with
5 autism. There's a huge need. Part of a
6 pharmaceutical's responsibility is to
7 support the community. This is nothing
8 more -- I don't know who was behind this,
9 what their intent is, but if you're
10 asking me, give my opinion on this, it's
11 about supporting the community. It's an

unrestricted grant. "Unrestricted"
meaning you don't control the content.

A B C D

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

DEFENDANT ELI LILLY AND COMPANY'S REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE TESTIMONY AND CALL NOTES FROM NON-ALASKA BASED SALES REPRESENTATIVES

Eli Lilly and Company ("Lilly") made two arguments in support of its motion to exclude call notes and testimony from Lilly sales representatives outside of Alaska: (a) the evidence is not relevant, and (b) the evidence is likely to confuse the jury. In its response, the State does not dispute the prospect of jury confusion and prejudice to Lilly, limiting its argument only to relevance. Even in arguing for the relevance of call notes from outside Alaska, the State insists that call notes from Alaska-based sales representatives can establish the elements of its claims, rendering the evidence of sales representative conduct outside Alaska cumulative and unnecessary.

In its response, the State also seeks to establish that sales representatives' call notes, which are rough, idiosyncratic shorthand concerning sales representatives' discussions with physicians, fall under the business records exception of the hearsay rule. This is not the case. Moreover, call notes provide no support for the State's case because, without

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interpretive testimony, the call notes are not admissible for the proposition for which they are being introduced.

I. TESTIMONY AND CALL NOTES OF LILLY SALES REPRESENTATIVES OUTSIDE ALASKA ARE NOT RELEVANT; AND, EVEN IF THEY ARE RELEVANT, THEY ARE CUMULATIVE AND PREJUDICIAL TO LILLY.

A. Testimony and Call Notes of Lilly Sales Representatives Outside Alaska are Not Relevant.

The State argues, without citing any authority, that call notes and testimony documenting sales representative activity outside Alaska is "certainly probative evidence of actual unfair or deceptive acts within Alaska."[1] The State bases this assertion on the fact that Lilly implemented a nationwide sales plan for Zyprexa.® According to the State's logic, because there was a nationwide sales plan, the specific conduct of sales representatives in other states is relevant to what Lilly sales representatives said or did in Alaska. The State is incorrect in this assertion.

"Relevancy is not an inherent characteristic of any item of evidence but exists as a relation between an item of evidence and a matter properly provable in the case."[2] In this case, the State must prove that Lilly violated the Unfair Trade Practices and Consumer

[1] Ptlf's Response to Defendant's Motion in Limine to Exclude Testimony and Call Notes of Non-Alaska Based Sales Representatives at 3.

[2] Alaska Rules of Evidence Commentary, Rule 401.

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Protection Act ("UTPCPA") in Alaska.[3] While the contents of a nationwide sales plan might be relevant to this case (and Lilly has not objected to this category of documents), idiosyncratic call notes reflecting discussions with non-Alaska physicians prove nothing as to how Lilly sales representatives behaved in Alaska. The introduction of evidence of conduct outside Alaska will not make it more or less plausible that Lilly's Alaska based sales representatives acted in a specific way.[4]

The State also argues that conduct outside of Alaska will help to establish "Lilly's motive, intent and plan."[5] But the State has previously argued that it need not prove Lilly's motive or intent in a UTPCPA claim.[6] Nor is Lilly's intent an element of a failure to warn claim.[7] The State cannot turn a non-element into a vehicle for introducing extraneous and prejudicial evidence it wants the jury to hear.

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[3] *See State v. O'Neill Investigations*, 609 P.2d 520, 523 (Alaska 1980) (noting, in a constitutional challenge to the UTPCPA, that the conduct regulated by the act was that of businesses "operating in this state."); *see also* Pltf's Response to Defendant's Motion in Limine to Exclude Testimony and Call Notes of Non-Alaska Based Sales Representatives at 3 (acknowledging that to be relevant to its UTPCPA claim, evidence must be probative of Lilly's "actual unfair or deceptive acts within Alaska").

[4] *Reeves v. Alyeska Pipeline Serv. Co.*, 56 P.3d 660, 669 (Alaska 2002) (holding evidence of future plans for a building were not relevant to a case about terms of a contract regarding the building and resulting damages for breach thereof).

[5] Pltf's Response to Defendant's Motion in Limine to Exclude Testimony and Call Notes of Non-Alaska Based Sales Representatives at 3.

[6] Pltf's Memorandum on Claims and Proof at 21.

[7] *Shanks v. The Upjohn Co.*, 835 P.2d 1189, 1200 (Alaska 1992).

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B. Testimony and Call Notes From Lilly Sales Representatives Outside Alaska Should Be Excluded Because They are Cumulative and Prejudicial.

Even if the evidence of the alleged conduct of sales representatives outside Alaska is relevant, it should be excluded because it is cumulative, and the prejudice stemming from its introduction outweighs its probative value.[8] The State insists that "[c]lear evidence that Lilly sales representatives delivered [messages misrepresenting Zyprexa] is available in the sampling of 'call notes' produced by Lilly."[9] The call notes produced by Lilly in this litigation consisted entirely of those generated by Alaska-based sales representatives.[10] If this sampling of call notes prepared by Lilly's Alaska sales representatives provides "clear evidence" of Lilly's misconduct, then it is cumulative and should be excluded on that basis.[11] If the Alaska evidence is not sufficient for the State to prevail, extraterritorial evidence cannot rescue it.

Moreover, this cumulative evidence will likely cause jury confusion.[12] The jury will not understand for what issues it may consider the evidence of sales representative

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[8] Alaska Rule of Evid. 403.

[9] Pltf's Response to Defendant's Motion in Limine to Exclude Testimony and Call Notes of Non-Alaska Based Sales Representatives at 3.

[10] Exhibit A, Discovery Master's Order of September 24, 2007, at 11.

[11] Alaska Rule of Evid. 403.

[12] *Hiibschman v. Valdez*, 821 P.2d 1354, 1366 (Alaska 1991) (upholding trial court determination that potential prejudice of a jury punishing party for other conduct outweighs (continued . . .)

conduct in states other than Alaska. The fact the jury might mistakenly consider the specific conduct of sales representatives in another state when deciding whether Lilly's specific Alaska conduct actually violated the UTPCPA is prejudicial to Lilly.

II. CALL NOTES ARE INADMISSIBLE BECAUSE THEY ARE HEARSAY NOT WITHIN ANY EXCEPTION AND REQUIRE THE JURY TO SPECULATE AS TO THEIR MEANING.[13]

A. Call Notes are Hearsay and do not Fall Under the Business Records Exception.[14]

Even if evidence of the conduct of sales representatives outside Alaska were relevant, such evidence suffers from admissibility defects. In particular, call notes contain

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(. . . continued)
probative value of evidence); *Korean Air Lines Co. v. State*, 779 P.2d 333, 340 (Alaska 1989) (upholding exclusion of evidence of an uncontested fact because potential confusion of jury as to what issues were before them).

[13] Lilly hereby objects to the introduction by the State of all call notes in this litigation, whether generated by Alaska based sales representatives or non-Alaska based sales representatives.

[14] An additional hearsay problem also exists that weighs against finding call notes qualify under the business records exception. Without the testimony of the sales representative who authored that particular call note, a jury cannot conclude whether the physician or the sales representative raised a particular topic. In many instances, the particular notation may represent a topic the physician had raised to the sales representative. Thus, there is a double hearsay problem, which would further undermine any finding that call notes fall under the business records exception to the hearsay rule. *See Colt Indus. Operating Corp. v. Frank W. Murphy Mfr.*, 822 P.2d 925, 933 n.12 (Alaska 1991) ("Because the reports appear to contain hearsay in the form of customers' descriptions of the problem with the returned devices, they may involve hearsay included within hearsay, and would therefore be inadmissible absent an independent hearsay exception."). Thus, Lilly reserves the right to object to each notation in each individual call note on this basis in the event that the Court does not agree with Lilly's initial hearsay objection.

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hearsay statements. Out of court statements offered to prove the truth of the matter asserted are inadmissible as hearsay under the Alaska Rules of Evidence.[15]

The State argues that call notes fall under the business records exception to the hearsay rule, stating that "[a] call note is a business record which contemporaneously details a sales representative's visit to a physician."[16] The State is incorrect. The business records exception "allows admission of a record made 'from information transmitted by[] a person with knowledge acquired of a regularly conducted business activity . . . if it was the regular practice of that business activity to make and keep the memorandum . . . unless the source of information or the method or circumstances of preparation indicate lack of trustworthiness'."[17] While regularly created after most visits with physicians, the text fields of call notes lack the regularity of form and process that is the hallmark of the business records exception.[18]

The basis for the State's argument that call notes fall under the business records exception is David Noesges' testimony regarding the nature of call notes.[19] When asked

[15] Alaska R. Evid. 801-802.

[16] Ptlf's Response to Defendant's Motion in Limine to Exclude Testimony and Call Notes of Non-Alaska Based Sales Representatives at 3.

[17] *Harris v. Keys,* 948 P.2d 460, 466 (Alaska 1997) (*quoting* Alaska R. Evid. 803(6)).

[18] Exhibit B, Deposition of David Noesges, January 11, 2008, at 200-01.

[19] The testimony cited by the State was based on questions asked of Mr. Noesges about a particular Lilly standard operating procedure. Ptlf's Response to Defendant's Motion in (continued . . .)

about the nature of call notes (the relevant information for this determination), Mr. Noesges explained, call notes are simply the "shorthand notes" that sales representatives make to themselves.[20] In fact, there is no regularity as to what information sales representatives place in call notes.[21] Moreover, although managers are able to access call notes, they are not routinely used by Lilly for any purpose; call notes are only used by sales representatives to remind themselves of topics discussed during pervious visits with a physician.[22] Commentary to the Alaska Rules of Evidence explains that the business records exception is based on an assumed reliability established "by systematic checking, by regularity and continuity which produce habits of precision, by actual experience of business relying on them, or by a duty to make an accurate record as part of a continuing job or occupation."[23] Call notes satisfy none of these factors. The clarity of call notes varies from one person to the next. An examination of representative call notes from outside Alaska, which the State has designated as trial exhibits, illustrate this fact:

(. . . continued)
Limine to Exclude Testimony and Call Notes of Non-Alaska Based Sales Representatives at 3. The document was for the everyday use of sales representatives, not legal professionals. And the use of the term business record in the document is the everyday sense, not the specific legal definition of the term the State is arguing for in its response.

[20] Exhibit B, Deposition of David Noesges at 201.

[21] *Id.*

[22] *Id.*

[23] Commentary to Alaska Rules of Evidence, Rule 803(6).

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Example 1

Name:	Dottie Griggers
Date:	11/6/2000
PrescriberLN:	Nunn
PrescriberFN:	Michael
Location:	New Bern, N.C.

core 4. Zy 3. Encouraged add on 15 mg to dep or Lithium.

Again told me he needed samples in Greenville.

**********R********** Zyp. v. Risp.

Example 2

Name:	Estie K. Moon-Houston
Date:	10/22/2001
PrescriberLN:	Nunn
PrescriberFN:	Michael
Location:	New Bern, N.C.

Shared new TD info w/ him- just another reason to use ZYP vs. others

Rushed by and said he was using ****R**** higher doses of ZYP- needed ZYP 15 and 20mg

Sit him down for a second and explain why adding zydis on to pts on shots is best thier [sic] health.[24]

These examples show the inscrutable nature of call notes. For this reason, the reliability of call notes for understanding what occurred at a particular meeting is questionable at best, not because the sales representative inaccurately portrayed what

[24] Exhibit C, State's Trial Exhibits, Zyprexa Plaintiff's Exhibit 10044, at 5, 11.

occurred, but because another person will have difficulty penetrating the idiosyncratic notations and shorthand that make up call notes. Call notes do not exhibit the continuity and regularity discussed in the commentary to the Alaska rules. Thus, even if the activities of sales representatives outside of Alaska were found relevant to Lilly's conduct in Alaska, the State cannot proffer call notes as evidence of that conduct; as such evidence would be hearsay.

B. The State will Improperly ask the Jury to Speculate as to the Meaning of the Call Notes.

In addition, the State has proposed to use call notes to support propositions far greater than their weight can bear. As discussed above, call notes are idiosyncratic shorthand concerning sales representatives' discussions with physicians. In many cases, it is impossible to determine whether a physician or the Lilly employee raised a given topic. In all cases, one cannot tell the extent to which any topic was covered or what was actually said. The State plans, however, to use call notes to recreate entire conversations between sales representatives and physicians in another State, in the absence of any testimony from those participants. This requires the jury to make inappropriate inferences and is an improper use of this evidence.

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"[A]n inference based on speculation and conjecture is not reasonable."[25] By this definition, the State's use of call notes is unreasonable because the State cannot identify what messages were actually delivered. The State argues that a jury can infer meaning from the appearance of certain words in a call note. For example, Alaska has argued that when a particular phrase, such as "weight gain," appears in a call note, the sales representatives "were delivering the company message that weight gain was manageable and that any risk of it was far outweighed by Zyprexa's superior efficacy."[26] The call notes do not actually contain such messages; instead, the State's lawyers will be telling the jury what they think was said, based solely on the limited notations in the call notes. The jury cannot infer the content of these conversations based on the limited notations in the call notes and lawyers' speculation, particularly without testimony from the meeting participants.[27]

III. CONCLUSION

For the foregoing reasons, the Court should preclude the State from introducing at trial any call notes or testimony from Lilly sales representatives outside of Alaska.

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[25] *CBS Broadcasting, Inc. v. FBC Television Affiliates*, 450 F.3d 505, 517 n.25 (11th Cir. 2006) (*quoting Chapman v. Am. Cyanamid Co.*, 861 F.2d 1515, 1518 (11th Cir. 1988)); *see also French v. Jadon, Inc.*, 911 P.2d 20, 27 (Alaska 1996) (finding an inference improper where a party failed to support that inference with evidence).

[26] Exhibit D, Pltf.'s Suppl. Responses to Lilly's Fourth Set of Interrogatories at 6.

[27] *Person v. Wal-Mart Stores, Inc.*, No. 90-5454, 1990 U.S. App. LEXIS 22456, at *4-5 (6th Cir. Dec. 20, 1990) (unreported) (holding inference improper where party asked jury to speculate as to what might have occurred).

DATED this 20th day of February, 2008.

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RE: State of Alaska v. Eli Lilly & Co., 3AN-06-05630 CI

DISCOVERY MASTER ORDER
State's First Motion to Compel
Lilly's Motion to Compel
Lilly's Motion for Commission for Subpoena

Introduction

The State of Alaska seeks damages from Eli Lilly & Co. for harm allegedly caused by Lilly's marketing and sale of the drug Zyprexa. The State asserts claims in strict product liability for failure to warn and design defect, for violation of the State's Unfair Trade Practices and Consumer Protection Act, and for negligence, negligent misrepresentation and fraud.

The State has not filed a class action and is not seeking damages for individual patients. Instead, the state seeks to recover for excess expenditures allegedly incurred by

communications made to the State and evidence of communications available in the MDL collection.

The evidence sought by the State is technically discoverable -- but it appears that the ability of other payors to influence the State is tenuous and the information sought is also likely redundant to information already available to the State. Given the State's interest in limiting unnecessary discovery so as to preserve the March 2008 trial date, Lilly's objection to the discovery as overbroad is sustained.

Int. # 3, RFP #3. Lilly withdrew is objection at oral argument.

Int. #6, RFP #9. DENIED. The State seeks information regarding communications about Zyprexa from Lilly to representatives of Alaska's executive or legislative branch. Lilly asserts the same objections noted above regarding Int. #2. The State does not have any evidence that other members of the Alaska executive branch or the Alaska Legislature influenced Alaska Medicaid regarding the use of Zyprexa. Lilly's objection is sustained.

Int. # 8, RFP #11; Int. #9, RFP # 12; Int. #10, RFP # 13; Int. # 11, RFP # 14. DENIED. The State seeks information regarding communications about Zyprexa from Lilly to patient advocacy groups, the American Psychiatric Association, the Texas Medication Algorithm Project, and Comprehensive NueroScience. Lilly's objections are sustained for the reasons stated above in Int. #2.

Int. #4, RFP #7. GRANTED in part. The State seeks information regarding call note references to Zyprexa generated by Lilly sales representatives in Alaska. Call notes are brief entries made by sales representatives documenting meetings with physicians. Lilly recognizes that the information may be discoverable but claims that retrieving the

information from its database is unduly burdensome. Lilly asserts that it must search approximately 40,000 entries in the call note database, a task that may take 1300 hours. The State disputes this assertion.

I do not have enough information to determine how burdensome the search for Alaska related Zyprexa call notes will be. But Lilly's proposed solution to the issue appears reasonable. Lilly proposes to produce a random sample of Zyprexa related call notes and suggests that any pattern relevant to these proceedings should reveal itself through that sample.

Lilly shall produce a random sample of 4,000 Alaska call notes referencing Zyprexa.

Int. #7, RFP # 10. Lilly withdrew its objection at oral argument.

Int. #12. GRANTED in part. The State seeks financial information regarding Lilly's worldwide revenue from Zyprexa sales, cost of products sold, gross margin, operating expenses, other expenses and income before taxes. Lilly agrees to produce publicly available information regarding sales and revenue, but objects to engaging in forensic accounting to calculate cost of products sold, gross margin, operating expenses and pre-tax income. While the more detailed financial information may help the State prove a motive for misrepresentation or corroborate the State's claim that Lilly's marketing tactics resulted in increased sales, the publicly available information offered by Lilly is relevant to the same issue. In light of the State's interest in efficient discovery to maintain the March 2008 trial date, Lilly's objections to produce other than publicly available information are sustained. Lilly must produce publicly available worldwide Zyprexa sales revenue responsive to this request.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA	)	
	)	
Plaintiff,	)	
	)	
vs.	)	CASE NO.
	)	3AN-06-5630 CIV
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	

The videotaped deposition upon oral examination of DAVID THOMAS NOESGES, a witness produced and sworn before me, Carolyn L. Smith, CSR, RPR, Notary Public, in and for the County of Hamilton, State of Indiana, taken on behalf of Plaintiff, at the offices of Ice Miller, One American Square, Suite 3100, Indianapolis, Indiana, on January 11, 2008, at 9:31 a.m., pursuant to all applicable rules.

MR. BOISE: Keep on working on it.

QUESTIONS BY MR. SUGGS:

Q I would like to show you some call notes that have been produced to us in the Alaska litigation, and I'll mark this next as Exhibit 10.

(Deposition Exhibit 10 marked for identification.)

QUESTIONS BY MR. SUGGS:

Q Which I'll represent to you is a page of call notes pulled from the sample that Lilly has produced to us in the Alaska litigation. And it would appear this particular page has call notes that were generated by Margaret Williams, several by her, and also by a Thea Jung.

Do you see that?

A Yes, I do.

Q It appears that this call note database has various fields that include the name of the sales rep, the call date, the call ID, the prescriber last name, the prescriber first name, the city in which the prescriber is, the state, and then it has action, reaction, follow up. And the rest of the information I think probably comes from this litigation.

Were you -- what's your understanding of what

the Action field was for?

A As I mentioned to you before, in this time frame this tool is really used for the reps to describe in shorthand notes to themselves as to the notes they wanted to record from their conversation with the doctor.

Q And then what is the Reaction supposed to be?

A The Reaction was designed to describe, kind of, a customer reaction to the calls. And my experience with these field notes is often it's not what you find in those fields. It all ends up really being shorthand notes to the representatives.

Q Is it the policy and practice of Lilly management to also review the call notes of the sales reps?

A No, we don't routinely review the call notes from the sales representatives.

Q Do you periodically do so?

A The district managers are able to access the call notes and if they choose to they can take a look at a call note or discuss it with a sales representative.

Q Do you know who Margaret Williams was?

A No, I do not know Margaret.

MR. SUGGS: Barry, can you tell me, is she the lady who is deceased?

^Moon-Houston, Estie K^	^9/9/1999^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^zyp vd typs^	^he talked about his exp w/zyp for cocaine addicts- says it helps them sleep and takes care of their anxietyt and seems to < theircravings- he thinks its a miracle^	^take in lunch or dinner**********R**********^
^Russo, Michael^	^9/22/1999^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^asked for sig. for samplws very busy came in 2 hours late^	^**********R**********^	^**********R**********^
^Woods, Derek M^	^9/29/1999^	^NUNN^	^MICHAEL^	^WINTER VILLE^	^NC^	^**********R**********^	^No time given today. Seems t~ve been catching him on very rushed days. Did get in**********R**********remi nders for Zyp.^	^i agree, dinner or lunch to develop more time will be key.**********R**********^
^Moon-Houston, Estie K^	^10/6/1999^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^Pushed the ZYP 30 day coupons**********R**********^	^^	^^
^Moon-Houston, Estie K^	^10/13/1999^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^**********R**********^	^**********R**********^	^**********R**********^
^Russo, Michael^	^10/22/1999^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^**********R**********^	^**********R**********^	^**********R**********^
^Moon-Houston, Estie K^	^11/3/1999^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^**********R**********ZYP psycklind**********R**********^	^**********R**********He wants the Bipolar psychlink video- says he already uses ZYp for bpolar^	^will tues nnite be best for a speaker program^
^Russo, Michael^	^11/17/1999^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^**********R**********^	^**********R**********is usinf lots of Z likes samples better than coupons^	^sell shweet on Z^
^Russo, Michael^	^11/18/1999^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^saw him yesterday **********R**********^	^**********R**********^	^**********R**********^
^Moon-Houston, Estie K^	^12/2/1999^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^Tis the season to be jolly**********R**********gave hima special gift for he and his wife^	^**********R**********he really appreciated the gift^	^zyp vs serq^

EXHIBIT 4

Zyprexa Plaintiffs' Exhibit 10044

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EXHIBIT 4 PAGE 1 OF 2

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^Charlier, Patricia M^	^10/9/2000^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^Lunch detail of new bipolar message with therapists^	^Good crew. They apparently had just come from a Risperdal talk and were full of questions (Hyperglycemia, bipolar depression, length of the studies, whether substance abuse people were allowed to be entered into the studies). Went through the hyperglyce^	^Zyp: Keep stressing the prolactin elevation, EPS/TD with risp.**********R* **********^
^Griggers, Dottie F^	^10/17/2000^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^Core 4 tuf pt. Zy 3 Zyp vs Dep.^	^Loves Zyp.**********R********** **********^	^******R*****Zyp vs Risp Zyp vs Dep^
^Griggers, Dottie F^	^10/18/2000^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^********R********Zy 3. Zyp vs Dep^	**********R* **********Loves Zyp.^	^***R****Risp Dep^
^Griggers, Dottie F^	^10/25/2000^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^Prod mention only.^	^Still requested rep in Greenville office.^	^**********R**********Zy 3 Zyp vs Dep^
^Charlier, Patricia M^	^10/31/2000^	^NUNN^	^MICHAEL^	^Morehead City^	^NC^	^Product mentions^	^He had a waiting room full**********R********** ********He just came out to sign. The nurse told me he had 30 pts scheduled for today so they will start working in Sat. He also works at a nursing home on the weekend.^	^Zyp: Stress safety and uses in elderly for dementia and low dose APS.**********R********** ****^
^Charlier, Patricia M^	^11/1/2000^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^Product mentions^	^Again asked for samples at the Greenville office. Product mentions only. Doing okay on samples.^	^Zyp vs. risp and add-on to depak.**********R* **********^
^Griggers, Dottie F^	^11/6/2000^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^core 4. Zy 3. Encouraged add on 15 mg to dep or Lithium.^	^Again told me he needed samples in Greenville.^	^******R******Zyp vs Risp.^
^Griggers, Dottie F^	^11/8/2000^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^*****R******Zy 3. BP add on^	^^	^See last notes.^
^Charlier, Patricia M^	^11/15/2000^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^Product mentions^	^He had a waiting room full of patients so he only came out to sign.^	^Zyp vs. risp and depk.**********R* **********^

^Vance, Amber M^	^9/19/2001^	^NUNN^	^MICHAEL^	^WINTERVILLE^	^NC^	^Mtg. date?, zydis, leave behind. ZYP gold pen.^	^Rmdr. of "crisis" in MC. Let him know spoke w/ NP @ health clinic who work jail, and primary care docs all int. in meeting. He said to give Pat a call in the morning. Asked to keep zydis leave behind. Needs ZYP samples.^	^Mtg. follow-up. Samples from Lori. ident. of zyd. NH pts.^
^Moon-Houston, Estie K^	^10/10/2001^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^Talked about Harvard and how they praised the zyp efficacy talked about his busy schedule asked about zydis***R****^	^he is having better effects w/ zyp- has used all the zydis samples- says he just writes for reg zyp and I let him know that is just fine- he asked for more zydis samples********R********I keep waiting to see #s go up**********^	^Go over diabetes info vs risp esp.**********R**********^
^Moon-Houston, Estie K^	^10/11/2001^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^Just took care of his samOle needs in MC^	^^	^^
^Moon-Houston, Estie K^	^10/22/2001^	^NUNN^	^MICHAEL^	^NEW BERN^	^NC^	^Shared new TD info w/ him- just another reason to use ZYP vs others^	^Rushed by and said he was using******R******higher doses of ZYP- needed ZYP 15 and 20mg^	^Sit him down for a second aND explain why adding zydis on to pts on shots is best for thier health^
^Vance, Amber M^	^10/24/2001^	^NUNN^	^MICHAEL^	^WINTERVILLE^	^NC^	^Brf. prod. rmdrs.^	^Gave a whole two seconds. Said well aren~t you working late.^	^Previous call notes.^
^Vance, Amber M^	^10/30/2001^	^NUNN^	^MICHAEL^	^WINTERVILLE^	^NC^	^ZYP*****R*****^	^Seen Nunn 2x~s this month. 1st call not recorded. Brf rmdrs.^	^Previous follow up. Invite to Derek~s pgm in G~ville.^
^Vance, Amber M^	^11/1/2001^	^NUNN^	^MICHAEL^	^WINTERVILLE^	^NC^	^Invite to G~ville pgm.^	^Invited to G~ville Petty pgm @ the Hilton. He was interested and will be in town, but will need to followup before next Thursday if I want him there.^	^Reinvite to G~ville pgm. Previous call notes.^

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff, v. ELI LILLY AND COMPANY, Defendant.	Case No. 3AN-06-05630 CI

PLAINTIFF'S SUPPLEMENTAL RESPONSES TO DEFENDANT'S FOURTH SET OF INTERROGATORIES

PRELIMINARY STATEMENT

In response to Lilly's First Interrogatories and Requests for Production, the State provided a general description of the kinds of proof it would offer underlying its claims in this case. In response to Lilly's Fourth Interrogatories and Requests for Production, the State provided a description of similar information with respect to its claims under the Unfair Trade Practices and Consumer Protection Act (UTPCPA). However, the evidence is incomplete at this point because of Lilly's reluctance to produce meaningful discovery in response to the State's discovery requests. Lilly delayed the production of virtually any discovery until ordered by the Discovery Master to produce it. Additionally, at Lilly's request, key depositions have been delayed.[1]

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[1] The recent 30(b)(6) deposition on the issue of Lilly's marketing practices was initially noticed for December 6, 2007, but at Lilly's request was delayed until January 11, 2008.

number of additional violations related to affirmative misrepresentations of Zyprexa's risks, benefits or uses which are detailed in call notes by sales representatives.[7]

Searching the call notes database with specific terms reveals numerous violations of the UTPCPA. The State will provide examples below of such searches and exhibits detailing the results of those searches. These exhibits detail specifically the dates and substance of the UTPCPA violations in response to these interrogatories.

A search of the call notes using the search term "weight gain" reveals 98 instances of Lilly sales representatives discussing the issue of Zyprexa-related weight gain with Alaska physicians between 1999 and 2004.[8] In none of these instances did the Lilly sales representative indicate the true extent and magnitude of Zyprexa weight gain to the physician. Instead, the sales representatives were delivering the company message that weight gain was manageable and that any risk of it was far outweighed by Zyprexa's superior efficacy. Each of these notes establishes a violation of the UTPCPA.

A search of the call notes using the terms "diabetes," "glucose," "no differences," "comparable," "cause" or "causal" reveals 170 instances of Lilly sales representatives discussing high glucose or diabetes with Alaska physicians between 2000 and 2004.[9] Lilly sales representatives did not advise physicians of the true risks of high glucose or diabetes in

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[7] The State has only received a sampling of call notes to date. It will require a full production of all call notes through the present to fully address the spectrum and magnitude of UTPCPA violations in Alaska.
[8] Exhibit 3 (Alaska call notes reflecting discussion of weight gain).
[9] Exhibit 4 (Alaska call notes reflecting discussion of diabetes, glucose or diabetes messages).