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State of Alaska vs. Eli Lilly & Co

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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 MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT**

COMES NOW Defendant Eli Lilly and Company ("Lilly"), by and through counsel of record, Lane Powell LLC, pursuant to Rule 56(b) and moves this Court for an order granting summary judgment to Lilly on all claims brought by the State of Alaska.

I. INTRODUCTION

Doctors in Alaska regularly prescribe Zyprexa to mentally ill patients. The State of Alaska's Medicaid program reimburses Zyprexa prescriptions, without restriction. The State has never communicated to Alaska prescribers that there is anything wrong with Zyprexa, or urged them to stop or reduce prescriptions. Nevertheless, the State plans to ask the jury in the first phase of the trial of this matter to find that Zyprexa is a defective product—that alternative antipsychotic medications are safer and equally effective for all mentally ill patients.

In order to prevail on that claim, the State needs an expert to say that alternative medications are safer than, and equally effective as, Zyprexa. But no expert for the State has offered that opinion, and none would be expected to, as it is well recognized that mentally ill patients respond differently to different antipsychotic medications, and that Zyprexa is the most effective treatment for some patients, just as other medications are for other patients.

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Indeed, one of the State's experts has testified that Zyprexa would be his first choice for some patients. The State also lacks evidence necessary to satisfy the ordinary expectation test for design defect.

The State also claims that Lilly failed to warn physicians of the dangers associated with Zyprexa use. But, as the Court is well aware, the State does not intend to introduce any evidence from the allegedly misled physicians. Although it has never clearly described its proofs on the issue of physician reliance, the State apparently plans to submit only undifferentiated, aggregate evidence about how prescribers responded to the allegedly misleading warnings and marketing. The State's aggregate evidence depends on the "fraud-on-the-market" theory developed in securities litigation, which cannot be applied to prescription drugs. A new federal court decision, arising in virtually identical circumstances to this case, explains why this form of proof is inadequate to meet the State's burden.[1] This new decision confirms that the State's proof is inadequate to support a liability verdict for the State's strict liability and negligent failure to warn claims, and its Unfair Trade Practice Act (UTPA) claim for actual damages.

Finally, Lilly moves to dismiss the State's UTPA claim on the basis that the State has not described what the alleged violations are, much less offered evidence that could satisfy the State's burden of proof for that claim. At this juncture in the case, with trial less than three months away, Alaska Rule of Civil Procedure 56 requires the State to move beyond allegations, and show that it has admissible evidence to support its claims. It has manifestly failed this burden, warranting dismissal of its UTPA claim.

[1] Exhibit A, *In Re Rezulin Prods. Liab. Litig.*, No. 00 Civ. 2843 (S.D.N.Y. Nov. 26, 2007).

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A. The State Cannot Satisfy the *Prima Facie* Elements of Its Design Defect Claim.

The State has alleged that Zyprexa is a defective product, that is dangerous for its citizens to consume, and less effective than other medications for mental illnesses.[2] But it has taken none of the actions that would be expected if it actually believed this to be true, such as imposing restrictions on the reimbursement of Zyprexa prescriptions, even though it has such powers available to it and has used them for other medications,[3] or warning prescribers in the State about the alleged danger.[4] Nor has it found any expert who will testify that Zyprexa is defective under the risk-benefit or physician expectation tests set forth in *Shanks v. UpJohn Co.*, 835 P.2d 1189 (Alaska 1992), requiring dismissal of the claim.[5]

1. The State lacks the necessary proof to meet the risk-benefit test for design defect.

To establish existence of a defect under the risk-benefit test, the Alaska Supreme Court has held that the plaintiff must prove "that the product's design proximately caused injury and the defendant fails to prove, in light of the relevant factors, that on balance the

[2] Compl., ¶ 36; Pltf's Memorandum on Claims and Proofs at 18.

[3] As of October 4, 2007, all atypical antipsychotics, including Zyprexa, were available through Alaska's Medicaid program with no restriction, as atypical antipsychotics have not been included on Alaska's Preferred Drug List. *See* http://hss.state.ak.us/dhcs/PDL/default_docs/drugs100407.pdf; *see also* Exhibit B, Campana Dep. 191:19 to 192:18, 208:17 to 211:15, Sept. 19, 2007.

[4] *See* Exhibit C, Plft's Responses to Def's Second Set of Requests for Production of Documents, No. 40.

[5] In most states, a prescription drug manufacturer can only be held strictly liable for failure to warn, not design defect, for the reasons set forth in comment k to Restatement (Second) Torts § 402a. That approach is the only reasonable one for medications like antipsychotics, which have variable efficacy and side effects for different patients, and Lilly urges the Court to adopt it for this case.

benefits of the challenged design outweigh the risk of danger inherent in such design."[6] By its terms, the risk-benefit design defect test set forth in *Shanks* requires in the first instance that the medication proximately caused injury. The jury assigned to decide design defect liability will not hear any evidence about whether Zyprexa did or did not proximately cause injury to Alaska Medicaid recipients (whether assessed individually or on an aggregate basis).

Nor could the State win a battle of the experts on the issue of whether on balance the benefits of Zyprexa's design outweigh the risks. The factors that are relevant to this determination are: (1) the seriousness of the side effects or reactions posed by the drug, (2) the likelihood that such side effects or reactions would occur, (3) the feasibility of an alternative design which would eliminate or reduce the side effects or reactions without affecting efficacy of the drug, (4) the harm to the consumer in terms of reduced efficacy and any new side effects or reactions that would result from an alternative design.[7]

The State has been explicit that it is not contending that there is a way for Lilly to redesign the molecule that comprises Zyprexa. Instead, the "alternative design" that it proposes are the other medications on the market.[8] But the experts on both sides of the case agree that a blanket statement that a different medication could provide the same efficacy

[6] *Shanks*, 835 P.2d at 1194.

[7] *Id.* at 1196-97.

[8] Pltf's Memorandum on Claims and Proofs at 18.

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with fewer side effects for the entire population of severely mentally ill patients is incorrect, as Zyprexa is the most effective drug for many patients. This point is demonstrated dramatically by the deposition testimony of plaintiff's expert, William C. Wirshing:

Question: So, if I understand what you're saying, different populations respond differently to these drugs.

Answer: Absolutely.

Question: Different individual patients respond differently to these drugs.

Answer: No question.

Question: You may not know how one individual may respond to one particular drug versus another particular drug until you have tried them on that particular drug.

Answer: Exactly right.

Question: And which partially explains why there are a number of different antipsychotics in this class, because they aren't really all duplicates of each other.

Answer: They are – for an individual patient, they are definitely not fungible, to use one of your words.

....

Question: And so there is a class of patients or at least people who may present to you for whom you would prescribe Zyprexa as sort of the first line treatment. Is that correct?

Answer: Sure.[9]

Dr. Wirshing also testified about Zyprexa's superior efficacy, as demonstrated by numerous studies. In testifying on the efficacy of Zyprexa demonstrated in studies,

[9] Exhibit D, Deposition of William C. Wirshing, M.D. at 160, 162.

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Dr. Wirshing stated, "[T]here's a couple of pretty big studies that, you know, olanzapine [Zyprexa] turns out to be superior."[10]

Lilly's experts are in agreement with Dr. Wirshing's testimony on the efficacy of Zyprexa for individual patients.[11] As Dr. David Kahn, a psychiatrist with years of experience treating severely mentally ill patients, explained, "I have seen patients for whom olanzapine [Zyprexa] is *uniquely effective compared to other antipsychotics*, and the same can be said for alternative treatments for other patients."[12] In addition, different medications bring different side effects, including tardive dyskenesia, a severe movement disorder, and

[10] *Id.* at 159; *see also* Exhibit E, Deposition of Laura M. Plunkett, Ph.D, D.A.B.T. at 293 (confirming that Zyprexa was the most efficacious drug in terms of time to discontinuation, the primary endpoint for the CATIE study); Exhibit F, Deposition of Robert Rosenheck, M.D. at 304 (Zyprexa scores higher than risperidone (Risperdal) and quetiapine (Seroquel) on PANSS scores).

[11] *See* Exhibit G, Report of William S. Gilmer, M.D. at 7 ("[W]hen successful outcome is achieved and sustained with any agent, including the atypical antipsychotics, a careful analysis must occur before discontinuing an effective agent, as other agents within or outside of the same class may not provide similar efficacy, and destabilization can occur whenever changes in medication occur."); Exhibit H, Report of David Kahn, M.D. at 5 ("Prescription decisions are individualized, heavily impacted by characteristics of the patients themselves. The factors include not only the patient's diagnosis, but also the particular symptoms of the condition that need treatment, such as the need for sedation versus activation, insomnia, anxiety, agitation, and prior history of treatment-induced EPS, or history of comorbid neurological or general medical disorders."); Exhibit I, Report of Thomas L. Schwenk, M.D. at 3 ("In my clinical experience, the use of atypical antipsychotics in general and Zyprexa in particular for bipolar disorder can lead to improved functional status and a decreased burden of disease."); Exhibit J, Report of Carol A. Tamminga, M.D. at 3 ("[I]ndividuals with the illness [schizophrenia] are less symptomatic with olanzapine, regardless of whether this advantage is 'primary' or 'secondary'.").

[12] Exhibit H, Report of David Kahn, M.D. at 5 (emphasis added).

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Parkinsonian conditions, which are experienced less by Zyprexa patients than users of other antipsychotic medications.[13]

As the foregoing demonstrates, the assertion that there is an alternative medication that is safer than, and equally effective as Zyprexa across the board for all patients, is not only not supported by expert testimony, it is illogical and incoherent in the context of actual medical treatment of severely mentally ill patients, who respond differently to different treatments. As Judge Weinstein has observed:

> There is little doubt about the usefulness of Zyprexa for both on-label and some off-label purposes. It assists many people with serious debilitating diseases. It has substantially increased the quality of life of many thousands of people. Its salutary effect is evidenced by the fact that there have been no changes in plaintiffs' formularies which continue to include Zyprexa without restrictions. Many treating physicians continue to rely on it after what is by now extensive revelation of information about Zyprexa's risks and benefits.[14]

Absent evidence on proximate causation, coupled with agreement by both parties' experts that no alternative medication provides a safer and more effective design than Zyprexa for all mentally ill patients, the State cannot meet its burden under the risk-benefit test for design defect.

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[13] *See* Exhibit J, Report of Carol A. Tamminga, M.D. at 5 ("The incidence of this side effect with FGAs [first-generation antipsychotics] is approximately 5% per treatment year, producing a relatively high prevalence in older schizophrenic populations that have had years of treatment. SGAs [second-generation antipsychotics, including Zyprexa] have a reduced incidence of TD [tardive dyskenesia], approximately 1% in adult populations.") (citations removed).

[14] *In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571, 575 (S.D.N.Y. 2007).

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2. The State lacks the necessary proof to meet the ordinary physician expectation test for design defect.

Under *Shanks*, the ordinary physician expectation design defect test requires the plaintiff to establish that "the product failed to perform as safely as an ordinary consumer (or for pharmaceutical products, the physician) would expect when used in an intended or reasonably foreseeable manner."[15]

An essential element of this test is proof of how the medication performed—or failed to perform—that will be measured against the ordinary physician's expectation. In this case, the jury will not hear any evidence about how well Zyprexa performed in the treatment of Alaska patients—whether assessed in the aggregate or individually. The jury will not hear whether Zyprexa patients' mental health conditions were improved by use of Zyprexa, whether their hospitalizations were reduced, or whether the incidence of diabetes amongst Zyprexa users was more or less than otherwise would have been expected. Without evidence of the performance of the medication, a design defect case using the ordinary physician expectation test cannot get off the ground.

Even if such evidence existed, the State has not mustered any evidence of what the ordinary physician that prescribed Zyprexa expected. The physician's expectation is not within the common knowledge of the average juror. Expert testimony is required to make

[15] *Shanks*, 835 P.2d at 1195.

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this showing.[16] None of the State's expert reports include an opinion regarding how the ordinary physician expected Zyprexa to perform.

Absent proof on the performance of Zyprexa, and expert testimony about how prescribers expected it to perform, the State cannot meet its burden under the ordinary physician expectation test, and Lilly is entitled to summary judgment on this design defect claim.

B. New Case Law Supports Dismissal of the State's Failure to Warn Claim and Its Unfair Trade Practices Claim for Actual Damages.

As Lilly has previously argued to the Court, any claim by the State that Lilly induced Zyprexa prescriptions through misrepresentations requires proof that doctors actually relied on the alleged misrepresentations. In implicit recognition that it cannot muster proof of this element, the State has already voluntarily dismissed with prejudice the fraudulent and negligent misrepresentation counts of its Complaint. But physician reliance is also a necessary component of the State's strict liability and negligent failure to warn claims,[17] and its UTPA claim for actual damages.[18] A new federal court decision addressing a prescription

[16] *See generally Marsingill v. O'Malley*, 58 P.3d 495, 504 (Alaska 2002); *Armstrong v. State*, 502 P.2d 440, 446 (Alaska 1972).

[17] *See, e.g., Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 383-84 (D.N.J. 2004); *Kernke v. Menniger Clinic, Inc.*, 173 F. Supp. 2d 1117, 1123 (D. Kan. 2001); *Huntman v. Danek Med., Inc.*, No. 97-2155, 1998 U.S. Dist. LEXIS 13431, at *19 (S.D. Cal. July 27, 1998); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1161 (D. Or. 1989); *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 349-50 (Minn. Ct. App. 2001).

[18] *See* AS 45.50.531(a) (2007) (requiring that an alleged unlawful practice caused an "ascertainable loss").

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drug liability claim by the State of Louisiana demonstrates why the State of Alaska cannot prove liability for those claims with the evidence it plans to submit in this case.

In Re Rezulin Prods. Liab. Litig., No. 00 Civ. 2843 (S.D.N.Y. Nov. 26, 2007) (attached as Exhibit A), involved a claim by the State of Louisiana on behalf of its Medicaid program for reimbursement of the costs of prescriptions for a diabetes drug, Rezulin, that had been removed from the market, as well as for the cost of injuries sustained by Medicaid patients who used that drug. Louisiana's theory of recovery, like that of Alaska's, was an indirect one: "[D]efendants misled patients and the medical community concerning 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 at prices that otherwise could not have been charged."[19] Louisiana pleaded failure to warn and UTPA claims, just like Alaska.[20]

Louisiana's theory of recovery parallels the State's theory here: the State alleges that Lilly's conduct led to Zyprexa being

> prescribed by Alaska physicians to many recipients of the Medicaid program of the State. As a result of ingesting Zyprexa, Alaska Medicaid patients have suffered serious health effects which now require further and more extensive medical treatment and health-related care and services. For these individuals, the State is the financially responsible party for these services.[21]

[19] Exhibit A, *In Re Rezulin.* at 8.

[20] *Id.* at 7-8 and n.18.

[21] Compl. ¶¶ 20-23, 26.

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The *Rezulin* Court rejected Louisiana's claims because they relied on a "fraud-on-the-market" theory of causation.[22] While recognizing that such a causation theory has a proper place in federal securities law, the Court noted that "courts repeatedly have refused to apply the fraud-on-the-market theory to state common law cases despite its widespread acceptance in the federal securities fraud context."[23] This type of causation theory has been soundly rejected in the prescription drug context because it relies on the notion that a perfect market of information about drug side effects exists and that any new information would automatically change decisions on whether a prescription would be written.[24] In a pharmaceutical case, the processing of additional information by individual physicians, who continually weigh risks and benefits, is essential to understanding why a prescription was written—in other words, for understanding causation. It also must account for changing information over time; the adequacy of a warning to a prescriber depends on what was known and knowable at the time the prescription was written.[25] Judge Kaplan recognized

[22] Exhibit A, *In Re Rezulin* at 8.

[23] *Id.* (quoting *Secs. Investor Prot. Corp. v. BDO Seidman, L.L.P.*, 222 F.3d 63, 73 (2d Cir. 2000)).

[24] *See Heindel,* 381 F. Supp. 2d at 380 (finding the application of the fraud-on-the-market theory to pharmaceuticals to be "patently absurd").

[25] *See Shanks,* 835 P.2d at 1200; *Beyette v. Ortho Pharm. Corp.*, 823 F.2d 990, 992-93 (6th Cir. 1987) (noting that warnings to the medical community change over time as new side effects to a device become apparent); *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 91 (2d Cir. 1980) (stating that warnings should change due to safety information learned through research, adverse reaction reports, and scientific literature); *Allen*, 708 F. Supp. at 1148 (noting that warnings to the medical community should change as knowledge of a medication's side effects changes).

this cannot be understood in the aggregate, as a "fraud-on-the-market" theory would attempt to do.

In this case, the State similarly relies on a fraud-on-the-market theory: the State has denied that it must prove that any particular physician relied on any particular misrepresentation or claimed inadequate warning, or that any particular patient suffered an injury. Rather, the State posits that causation can be established by examining "the aggregate effect upon the State's Medicaid program."[26] This approach, like that in *In Re Rezulin*, is "a quintessential fraud-on-the-market theory."[27]

While the *Rezulin* decision is not binding on Alaska courts, there is no case law in Alaska, or any state or federal court in the country, that provides more on-point guidance on the viability of a state agency's claim for damages based on alleged misrepresentations to prescribers of medications.[28] Indeed, there is only one significant difference between this case and *In re Rezulin*: Rezulin has been removed from the market, while Zyprexa continues to be prescribed, used, and reimbursed by the State of Alaska, making this case an even stronger candidate for dismissal than the one disposed of by Judge Kaplan.

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[26] Pltf's Memorandum on Claims and Proofs at 6.

[27] Exhibit A, *In re Rezulin*, at 8.

[28] The only case proffered by the State for the proposition that a State can bring a products suit to recover for monies expended by a State Medicaid agency, *State v. The American Tobacco Company*, 14 F. Supp. 2d 956 (E.D. Tex. 1997), arises from the very different context of tobacco, where there is no prescriber intermediating the use of the product by the end consumer, and says nothing about the type of proof that will determine reliance in the prescription drug context.

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C. **The State's Unfair Trade Practices Act Claim Fails Because It Presents No Evidence of What Misconduct Occurred.**

Lilly has sought discovery of what actual practices the State believes were in violation of the Alaska Unfair Trade Practices Act (UTPA). Despite repeated requests by Lilly to provide specifics of the acts alleged to have violated the UTPA, the State has failed to do anything other than repeat the general allegations found in the Complaint.[29] Under Alaska law, this is insufficient to survive a motion for summary judgment under Alaska Rule of Civil Procedure 56.[30] Lilly will be filing under separate cover this week a motion to compel responses to discovery of the evidence supporting the State's allegations that Lilly violated the UTPA. If the State now fails to provide information about what specific conduct is at issue and the evidence supporting it, Lilly is entitled to summary judgment.

CONCLUSION

For the foregoing reasons, Lilly requests that this Court grant summary judgment on all of the State's claims.

DATED this 10th day of December, 2007.

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[29] *See* Exhibit K, Pltf's Responses to Def's Fourth Set of Interrogatories.

[30] *See generally Zok v. Collins*, 18 P.3d 39, 41 (Alaska 2001).

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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In re:

REZULIN PRODUCTS LIABILITY
LITIGATION (MDL No. 1348)

MASTER FILE

00 Civ. 2843 (LAK)

This Document Relates to: 05 Civ. 8397
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MEMORANDUM OPINION

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LEWIS A. KAPLAN, *District Judge.*

This action was brought by Charles A. Foti, Jr., in his official capacity as the Attorney General of the State of Louisiana and as *parens patriae* on behalf of Louisiana and its citizens, the State of Louisiana, and the Louisiana Department of Health and Hospitals ("LDHH"). The matter is before the Court on the motion of defendants Warner-Lambert Company LLC and Pfizer Inc. for summary judgment dismissing the complaint.

Facts

Plaintiff here seeks to recover amounts paid to fill Rezulin prescriptions for Louisiana Medicaid recipients and to treat their illnesses allegedly caused by Rezulin. Their claims are premised on their allegations that Louisiana would not have paid for Rezulin prescriptions filled by Medicaid recipients had it known information that allegedly was withheld or misrepresented by Warner-Lambert and that Louisiana Medicaid recipients would not have used the drug had the State not paid for it. The facts pertinent to this motion, however, are undisputed.[1] As they all relate to the

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[1] Defendants submitted a S.D.N.Y. Rule 56.1 Statement that is supported by admissible evidence properly referred to therein. Plaintiffs' opposition to defendants' Rule 56.1 statement in some cases purports to dispute statements in defendants' filing (¶¶ 1, 4) and in another instance to dispute relevancy and admissibility (¶3). In no case do plaintiffs cite admissible evidence demonstrating the existence of a genuine issue of fact for trial as required by S.D.N.Y. Civ. R. 56.1(d). The failure to do so results in the well supported factual assertions in defendants' statement being deemed admitted. *E.g., Archie Comic Publ'ns, Inc. v. DeCarlo*, 258 F. Supp.2d 315, 317-19 (S.D.N.Y. 2003), *aff'd*, 88 Fed.Appx. 468 (2d Cir.), *cert. denied*, 543 U.S. 813 (2004).

Even if the Court were to consider paragraph 1 of plaintiffs' Rule 56.1 opposition notwithstanding the lack of evidentiary support, the statements there set forth would not create a genuine issue of fact as to the proposition asserted by defendants, viz. that "Rezulin was a prescription drug that was approved as safe and effective for the Treatment of Type 2 diabetes by the Federal Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act."

legal framework of the Medicaid program, they are discussed below.

Discussion

The Merits

Louisiana's Legal Obligation to Pay for Rezulin

Federal statutory provisions regulating Medicaid govern what can be included in or excluded from State Medicaid formularies. They also mandate the medications for which Louisiana is required to pay and the exclusive circumstances under which it could refuse such payment. Under those provisions and Louisiana statutes enacted to implement them, the State of Louisiana was required to pay to fill Rezulin prescriptions for Louisiana Medicaid recipients.

Medicaid is a federal program established in 1965 as part of the Social Security Act to provide medical assistance, including the cost of prescription drugs, to low-income individuals and their families by authorizing federal grants to States to accomplish that purpose.[2] To participate in the Medicaid program and receive federal funding, States must comply with a comprehensive

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Paragraph 4 of plaintiffs' Rule 56.1 opposition purports to dispute defendants' allegation that "[p]rior to 2001 Louisiana had an open formulary law which required Medicaid reimbursement of all FDA approved legend drug and none of the exemptions applied to Rezulin." The text of plaintiffs' statement disputes only that Rezulin was a "legend drug" and whether the FDA uses that term. But defendants have submitted a report of the LDHH that states that "[p]rior to 2001 Louisiana had an open formulary law which required Medicaid reimbursement of all FDA approved legend drugs, with a few exceptions." Grass Decl. Ex. B, at 1. That report is of unquestioned admissibility. As plaintiffs have submitted no evidence to the contrary, the quoted statement in the report is deemed admitted for purposes of this motion. Moreover, it is immaterial whether the FDA used the term "legend drug."

2 42 U.S.C. § 1396, *et seq.*; 42 C.F.R. § 430, *et seq.*

federal statutory and regulatory scheme.[3]

Under 42 C.F.R. § 431.10(b), States must provide the federal government with a detailed plan of operation that, among other things, specifies "a single State agency established or designated to administer or supervise the administration of the [Medicaid] plan." Louisiana has designated LDHH to administer the Medicaid program in Louisiana.

The LDHH was created in 1988 to "be responsible for the development and providing of health and medical services for the prevention of disease for the citizens of Louisiana" and to provide "health and medical services for the uninsured and medically indigent citizens of Louisiana."[4] In Louisiana, the LDHH is the sole agency designated to administer the Medicaid program. The program is directed by the Secretary of the LDHH.[5]

The Social Security Act has a detailed statutory and regulatory framework that sets forth specific requirements for Medicaid programs, such as that administered by the LDHH, which received federal funding. Under federal law, a "covered outpatient drug" is one "which may be dispensed only upon prescription" and "which is approved for safety and effectiveness as a prescription drug" under the Federal Food, Drug and Cosmetic Act the "FDCA").[6] At all times,

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3 *Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 502 (1990) ("Although participation in the program is voluntary, participating States must comply with certain requirements imposed by the Act and regulations promulgated by the Secretary of Health and Human Services").

4 LA. REV. STAT. ANN. § 36:251.

5 *Id.* § 36:254.

6 42 U.S.C. § 139r-8(k)(2)(A)(i).

while it was marketed, Rezulin was a prescription drug that was approved as safe and effective for the treatment of Type II diabetes by the FDA under the FDCA.[7] Thus, Rezulin was a "covered outpatient drug."

Federal law expressly limits a State's ability not to pay for "covered outpatient drugs" under the Medicaid programs.[8] Under federal law, a "State may establish a formulary if the formulary meets" certain specified requirements.[9] Among those requirements is that the formulary must "[i]nclude[] the covered outpatient drugs of any manufacturer which has entered into and complies" with a rebate agreement with the Secretary of Health and Human Services.[10] To have its drugs qualify for Medicaid reimbursement, federal law requires that a manufacturer enter into a "rebate agreement" with the Secretary of Health and Human Services pursuant to which the manufacturer pays rebates in statutorily mandated amounts to States based on Medicaid sales of its covered outpatient drugs.[11] At all times while Rezulin was marketed, Warner-Lambert was a party to a "rebate agreement" with the Secretary of Health and Human Services,[12] which made Rezulin eligible for medicaid reimbursement.

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7 *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 63 (S.D.N.Y. 2002).

8 42 U.S.C. § 1396r-8(d)(1)(B).

9 42 U.S.C. § 1396r-8(d)(4).

10 42 U.S.C. § 1396r-8(d)(4)(B).

11 42 U.S.C. § 1396r-8(a)(1), 1396r-8(b)(1)(A), 1396r-8(c).

12 Grass Decl. Ex. A.

Rezulin was withdrawn from the market in the United States on March 21, 2000.[13] Prior to June 13, 2001, however, the applicable Louisiana statute provided, in pertinent part, that:

> "(2) The department shall provide reimbursement for any drug prescribed by a physician that, in his professional judgment and within the lawful scope of his practice, he considers appropriate for the diagnosis and treatment of the patient.
>
> "(3) The department shall not establish a drug formulary that restricts by any prior or retroactive approval process a physician's ability to treat a patient with a prescription drug that has been approved and designated as safe and effective by the Food and Drug Administration . . . ."[14]

Hence, the LDHH could not have had a restricted formulary, *i.e.*, one that excluded Rezulin or other covered outpatient drugs, during any part of the period in which Rezulin was on the market. Nor could LDHH have refused payment for Rezulin because LDHH was prohibited from "establish[ing] a drug formulary that restricts by any prior or retroactive approval process a physician's ability to treat a patient with a prescription drug that has been approved and designated as safe and effective" by the FDA.[15] Reflective of the requirements of this statutory provision, the March 24, 2005 LDHH

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13 Complaint ¶ 8.

14 LA. REV. STAT. ANN. § 46-153.3(B). An amendment to the statute effective July 2, 1999 has no impact on the pending motion. The statute was amended to permit LDHH to "develop peer-based prescribing and dispensing practice patterns for health care providers who participate in the Louisiana Medicaid program and [to] develop a process to promote such practice patterns through the Drug utilization review Board." La. R.S. § 46:153(B)(4)(a) (attached as Exhibit D to Grass Declaration). As the amended statute expressly stated: "The intent of this [newly added] Paragraph is to limit aberrant practice patterns upon peer-based practice patterns." Nothing in the 1999 amendment permitted LDHH to refuse payments for medications prescribed to Louisiana Medicaid recipients based on LDHH's view of the safety, efficacy or cost of those medications relative to other medications. Indeed, the amended statute expressly provided: "Nothing contained herein shall be interpreted or construed as to interfere with the provisions of paragraph (3) of this Subsection," which prohibited LDHH from doing those things. Thus, for purposes of this motion, the 1999 amendment made no material changes to the applicable provisions set forth above.

15 *Id.*

report to the Governor and the Legislature stated "prior to 2001 Louisiana had an open formulary law which required Medicaid reimbursement of all FDA approved legend drugs, with a few exemptions"[16] none of which is applicable here.[17] In sum, the State of Louisiana was required by federal and Louisiana law to pay pharmacies for the cost of Rezulin prescriptions for Medicaid recipients.

Louisiana's Fraud on the Market Theory

Plaintiffs sue entirely on Louisiana state law theories, all of which require proof of causation.[18] They therefore are obliged to adduce admissible evidence that, if credited, would be

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16 Grass Decl. Ex. B, at 1.

17 Act 395 of 2001 deleted § 153.3(B)(2) and replaced § 153(B)(3) with the current § 153.3(B)(2)(a), which allows the LDHH to condition payment on prior authorization as defined by federal law. Act 395 of June 13, 2001, § 153.3(B)(3), 2001 La. Sess. Law Serv. 840 (West). Under federal law, a covered outpatient drug subject to a rebate agreement may be excluded from a State's formulary "with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion." 42 U.S.C. § 1396r-8(d)(4)(C). In that event, a State may impose a prior authorization requirement – *i.e.*, decline to pay for prescriptions of the excluded drug unless the Medicaid recipient's doctor first establishes to the State's satisfaction that the prescription is necessary for the patient. *See id.* § 1395r-8(d)(4)(D). Prior to the enactment of Act 395 of 2001, which postdated the withdrawal of Rezulin from the market, Louisiana was obliged to reimburse for any prescribed drug and was prohibited from imposing any restrictions, including a prior authorization requirement, on such reimbursement.

18 *See* LA. REV. STAT. ANN. § 9.2800.54(A) (Louisiana Products Liability Act, which governs plaintiffs' strict liability, failure to warn, and breach of warranty claims, requires proof of "damage proximately caused by" defendants); LA. CIV. CODE ANN. art. 2520 (redhibition claim requires proof that plaintiffs "would not have bought the thing had [they] known of the defect"); LA. REV. STAT. ANN. § 51.1409(A) (Louisiana Unfair Trade Practices Act

sufficient to permit a finding of proximate cause. They argue that 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 at prices that otherwise could not have been charged. This, as defendants maintain, is "a quintessential fraud-on-the-market" theory.

The fraud-on-the-market theory is a creature of the federal securities laws. As the Second Circuit recognized not long ago, "courts repeatedly have refused to apply the fraud on the market theory to state common law cases despite its widespread acceptance in the federal securities fraud context."[19] Only this year, the New Jersey Supreme Court reversed a grant of class certification and rejected application of the fraud-on-the market theory in a suit relating to the ethical drug Vioxx in circumstances identical to those at Bar.[20] Other cases are to similar effect.[21] Plaintiffs have given the Court no reason to believe that Louisiana's Supreme Court would reach a different

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requires proof of loss "as a result of the use or employment by another person of an unfair or deceptive method, act or practice"); *Edwards v. Conforto*, 636 So.2d 901, 907 (La. 1993) (unjust enrichment requires proof of "a causal relationship between the enrichment and the impoverishment").

19 *Secs. Investor Prot. Corp. v. BDO Seidman, L.L.P.*, 222 F.3d 63, 73 (2d Cir. 2000).

20 *Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co.*, 929 A.2d 1076, 1088 (N.J. 2007). *Accord, Heindel v. Pfizer, Inc.*, 381 F. Supp.2d 364 (D. N.J. 2004).

21 *See, e.g., Oliviera v. Amoco Oil Co.*, 776 N.E.2d 151, 155 (Ill. 2002); *Weinberg v. Sun Co., Inc.*, 777 A.2d 442 (Pa. 2001); *Ex parte Household Retail Servs., Inc.*, 744 So.2d 871, 880 n.2 (Ala. 1999).

result.[22] Plaintiffs' reliance on two RICO decisions by Judge Weinstein[23] therefore is misplaced.[24]

Finally, plaintiffs seek to draw comfort from the Second Circuit's decision in *DeSiano v. Warner-Lambert Co.*,[25] where it upheld the legal sufficiency of a complaint by health benefit plan providers ("HBPs"). But *DeSiano* made clear that it upheld the complaint because the HBP plaintiffs alleged that they themselves had been misled as purchasers of the drug:

> "In the instant case, . . . Plaintiffs allege an injury directly to themselves; an injury, moreover, that is unaffected by whether any given patient who ingested Rezulin became ill. Plaintiffs' claim is that the Defendants' wrongful action was their misrepresentation of Rezulin's safety, *and that this fraud directly caused economic loss to them* [i.e., to the third-party payers] *as purchasers, since they would not have bought Defendants' product, rather than available cheaper alternatives, had they not been misled by Defendants' misrepresentations. Thus the damages – the excess money Plaintiffs paid Defendants for the Rezulin that they claim they would not have purchased 'but for' Defendants' fraud – were in no way 'derivative of damage to a third party.'*"[26]

Here, in contrast, plaintiffs allege that they were injured because patients and the medical community were misled. The undisputed facts show that Louisiana allegedly was injured only because it was

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22 As this case rests entirely on state law, the Court is obliged to make its best judgment as to the rule that would be formulated by Louisiana's highest court. *Travelers Ins. Co. v. Carpenter*, 411 F.3d 323, 329 (2d Cir. 2005); *Maska, U.S., Inc. v. Kansa Gen. Ins. Co.*, 198 F.3d 74, 78 (2d Cir. 1999).

23 *In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp.2d 571 (E.D.N.Y. 2007); *Schwab v. Philip Morris Cos.*, 449 F. Supp.2d 992 (E.D.N.Y. 2006), *appeal pending* No. 06-4666 (2d Cir. argued July 10, 2007).

24 The Court notes the Second Circuit's recognition that the law of proximate cause under RICO differs from that under state law. *DeSiano v. Warner-Lambert Co.*, 326 F.3d 339, 348 (2d Cir. 2003).

25 326 F.3d 339.

26 *Id.* at 349 (emphasis added) (footnote omitted).

obligated by law to pay for the drugs prescribed for Medicaid recipients and not because Louisiana itself was deceived. *DeSiano* therefore has no bearing here.

The Claim of Inadequate Discovery

Plaintiffs resist summary judgment also on the ground that they have conducted no discovery in this case and refer also to FED. R. CIV. P. 56(f). These assertions are frivolous.

As an initial matter, plaintiffs served discovery requests which the defendants answered in August 2007. The responses brought to plaintiffs' attention the comprehensive discovery already conducted over a period of years by the Plaintiffs' Executive Committee. Plaintiffs to this day have not indicated any dissatisfaction with defendants' responses.[27]

Even putting aside the inaccuracy of plaintiffs' claim that there has been no discovery, the fact remains that this case was docketed in this Court on September 28, 2005, over two years ago, pursuant to a Multidistrict Panel transfer. If in fact plaintiffs had conducted no discovery either prior or subsequent to the transfer, they would have had no one to blame but themselves. Their inaction cannot afford a basis for denying or deferring summary judgment.

Even more basically, this Circuit has made crystal clear the showing that is required under Rule 56(f) where a party seeks to avoid the entry of summary judgment on the ground that it believes that more discovery is necessary:

> "[A] party resisting summary judgment on the ground that it needs discovery in order to defeat the motion must submit an affidavit showing '(1) what facts are sought [to resist the motion] and how they are to be obtained, (2) how those facts are reasonably

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27 Plaintiffs, on the other hand, responded to defendants' interrogatories by what can be described only as categorical stonewalling. Vicari Decl. Ex. B.

> expected to create a genuine issue of material fact, (3) what effort affiant has made to obtain them, and (4) why the affiant was unsuccessful in those efforts."[28]

"Indeed, the failure to file such an affidavit is fatal to a claim . . . even if the party resisting the motion for summary judgment alluded to a claimed need for discovery in a memorandum of law."[29]

Here, plaintiffs have submitted no Rule 56(f) affidavit. They have not shown what facts are sought to resist the motion and how they are to be obtained. They have made no effort to show how those facts might create a genuine issue of material fact. By their own admission, they have made no effort to obtain them. They have failed utterly to make the requisite showing.

Conclusion

For the foregoing reasons, defendants' motion for summary judgment dismissing the complaint [00 Civ. 2843 docket item 5030] is granted and the action dismissed.

SO ORDERED.

Dated: November 26, 2007

Lewis A. Kaplan
United States District Judge

(The manuscript signature above is not an image of the signature on the original document in the Court file.)

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[28] *Miller v. Wolpoff & Abramson, L.L.P.*, 321 F.3d 292, 303 (2d Cir. 2003) (quoting *Gurary v. Winehouse*, 190 F.3d 37, 43 (2d Cir. 1999) (internal quotation marks and citations omitted)). *Accord, e.g., Concourse Rehabilitation & Nursing Center Inc. v. Whalen*, 249 F.3d 136, 146 (2d Cir. 2001).

[29] *Gurary*, 190 F.3d at 43-44.

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

VIDEOTAPED 30(b)(6) DEPOSITION OF
STATE OF ALASKA
DESIGNEE: DAVID CAMPANA

Wednesday, September 19, 2007
9:30 a.m.
Volume II

Taken by Counsel for Defendant
at
Lane Powell, LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

A-P-P-E-A-R-A-N-C-E-S

For Plaintiff:
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For Defendant:

Eric J. Rothschild
Barry Boise (via speaker phone)

there is no formulary?
A. Well, there is a drug list. As far as a formulary, and my definition of a formulary is that you would have a list of drugs.
On there would be drugs that are covered and drugs that are not covered. It would be nice and easy to find and it would be go search on it by NDC and find what is covered what is not.
We don't have that, so we have a regulation that tells generally classes that are covered and not covered.
Q. It tells by list what are not covered and everything else --
A. Is covered.
Q. -- is covered?
A. Correct.
Q. If, for example, anti-psychotics are a class of drugs that are covered, correct?

0191

A. Correct.
Q. And if since it's not listed, therefore, the class of anti-psychotics does not appear in that regulation, correct?
A. Correct.
Q. And that means that every drug in that class is covered, correct?
A. Correct, as long as there is a federal rebate.
Q. You sound like you are a fan of formularies. Why doesn't Alaska have one?
A. Well, formularies really don't fit in the Medicaid program. They fit in a PBM program, PBM insurance program where you can say, "Well, we don't cover this. We don't cover that."
Unfortunately, with Medicaid, it's out there in federal law what you can cover and what you can't cover. And if there is a federal rebate, you virtually can't not cover it.
Q. Does the state have the discretion to disallow reimbursement of a medication because of safety issues?
A. We can put it on restriction for safety issues, and our regulation allows us to do that.
Q. What regulation is that?
A. That would be 7AAC43.598 or 594.
Q. What does that do? What does that regulation

0192

allow Alaska to do?
A. Allows us to place, under some type of restriction, medications for safety or abuse issues.
Q. What kind of restrictions can Alaska impose on drugs that fit that description?
A. We can put quantity limits on those. We can change the definition for early refill on those.
We could do step edits, and we could also do prior authorizations.
Q. What is a step edit?
A. Step edit is a process where you are doing edits on a medication. They would have to fill one type of medication before they can get another type of medication.
The good example of that is when Vioxx was available, you had to take Ibuprofen or you had to take Naprosyn before you could get a prescription of Vioxx filled.

Q. This was before, obviously, Vioxx was taken off the market?
A. Correct.
Q. Do you remember the date of that, estimate when Vioxx went off the market? I'm just trying to orient ourselves.
A. It was September of '04 or '03.

Q. Was the step edit in place for Vioxx in Alaska -- was the step edit in place the entire time Vioxx was on the market?
A. Actually, we did not implement it. We had the programming ready to go and then did not implement it.
Q. When did Alaska start the process of, you know, developing the step edit?
A. In 2003.
Q. Do you remember when in 2003?
A. It was when we were implementing HIPAA. It was February to May of 2003.
Q. What caused the state to start the process of developing this step edit?
A. Due to safety issues with Vioxx and then also cost issues. Vioxx was much more expensive than Ibuprofen was.
Q. Were you sort of the person in HSS who was leading this effort to put in this step edit?
A. Yes.
Q. What safety issues did you -- caused you to -- were you the one who suggested the step edit?
A. I'm not -- I don't remember as to whether I was or it was suggested by our fiscal agent, First Health.
Q. You agreed with it?
A. I agreed with it.

Q. And was your agreement with introducing the step edit based on the financial issues, the safety issues or both?
A. Both. The safety issues were that Vioxx had claimed that there was much less gastric upset and gastric issues with Vioxx versus the other NSAIDs, non-steroidal anti-inflammatory drugs. And it was our findings that that was not necessarily true.
I looked at some Medicaid claims for people who had taken NSAIDs, and including Vioxx, and found that the incidence of gastric problems was just as high with Vioxx as the other NSAIDs.
There was some literature on that also at the same time.
Q. Why did it take from, you know, late winter of 2003 until September 2004 for this step edit -- the step edits never went into place?
A. Right, they never went into place.
Q. Why did it take so long from the time this decision was made to introduce the step edit?
A. Well, basically, you have an idea to do something, then it has to the go to the programmers, and it takes them a long time to come up with how to do it and then do the actual programming for it.
We had put in the work orders or put in the

requirement for the step edit in April 2003. We implemented the system in May of 2003, and the step edit had been stopped before that time.

New York, Nebraska. Just all different states.
Q. And you have been doing that over the years?
A. Over the years.
Q. For various different medications?
A. Correct.
Q. The state -- we talked a little bit yesterday about the state having a preferred drug list?
A. Yes.
Q. Explain what the preferred drug list is.
A. The preferred drug list is a list of medications that actually lists preferred medications and non-preferred medications.
The list is developed by the state through or with the pharmacy and therapeutics committee.
Q. So when did Alaska start developing preferred drug lists?
A. It was in the fall of 2003. We put together a pharmacy and therapeutics committee. We had amended our contract with First Health to use their services for the

0208

project and we went out with their national pooling initiative and then gained CMS approval for that.
Q. What do you mean by "national pooling initiative"?
A. They have what's called a National Medicaid Pooling Initiative where it pulls the members or the eligibles from various states into one pool and then contracts with manufacturers for supplemental rebates for the drugs that are added to the preferred drug list.
Q. I want to get back to this, but it just occurred to me I left one issue hanging in terms of state procedure or a couple of issues.
You talked about the step edits and I want to talk a little bit more about that. But you also said that the regulations allow prior authorizations?
A. Correct.
Q. Let me just clarify, you had said that the regulation that allowed restrictions on reimbursements is 43598?
A. Yeah, or 594.
Q. Okay. Let me just show you. I think that's what I wanted to confirm. I'm going to show you 594, and I have the book as well. Did you mean to say 594?
A. Yeah. It's changed. It had been 598 and back to 594.

0209

Q. 594 seems to describe a prior authorization process, correct?
A. Correct.
Q. Maybe I'm not reading it correctly, but I don't see the step edit process included in 594. Am I missing something?
A. Under B it says, "As necessary to prevent waste and to address fraud and abuse, the division may place limitations on the maximum or minimum quantities allowed of a specific prescribed drug or therapeutic class, or on the number of refills of a specific prescribed drug or therapeutic class," so as far as placing limitations.
Q. In the section on prior authorization, it talks about considerations of cost and clinical effectiveness, correct?
A. Correct.
Q. And clinical effectiveness would include safety

issues?
A. Correct.
Q. In the section B, which you are referring to, it talks about waste or fraud and abuse, and it doesn't talk about cost effectiveness or -- I'm sorry -- clinical effectiveness or safety.
Is there a distinction, as you understand the regulation, in terms of when step therapy, step edits

0210

can be used relative to prior authorizations?
A. Well --
Q. I'm sorry. Let me withdraw that and ask it this way: Is it your understanding that the state may institute step edits to address safety issues?
A. Yes.
Q. And similarly, can use prior authorizations to address safety issues?
A. Yes.
Q. What is a prior authorization?
A. Is that an exhibit?
Q. We don't need to mark that as an exhibit.
What is a prior authorization?
A. A prior authorization is an edit that is placed on medications to prevent the filling or the paying of that medication unless certain criteria or certain administrative references are fulfilled before that is authorized.
Q. What do you mean by that? What has to be done?
A. The physician, the prescriber or the pharmacist who is filling the prescription has to call an 800 number, let us know what the -- or what the diagnosis is, and then we determine whether or not the prescription drug can be paid for by the Medicaid program.

0211

Q. And the prior authorization, that's a mechanism to address safety issues with the medications?
A. That's one of the tenants on that.
Q. What are the other tenants?
A. To address safety, to address the utilization, keep it within the labeled indications, and to address fraud or abuse.
Q. Has Alaska instituted prior authorizations for medications because of safety issues?
A. Yes.
Q. What medications?
A. The opioid medications.
Q. Can you give me some examples of those?
A. Morphine, Methadone, Oxycodone, Fentanyl patches, Fentanyl lozenges.
Q. Any other medications which have -- where you have instituted prior authorizations because of safety reasons?
A. I'm not remembering any right now.
Q. Do you think there have been others?
A. I'm drawing a blank right now. In fact, it's a good time for a break.
VIDEOGRAPHER: Going off record. The time is 10:54.
(There was a short break.)

0212

VIDEOGRAPHER: Back on the record. The time is 11:06.

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 RESPONSES TO DEFENDANT'S SECOND SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS

Pursuant to Rule 34 of the Alaska Rules of Civil Procedure, Plaintiff provides the following Responses to Defendant's Second Set of Requests for Production of Documents. Plaintiff specifically reserves the right to supplement and amend these responses as provided by the applicable rules of procedure.

REQUESTS FOR PRODUCTION

REQUEST FOR PRODUCTION NO. 38: All documents relating to or reflecting any audits of the Alaska Medicaid program conducted by the State of Alaska, the federal government, or any unit of the federal government, or any other audit, including but not limited to the procedures for conducting the audits, documents considered during the audit, the results of the audits, and any actions taken as a result of the audits.

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

REQUEST FOR PRODUCTION NO. 40: Any correspondence sent to Alaska physicians relating to weight gain, metabolic issues, metabolic disorders, or diabetes and antipsychotic medications.

RESPONSE: The State is unable to locate any responsive documents.

REQUEST FOR PRODUCTION NO. 41: The data dictionaries for the Alaska MMIS system for 1991 – present.

RESPONSE: The State is providing the following data element dictionaries:

Accounting Interface Subsystem; See Bates Nos. ZYP-AK-05731-ZYP-AK-05836
Bank Account Reconciliation Subsystem; See Bates Nos. ZYP-AK-05187-ZYP-AK-05217
Claims Processing Subsystem; See Bates Nos. ZYP-AK-05218-ZYP-AK-05730
EPSDT Subsystem; See Bates Nos. ZYP-AK-04258-ZYP-AK-04372
Management and Administrative Reporting Subsystem; See Bates Nos. ZYP-AK-04373-ZYP-AK-04852
Provider Subsystem; See Bates Nos. ZYP-AK-04853-ZYP-AK-05147
Recipient Subsystem; See Bates Nos. ZYP-AK-04099-ZYP-AK-04257
Reference Subsystem; See Bates Nos. ZYP-AK-03703-ZYP-AK-03937
Surveillance and Utilization Subsystem; See Bates Nos. ZYP-AK-03938-ZYP-AK-04081
Third Party Subsystem; See Bates Nos. ZYP-AK-03619-ZYP-AK-03702

REQUEST FOR PRODUCTION NO. 42: All documents, including electronic records, disclosing the identity of providers whose provider codes appear in the State's MMIS claims data.

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IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF NEW YORK

In re: ZYPREXA PRODUCTS LIABILITY LITIGATION	MDL No. 1596 04 MD 1596
THIS DOCUMENT RELATES TO: ALL CASES	
UFCW LOCAL 1776 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, et al. v. ELI LILLY AND COMPANY	
LOCAL 28 SHEET METAL WORKERS, et al. v. ELI LILLY AND COMPANY	
SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, et al. v. ELI LILLY AND COMPANY	

DEPOSITION OF: WILLIAM C. WIRSHING, M.D.

DATE: May 1, 2007

TIME: 9:38 a.m.

LOCATION: 22122 Victory Boulevard
Pacific Room
Woodland Hills, CA 91367

TAKEN BY: Counsel for Eli Lilly and Company

REPORTED BY: K.C. Belden, RPR, CRR
Certified Shorthand
Reporter No. 6728

effect, is this drug better than this drug. And in certain situations, olanzapine does appear to occasionally be superior. In other situations, it is worse. In other situations, it's the same.

If I had to generalize, I would say that the studies that have enrolled patients who are sort of early in the course of their illness, patients who do -- who are definitely not treatment refractory, so have not demonstrated themselves to be unresponsive, and haven't had a great deal of experience with other antipsychotic compounds, I think olanzapine may, in fact, be superior. And there's a couple of pretty big studies that, you know, olanzapine turns out to be superior.

When you go to the treatment-refractory population and you compare it to either clozapine or typical antipsychotics, olanzapine is not superior and, in fact, sometimes appears worse.

So, depending on the details of which population you're looking at olanzapine can be better. And in a big population, I think it is better, what I use it in. And populations for which it's not superior or, indeed, is not even equivalent to, say, clozapine. So that the statement was in regards to the totality of the experience.

Q So, if I understand what you're saying, different populations respond differently to these drugs?

A Absolutely.

Q Different individual patients respond differently to these drugs.

A No question.

Q You may not know how one individual may respond to one particular drug versus another particular drug until you have tried them on that particular drug.

A Exactly right.

Q And which partially explains why there are a number of different antipsychotics in this class, because they aren't really all duplicates of each other.

A They are -- for an individual patient, they are definitely not fungible, to use one of your words.

Q All right. You may find that a person may respond well for a period of time on one particular antipsychotic, and then, for some reason which we cannot explain, they may no longer respond to that particular medication. Is that correct?

A Yeah, that's -- Thankfully, that is a less common scenario. Most of the time, a person who

once your horse has got to the finish line, you know, don't be changing in the off season kind of thing. I stick with that horse.

And it takes a lot to convince me that a drug which previously has demonstrated itself doesn't work. The usual explanations are "I forgot to take it." "I have been out of town for like three weeks," you know, "I started using crystal meth." Go figure; it doesn't help schizophrenia. Whatever. But not the drug itself. The drug that worked first in schizophrenia, not in other illnesses, but in schizophrenia, tends to be the drug I like to try to work with.

Occasionally 15 percent or so, yeah, treatment-refractory patients do get made. It's unfortunate, tragic, it's terrible. But usually there are other more prosaic explanations.

Q And so there is a class of patients or at least people who may present to you for whom you would prescribe Zyprexa as sort of the first-line treatment. Is that correct?

A Sure.

Q Same thing with all of the other drugs; you may look at a particular patient and you may decide that this particular drug for this particular patient, given the circumstances they present, "I would go with

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
X

In Re: ZYPREXA PRODUCTS LIABILITY LITIGATION

MDL NO. 1596 (JBW)
CV-06-1924
X

AMBER L. MURRAY and JAMES M. MURRAY,

Plaintiffs,

v.

ELI LILLY AND COMPANY,

Defendant.
X

April 25th, 2007

Oral deposition of LAURA M. PLUNKETT, Ph.D., D.A.B.T., held in the offices of Fibich, Hampton, Leebron, LLP, 1401 McKinney Street, Suite 1800, Houston, Texas, commencing at 9:37 a.m., on the above date, before Daniel J. Skur, Certified Shorthand Reporter and Notary Public.

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1880 John F. Kennedy Blvd., Suite 760
Philadelphia, PA 19103
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piece of information, yes.

Q. How long was the clinical trial?

A. I have to look. Over a year.

Q. It was 18 months, right?

A. Yes, 18 months.

Q. Okay. What was the primary aim of the New England Journal of Medicine portion of the report?

A. It was an efficacy trial --

Q. Yeah.

A. -- looking at antipsychotic drugs in chronic schizophrenia, so they were comparing olanzapine with perphenazine, Seroquel, clothiapine, and then Risperdal, Risperdal or Risperidone.

Q. And Zyprexa was the most efficacious drug among those, right?

A. Well, in terms of rates of continuation -- discontinuation, yes.

Q. That was the end point for marker for efficacy in this study, wasn't it?

A. Yes, that's what they looked at.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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In re: ZYPREXA PRODUCTS LIABILITY LITIGATION — MDL No.1596 04 MD 1596

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UFCW LOCAL 1776 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, et al. — 05 CV 2948 (JBW) 05 CV 4115 (JBW)
v.
ELI LILLY AND COMPANY

- - - - - - - - - - - - - - - - - -x
LOCAL 28 SHEET METAL WORKERS, et al, — 06 CV 0021 (JBW)
v.
ELI LILLY AND COMPANY

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SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, et al. — 06 CV 6322 (JBW)
v.
ELI LILLY AND COMPANY

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April 26, 2007
9:37 a.m.

Videotaped Deposition of ROBERT ROSENHECK, M.D., taken by attorneys for Defendant, pursuant to Notice, held at the offices of Tyler Cooper & Alcorn LLP, 205 Church Street, New Haven, Connecticut, before Andrew Walker, a Registered Professional Reporter (1991) and Notary Public.

quetiapine didn't look so good in the study, what are you referring to?

A. I really shouldn't have commented on that then. You know, my view is -- on some outcomes they did less well than other drugs but, you know, my conclusion is, you know, I think on the PANSS -- olanzapine in my study, olanzapine might have been better than them on the PANSS -- oh, that's on the online supplement, so that's --

Q. Well, you say on page 13 of your report that olanzapine was superior to risperidone and quetiapine on the PANSS score.

A. Oh, okay.

Q. Do you see that reference on top of page 13?

A. Yes. And I would stand by that.

Q. So you certainly wouldn't say that olanzapine was demonstrated as equally effective to quetiapine?

A. So where we're going back and forth is on the issue of the generalizability in this study, in this analysis on this measure, just the PANSS, not dealing with the weight gain, so that's why you've got to go to the

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Plaintiffs,	:	
-vs.-	:	
ELI LILLY AND COMPANY,	:	
Defendant.	:	

DEFENDANT ELI LILLY AND COMPANY'S RULE 26(A)(2) EXPERT WITNESS DISCLOSURE FOR WILLIAM S. GILMER, M.D.

Defendant Eli Lilly and Company ("Lilly"), by and through its attorneys, Pepper Hamilton LLP, and in accordance with Federal Rules of Civil Procedure 26(a)(2)(B), hereby discloses that it may offer William S. Gilmer, M.D., as an expert witness at trial. Pursuant to the above, Dr. Gilmer has provided the attached reports.

Antipsychotics have been used in bipolar illness for over three decades, however the earlier typical (first-generation) neuroleptics only demonstrated clear efficacy for treatment of acute mania. Risks associated with the early typical neuroleptics include extrapyramidal symptoms and tardive dyskinesia, which may occur in greater frequency in patients with mood disorders than with schizophrenia. Extraypyramidal symptoms are often not managed satisfactorily by the simple use of anticholinergic agents, as anticholinergic activity also interferes with cognition, a problem in patients already experiencing cognitive compromise, and may even cause overt delirium or organic psychoses, a risk especially great in elderly patients and patients with other with central nervous system diseases. Anticholinergic side-effects also include dry mouth, constipation, urinary retention and visual changes that are unacceptable to some patients. An additional concern regarding typical neuroleptics is the possible worsening of depressive symptoms including affective blunting and apathy due to their more limited pharmacodynamic profile.

Because of the broader range of application and advantages over the earlier first generation drugs, the newer atypical neuroleptics have gained greater use in the treatment of bipolar conditions. While side-effect profiles vary among all the antipsychotics, side-effects potentially associated with both typical and atypical neuroleptics are weight gain, sedation, cardiovascular side-effects, dry mouth, akathisia, tremor and prolactinemia.

However, atypical antipsychotics have far less liability for extrapyramidal symptoms, anticholinergic side-effects or risk for tardive dyskinesia than first generation neuroleptics. Because of their pharmacological profile, they are also less likely to induce depressive symptoms or cause cognitive dulling, and the varying activity upon serotonin receptors may provide potential antidepressant activity. Furthermore, some of the atypicals, specifically Zyprexa and Abilify, have demonstrated benefit in monotherapy maintenance studies, thus leading to the approved indication of those drugs for bipolar maintenance. No typical neuroleptics have demonstrated this efficacy.

While atypical neuroleptics may or may not be any more effective than earlier neuroleptics for psychotic symptoms in bipolar illness, the broader therapeutic advantages of atypicals generally outweigh the benefits of long-term use of typical neuroleptics, with or without anticholinergics, in bipolar illness. Within the class of atypical neuroleptics, each drug has its own unique characteristics. Clearly, individual differences in patient response exist and these agents may not work interchangeably for all patients. Similarly, it cannot be assumed that the different atypical neuroleptics are equally effective in the treatment of all states or dimensions of bipolar illness.

VII. All treatment options are necessary to provide optimal treatment to the greatest number of patients.

At this point, clinicians are left to a process of trial and error, exploiting pharmacological effects such as sedating or activating properties when possible, and carefully evaluating risks and benefits to determine the most effective treatments for a given patient. Notably,

when successful outcome is achieved and sustained with any agent, including the atypical antipsychotics, a careful analysis must occur before discontinuing an effective agent, as other agents within or outside of the same class may not provide similar efficacy, and destabilization can occur whenever changes in medications occur.

Other elements in the treatment of bipolar disorder include psychoeducation about disease state, disease management techniques, individual and group psychotherapy, social rhythms therapy, sleep manipulation and circadian entrainment, and numerous investigational treatments when standard treatments fail. Limiting factors that can cause destabilization is critical to sustaining positive outcomes; these factors include alcohol and substance use, drug-drug interactions, circadian rhythm disruption, unnecessary medication changes, and treatment non-adherence.

VIII. Summary

In summary, multiple different treatments are available for use in bipolar disorder, but none has the necessary efficacy to be used alone long-term for the majority of patients. Rather, bipolar disorder requires a multi-faceted approach, often comprised of judicious polypharmacy as well as chronic disease management. Comprehensive efforts are required to manage a highly complex illness in a manner that prevents further deterioration, minimizes symptoms of the illness and comorbid conditions, maintains or increases a patient's level of functioning, achieves the best balance of treatment benefit versus side-effects of multiple medications, and keeps a patient alive with a life worth living. In all of these regards, Zyprexa has been and remains an important and valuable agent in the effective management of bipolar illness.

My reviews of the cases of plaintiffs Robert Cusella and Monty Souther follow.

The hourly rate at which I have charged for my time in this matter is $450. I have not testified in any other cases within the past four years.

Respectfully submitted,

William S. Gilmer, M.D.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

In re: ZYPREXA PRODUCTS LIABILITY LITIGATION	MDL No. 1596
UFCW LOCAL 1776 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, ERIC TAYAG, and MID-WEST NATIONAL LIFE INSURANCE COMPANY OF TENNESSEE, on behalf of themselves and other similarly situated, Plaintiffs, -vs.- ELI LILLY AND COMPANY, Defendant.	05 CV 2948 (JBW) 05 CV 4115 (JBW)

DEFENDANT ELI LILLY AND COMPANY'S RULE 26(A)(2) EXPERT WITNESS DISCLOSURE FOR DAVID KAHN, M.D.

Defendant Eli Lilly and Company ("Lilly"), by and through its attorneys, Pepper Hamilton LLP, and in accordance with Federal Rules of Civil Procedure 26(a)(2)(B), hereby discloses that it may offer David Kahn, M.D., as an expert witness at trial. As part of this disclosure, Lilly provides:

Opinions

A. Treatment decisions for mental health patients are based on many sources of information and the unique circumstances of each patient.

I have been asked to provide my opinion about what factors are relevant to a physician's decision to prescribe a mental health medication. It is my opinion that any evaluation of the factors influencing prescription decisions by an individual physician or group of physicians must include all the sources of information about the drug available to the prescriber(s), and information about the specific patients being treated.

1. Physicians' Sources of Information About Prescription Drugs

Physicians' knowledge about treatment alternatives comes from numerous sources. The medical and scientific community generates and shares research and information about medications. This is done through medical literature, Continuing Medical Education, professional meetings, guidelines and algorithms, and exchanges between colleagues. The physician's experience using the drug will also be significantly determinative of his future use. Other sources include information from drug manufacturers (about their products and other products), such as product labels, sales representative detailing, journal advertisements, and responses to questions posed to the companies. The amount and nature of information communicated to a physician by a manufacturer will vary from physician to physician. Different physicians are differentially receptive to information provided by pharmaceutical companies.

2. Importance of Individual Patient Characteristics to Treatment Decisions

Prescription decisions are individualized, heavily impacted by characteristics of the patients themselves. The factors include not only the patient's diagnosis, but also the particular symptoms of the condition that need treatment, such as the need for sedation versus activation, insomnia, anxiety, agitation, and prior history of treatment-induced EPS, or history of comorbid neurological or general medical disorders. Other patient specific factors that go into the choice of a medication include patient's response to current and previous treatments, particularly the agent being considered; willingness and ability to adhere to treatment; susceptibility to side effects associated with different treatments; medical history; family history; and patient management issues, such as psychosocial support, ability to comply with instructions regarding issues such as diet and blood monitoring; and the opportunity to follow up.

B. Rosenheck's CATIE cost-effectiveness study does not provide a basis for the generalized statement that quetiapine (Seroquel) and perphenazine are equally effective to olanzapine (Zyprexa).

The CATIE study only addresses schizophrenia, not the full spectrum of conditions, including bipolar disorder, that olanzapine was likely used for by the insureds of the payers that have sued Lilly. (Lieberman 2005) Second, even when limited to schizophrenia, the study excluded by design patients who were first break or treatment refractory. (Rosenheck

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DEFENDANT ELI LILLY AND COMPANY'S RULE 26(A)(2) EXPERT WITNESS DISCLOSURE FOR THOMAS L. SCHWENK, M.D.

Defendant Eli Lilly and Company ("Lilly"), by and through its attorneys, Pepper Hamilton LLP, and in accordance with Federal Rules of Civil Procedure 26(a)(2)(B), hereby discloses that it may offer Thomas L. Schwenk, M.D., as an expert witness at trial. Pursuant to the above, Dr. Schwenk has provided the attached report.

In my clinical experience, the use of atypical antipsychotics in general and Zyprexa in particular for bipolar disorder can lead to improved functional status and a decreased burden of disease.

Off-Label Use of Medications by Primary Care Physicians

PCPs spend much of each day making difficult judgments about psychiatric patients who do not meet standardized criteria, have significant medical co-morbidity, lack the psychological and financial resources to seek or benefit from psychiatric care, and yet still deserve treatment. PCPs make many off-label treatment decisions every day, decisions that are appropriate and part of the usual practice of medicine. Physician experience is critical in making decisions about use for unapproved indications. Such decisions are a careful balance, leavened with considerable experience, of the risks and benefits of treatment with a particular medication, versus risks and benefits of another medication, versus risks and benefits of no treatment. Such decisions represent much of the art and science of medical practice.

Studies are clear that the functional impact and psychiatric morbidity of bipolar II patients is as great as, and possibly greater than, that of bipolar I patients (19,20,21,25,26). Patients with both bipolar I and II disorder are often seen in primary care settings. The prevalence of bipolar II is relatively more common and patients are often equally ill, but often seek care exclusively from PCPs. Bipolar II patients are often treated with medications off-label, but they are equally deserving of treatment and care.

Managing Side Effects

All medications have side effects. Balancing the risks, side effects and benefits of medications is what primary care physicians, and, in fact, all physicians do as a usual part of daily practice. The fact that atypical antipsychotics have significant potential side effects, as do all medications used to treat mental illness, is secondary to the larger fact that all medications have side effects. PCPs make many judgments every day about balancing risks and benefits of all chronic disease treatments. Based on my personal experience, the risk of weight gain with the use of Zyprexa has been well-known, as are the potential consequences of weight gain. The fact that Zyprexa may cause weight gain, with potential attendant risks, is just one of many factors to be taken into account in individualized risk-benefit calculations. In addition, weight gain and its potential associated risks are commonly and frequently managed by primary care physicians, in part because they are approaching epidemic prevalence in patients not taking atypical antipsychotics.

Use in Children and Adolescents

PCPs, both family physicians and pediatricians, are confronted with an increasing number of children and adolescents with complex psychiatric disorders for whom psychiatric referral is

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ELI LILLY AND COMPANY,	:	
Defendant.	:	

DEFENDANT ELI LILLY AND COMPANY'S RULE 26(A)(2) EXPERT WITNESS DISCLOSURE FOR CAROL A. TAMMINGA, M.D.

Defendant Eli Lilly and Company ("Lilly"), by and through their attorneys, Pepper Hamilton LLP, and in accordance with Federal Rules of Civil Procedure 26(a)(2)(B), hereby discloses that it may offer Carol A. Tamminga, M.D., as an expert witness at trial. As part of this disclosure, Lilly provides:

ANTIPSYCHOTIC EFFECTS AND TARGETS FOR SUPERIORITY

APDs were first developed in the 1950s, after chlorpromazine was tested for its "calming" actions. When its action was serendipitously noted to be specifically antipsychotic by Delay and Denniker, this treatment spread quickly around the world. Once the mechanism of action was discovered by Arvid Carlsson to be blockade of dopamine and other monoamine receptors, the development of additional APDs could be pursued. Because clozapine is the only APD with superior psychosis efficacy in treatment non-responders, drug development programs tried to generate compounds similar to clozapine but with a lesser side effect burden. Those attempts generated the SGA drugs, each of which has its own pharmacologic characteristics.

While SGAs, including olanzapine, are generally known to have a better effect on cognitive symptoms than FGAs, that effect, although important, is modest. Moreover, the idea that treatments will have to be broader than medication alone is recognized by the effectiveness of cognitive remediation approaches and work training programs (McGurk SR et al., 2007) already being studied.

Since psychotic symptoms in schizophrenia are diverse and dysfunction severe, the opportunities for therapeutic actions of the APDs are broad, and the outcome measures to track those actions are multiple. Efficacy of APD action against primary psychotic symptoms is characteristically measured by the total PANSS or BPRS score; PANSS subscale scores (e.g., positive or negative) are often used as secondary outcomes. More recently "effectiveness" has been a targeted outcome measure, represented in the CATIE study, defined by "duration of drug treatment." Cognition outcomes are measured with neuropsychological tests and further evaluated with surrogate tests of overall psychosocial function. Psychosocial outcome is measured with Quality of Life (QOL) and Social Function Scales (SFS). Also, cost effectiveness studies provide a vehicle for examining treatments from an economic perspective. In addition to the symptomatic outcomes, side effect profiles add another dimension to drug action. Therefore, superiority of a drug treatment could be in the domains of (1) efficacy, (2) effectiveness, (3) side effects, (4) cognition, (5) psychosocial function and quality of life or (6) cost effectiveness.

Several studies show that negative symptoms respond differentially to olanzapine during the active phase of schizophrenia. Negative symptoms can be primary to the illness or can be secondary to other conditions (like parkinsonism or acute psychosis). Primary negative symptoms are characteristically evaluated during stable phases of illness. The negative symptoms seen during an acute episode are generally considered to be at least partially secondary to the psychosis itself. Some component of olanzapine's advantage on negative symptoms could also be due to its beneficial profile with respect to EPS. Nonetheless, individuals with the illness are less symptomatic with olanzapine, regardless of whether this advantage is "primary" or "secondary". The advantage

(EPS), akathisia, and the chronic hyperkinetic disorder, tardive dyskinesia (TD). Haloperidol shows EPS at all clinically effective doses and antipsychotic efficacy across a range of 4-16 mg/day.

One of the most serious and use-limiting side effects of haloperidol and all FGAs is tardive dyskinesia. This is a hyperkinetic, delayed onset motor effect that does not remit when drug treatment is terminated; that is to say it is characteristically a permanent side effect of treatment. The incidence of this side effect with FGAs is approximately 5% per treatment year (Kane JM et al., 1984), producing a relatively high prevalence in older schizophrenic populations that have had years of treatment. SGAs have a reduced incidence of TD, approximately 1% in adult populations (Kane JM et al., 2004). It is a wholly disfiguring side effect, compromising many aspects of psychosocial recovery and function. Certain populations have particular vulnerability and a higher incidence: (1) the elderly (Kane JM et al., 2004); (2) people with an affective diagnosis like bipolar disorder (Kane JM et al., 1999); and (3) patients with particularly high EPS at initial treatment. The risk of TD is not diminished with anticholinergic drugs, making any prophylactic approach ineffective.

During the years spanning olanzapine development, haloperidol was the most widely used APD worldwide, and was, therefore, logical to select as a comparator for olanzapine studies. In many ways haloperidol was ideal for this, since it was only in the motor side effect domain that its major side effects manifest themselves. Therefore, in the areas of unwanted metabolic effects (weight gain, lipid changes), cardiac side effects (hypotension, QTc changes, myocarditis) and anticholinergic actions, haloperidol was a low side effect compound. Each of the SGAs was compared to haloperidol in its initial registration studies. Haloperidol is still widely used worldwide. The FGA's have considerable superiority when comparing drug costs because they are beyond their patent life and their costs are low.

PROPHYLACTIC ANTICHOLINERGIC TREATMENT FOR EPS

Using treatments prophylactically results in some fraction of patients who needlessly endure drug side effects without any clinical benefit. In the case of a disease with a dire outcome, e.g., cancer, since the feared outcome is death, this over-treatment is generally considered worth the risk. With other less dire outcomes, one could question the prophylaxis, based on what the consequences are of the needless treatment. The prevalence of EPS with haloperidol is approximately 35%-45%, while the prevalence of EPS with olanzapine is 14%-17%, suggesting that 55%-65% of the individuals with haloperidol will be needlessly treated if prophylactic anticholinergics are used. In addition to the well known side effects of anticholinergic treatment (eg, dry mouth and constipation), anticholinergic actions provide a measurable and clinically significant burden for cognition, a domain already compromised in schizophrenia. Furthermore, we now know that this cognitive burden will translate to lower

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 RESPONSES TO DEFENDANT'S FOURTH SET OF INTERROGATORIES

Pursuant to Rule 33 of the Alaska Rules of Civil Procedure, Plaintiff, the State of Alaska, provides the following Answers to Defendant's Fourth Set of Interrogatories. The State specifically reserves the right to supplement and amend these responses as provided by the applicable rules of procedure.

INTERROGATORIES

INTERROGATORY NO. 66: State the number of times that you contend Lilly violated the Alaska Unfair Trade Practices and Consumer Protection Act, AS 45.50.471, et seq., as alleged in the Fifth Claim for Relief in the Complaint by:

(a) "represent[ing] Zyprexa had characteristics, uses, benefits and/or qualities that it did not have;"

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(b) "represent[ing] that Zyprexa was of a particular standard, quality and grade suitable for consumption when in fact it was not;"

(c) "advertis[ing] Zyprexa with an intent not to sell it as advertised;"

(d) "engag[ing] in conduct creating a likelihood of confusion or a misunderstanding and which misled or damaged buyers of Zyprexa, including the State of Alaska;"

(e) "us[ing] misrepresentations or omissions of material facts with the intent that others rely on the misrepresentations or omissions in connection with the sale of Zyprexa;" and/or

(f) "violat[ing] the labeling and advertising provisions of AS 17.20."

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly and is still in the process of taking depositions of Lilly witnesses with information relevant to the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label

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uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

INTERROGATORY NO. 67: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's representing that "Zyprexa had characteristics, uses, benefits and/or qualities that it did not have, in violation of AS 45.50.471(b)(4)," as alleged in paragraph 53(a) of Complaint. For each representation, your response should identify who made the representation, the recipient(s) of the representation, the method of communication, the date of the representation, the content of the representation, and the basis for your contention that the representation was false, including but not limited to identifying what characteristics, uses, benefits and/or qualities Lilly represented Zyprexa to have, which it did not have.

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly and is still in the process of taking depositions of Lilly witnesses with information relevant to the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates

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comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

INTERROGATORY NO. 67: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's representing that "Zyprexa was of a particular standard, quality and grade suitable for consumption when in fact it was not, in violation of AS 45.50.471(b)(6)," as alleged in paragraph 53(b) of Complaint. For each representation, your response should identify who made the representation, the recipient(s) of the representation, the method of communication, the date of the representation, the content of the representation, and the basis for your contention that the representation was false, including but not limited to identifying what characteristics, standard, quality and grade Lilly represented Zyprexa to have, which it did not have.

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly and is still in the process of taking depositions of Lilly witnesses with information relevant to the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal

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relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

INTERROGATORY NO. 68: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's "advertis[ing] Zyprexa with an intent not to sell it as advertised, in violation of AS 45.50.471(b)(8)," as alleged in paragraph 53(c) of the Complaint. Your response should identify each and every representation you contend constitutes an advertisement, the content of the advertisement, where the advertisement was published, transmitted, or otherwise communicated, the date of the advertisement, who received the advertisement, and the basis for your contention that Lilly's intent contradicted the content of the advertisement.

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly and is still in the process of taking depositions of Lilly witnesses with information relevant to the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by

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minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

INTERROGATORY NO. 69: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's "engag[ing] in conduct creating a likelihood of confusion or a misunderstanding and which misled or damaged buyers of Zyprexa, including the State of Alaska, in violation of AS 45.50.471(b)(11)," as alleged in paragraph 53(d) of the Complaint. Your response should describe in detail each incidence of alleged conduct, identify who engaged in the conduct and describe their involvement, identify when the conduct occurred, identify where the conduct occurred, and identify what was confusing or misleading about the conduct, and identify what buyers were misled and/or damaged by the conduct.

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly and is still in the process of taking depositions of Lilly witnesses with information relevant to

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the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

INTERROGATORY NO. 70: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's "us[ing] misrepresentations or omission of material facts with the intent that others rely on the misrepresentations or omissions in connection with the sale of Zyprexa, in violation of AS 45.50.471(b)(12)," as alleged in paragraph 53(e) of the Complaint. For each representation, your response should identify who made the representation, the recipient(s) of the representation, the method of communication, the date of the representation, the content of the representation, and the basis for your contention that the representation was false. For each omission, your response should identify the information that was omitted, the date that the information should have

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been communicated, and the person(s) to whom the information should have been communicated.

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly and is still in the process of taking depositions of Lilly witnesses with information relevant to the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

INTERROGATORY NO. 71: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's "violat[ing] the labeling advertising provisions of AS 17.20, in violation of AS 45.50.471(b)(48)," as alleged in paragraph 53(f) of the Complaint. Your response should identify each provision of AS 17.20 that you contend was violated, describe in detail each incidence of alleged conduct resulting

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in that violation of AS 17.20, identify who engaged in the conduct and describe their involvement, identify when the conduct occurred, and identify where the conduct occurred.

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly and is still in the process of taking depositions of Lilly witnesses with information relevant to the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

INTERROGATORY NO. 72: For each individual violation enumerated in response to Interrogatory No. 66, identify the "ascertainable loss of money or property" that you contend resulted from that specific violation.

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly

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and is still in the process of taking depositions of Lilly witnesses with information relevant to the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

Respectfully SUBMITTED and DATED this 28 day of November, 2007

FELDMAN, ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
Alaska Bar No. 7510085

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

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

Certificate of Service
I hereby certify that a true and correct copy of **Plaintiff's Responses to Defendant's Fourth Set of Interrogatories** was served by mail messenger facsimile 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 Peggy J. Crowe
Date 11/28/07

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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-06-5630 CIV

STATUS REPORT

Pursuant to the Court's Order dated November 27, 2007, the State of Alaska ("the State") hereby submits the following report to the Court regarding the production of Medicaid data and the estimated length of the liability trial commencing March 3, 2008:

1. Unless some unexpected problem arises, the State anticipates the production of Medicaid data will be complete by January 31, 2008; and

2. The State expects to complete the presentation of its case within eight trial days, including any rebuttal testimony.

DATED this 7 day of December, 2007.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

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(843) 727-6500
Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of the foregoing **Status Report** was served by mail/ messenger / facsimile on:

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

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

By Peggy S Crowe
Date 12/7/07

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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 ESTIMATE OF TRIAL TIME NEEDED

Pursuant to the Court's Order of November 27, 2007 requiring the parties to "provide the Court with an estimate of the time needed to complete the trial of liability only," Lilly advises that the scope and nature of a "liability only" trial is too uncertain for Lilly to provide a useful estimate. The State has not provided a sufficient description of what evidence and issues it proposes to present at the trial to guide Lilly's estimate of the time needed for its defense.

Based on the limited information available to it, Lilly believes it would need 15-20 days to present a defense.

DATED this 7th day of December, 2007.

Attorneys for Defendant

PEPPER HAMILTON LLP
Nina M. Gussack, admitted *pro hac vice*
Andrew R. Rogoff, admitted *pro hac vice*
Eric Rothschild, admitted *pro hac vice*
3000 Two Logan Square, Suite 3000
Philadelphia, Pennsylvania 19103-2711
(215) 981-4000

LANE POWELL LLC

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

I certify that on December 7, 2007, a copy of the foregoing was served by hand-delivery on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
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009867.0038/162449.1

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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-06-5630 CIV

MOTION AND APPLICATION OF NON-RESIDENT ATTORNEY DAVID C. BIGGS FOR PERMISSION TO APPEAR AND PARTICIPATE

Pursuant to Alaska Rule of Civil Procedure 81(a)(2), attorney David C. Biggs of the law firm of Siegfried & Jensen, whose mailing address is 5664 South Green Street, Murray, Utah 84123 (telephone: (801) 266-0999), applies for permission to appear and participate as co-counsel for plaintiff State of Alaska in this action.

Mr. Biggs will associate with the undersigned, Eric T. Sanders, a member of the Bar of this Court, who maintains an office at a place within the district, with whom the Court and opposing counsel may readily communicate regarding this case. My Consent of Local Counsel in support of this motion is filed herein.

Mr. Biggs is a member in good standing of the Bar of the State of Utah. A copy of his Certificate of Good Standing with the Bar of the State of Utah is attached as Exhibit

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A. Proof of payment of the required fee to the Alaska Bar Association is also attached as Exhibit B.

DATED this 3 day of December, 2007.

FELDMAN ORLANSKY & SANDERS
Attorneys for State of Alaska

By _____
Eric T. Sanders
Alaska Bar No. 7510085

CONSENT OF LOCAL COUNSEL

The undersigned consents and moves for the granting of the application of David C. Biggs to appear and participate as co-counsel in this action on behalf of plaintiff State of Alaska. The undersigned is authorized to practice law in the State of Alaska and is admitted to the Superior Court for the Third Judicial District at Anchorage.

Dated this 3 day of December, 2007.

FELDMAN ORLANSKY & SANDERS

By: _____
Eric T. Sanders
Alaska Bar No. 7510085
500 L Street, Suite 400
Anchorage, Alaska 99501
Telephone: (907) 272-3538
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Certificate of Service

I hereby certify that a true and correct copy of the foregoing **Motion and Application of Non-Resident Attorney David C. Biggs for Permission to Appear and Participate** 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 Peggy S Crowe
Date 12/3/07

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Utah State Bar

645 South 200 East, Suite 310 • Salt Lake City, Utah 84111-3834
Telephone: 801-531-9077 • Fax: 801-531-0660

John C. Baldwin
Executive Director

November 30, 2007

To Whom It May Concern:

This is to certify that **David C. Biggs**, Utah State Bar **No. 00321**, was admitted to practice law in Utah on **July 13, 1981** and is an active member of the Utah State Bar in good standing. "Good standing" is defined as a lawyer who is current in the payment of all Bar licensing fees, has met mandatory continuing legal education requirements, if applicable, and is not disbarred, presently on probation, suspended, or has not resigned with discipline pending, from the practice of law in this state.

No public disciplinary action involving professional misconduct has been taken against the license of **David C. Biggs** to practice law.

Katherine A. Fox
General Counsel
Utah State Bar

Exhibit A
Motion to Participate – Biggs
Case No. 3AN-06-5630 Civ

ALASKA BAR ASSOCIATION
P.O. Box 100279, Anchorage, Alaska 99510-0279
(907) 272-7469

Customer's Order No. | Phone No. 801-266-0999 | Date 12-03-07

Sold to: Siegfried & Jensen
Address: 5664 South Green Street
City: Murray UT

Sold By | Cash | C.O.D. | Charge | On Acct. | Mdse. Retd. | Paid Out

Qty.	Description	Price	Amount
	Rule 81		550. 00
	David Biggs NA		
	assoc. w/ Eric Sanders 7510085		
	case # 3AN-06-5630		
	check # 100628		
	2007		

All claims and returned goods MUST be accompanied by this bill.

Rec'd By: Dixon Richardson

Tax

Total 550. 00

029623 Thank You!

Items G3R
To Reorder:
Please Call Toll Free: 1-800-556-0220

001530

Exhibit B
Motion to Participate – Biggs
Case No. 3AN-06-5630 Civ

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

ORDERS RE: MOTION FOR BIFURCATION AND FOR SIX MONTH EXTENSION OF DEADLINES

1. Plaintiff's Motion for Bifurcation of trail in this matter is granted. Trail on liability only will commence on March 3, 2008. Trial on issues of causation and damages will be scheduled, if necessary, after the trial on liability is held. The parties shall, within ten days of this order, provide the Court with an estimate of the time needed to complete the trial on liability only.

2. The parties should adhere to the current pretrial order and all stipulations to which they previously agreed. The State shall advise the Court by December 7, 2007 when the Medicaid data will be produced so that phase two of this case is not delayed. The parties shall, by December 21, 2007 meet and confer and attempt to reach agreement on how discovery unrelated to liability should proceed. By January 2, 2007 they

will either provide the Court with a stipulation as to such discovery or file memorandum on their respective positions on how such discovery should proceed. Subject to this Order defendant's motion for extension of court deadlines is denied.[1]

DATED at Anchorage, Alaska, this 27th day of November 2007.

MARK RINDNER
Superior Court Judge

I certify that on November 27, 2007 a copy was mailed to:
E. Sanders B. Jamieson
Administrative Assistant

[1] Defendant's request for oral argument on the motions covered by this order is denied.

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

ORDERS

Defendant's Motion for Reconsideration of the November 17, 2007 Order of this Court affirming the ruling of the Discovery Master is denied.

DATED at Anchorage, Alaska, this 27th day of November 2007.

MARK RINDNER
Superior Court Judge

I certify that on November 27, 2007 a copy was mailed to:
E. Sanders B. Jamieson
Administrative Assistant

Rindner 11/7

FILED
STATE OF ALASKA
THIRD DISTRICT
2007 NOV 26 PM 2:01
CLERK TRIAL COURTS
BY DEPUTY CLERK

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

STIPULATION FOR PARTIAL DISMISSAL WITH PREJUDICE

COME NOW, the parties, by and through their respective counsel, pursuant to Rule 41(a) of the Alaska Rules of Civil Procedure, and stipulate that the Third Claim for Relief (Fraud and Negligent Misrepresentation) asserted by plaintiff in its Complaint against defendant Lilly in paragraphs 41-47, may be dismissed with prejudice.

FELDMAN ORLANSKY & SANDERS
Attorneys for Plaintiff

Dated: November 21, 2007

By _____
Eric T. Sanders, ASBA No. 75100085

LANE POWELL LLC
Attorneys for Defendant

Dated: November 13, 2007

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

ORDER

IT IS HEREBY ORDERED that plaintiff's Third Claim for Relief (Fraud and Negligent Misrepresentation) is hereby dismissed with prejudice.

ORDERED this 27 day of November, 2007.

_____
The Honorable Mark Rindner

I certify that on 11-27-07 of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

_____
Administrative Assistant

009867.0038/162162.1

001534

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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

MOTION TO RECONSIDER

Eli Lilly and Company ("Lilly") moves for Reconsideration of the Order of this Court affirming the ruling of the Discovery Master that denied Lilly discovery of medical records. Lilly moves for reconsideration pursuant to Alaska Rule of Civil Procedure 77(k)(ii), on the basis that "[t]he court has overlooked or misconceived some material fact or proposition of law."[1]

The Court's Order of November 14, 2007, stated that "[t]he Discovery Master has correctly balanced the competing interests in ruling that Lilly is not entitled to access individual patient records." However, that balance changed after the Discovery Master's decision. In particular, the time available to take Alaska-specific discovery has expanded, at the insistence of the State, thereby removing a foundation for the decision. The Discovery Master also overlooked material facts before him, such as the uncontested record that medical

[1] Lilly also incorporates by reference the arguments made in its appeal of the Discovery Master's ruling.

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records are relevant to, and necessary for, Lilly's defense, including challenging the State's reliance on the Medicaid database.

The Alaska Supreme Court has explained that reconsideration under Rule 77(k) may "remedy mistakes in judicial decision-making where grounds exist while recognizing the need for a fair and efficient administration of justice." *Neal & Co., Inc. v. Ass'n of Vill. Council Presidents Reg'l Housing Auth.*, 895 P.2d 497, 506 (Alaska 1995). Lilly asks this Court to reconsider its Order of November 14, 2007, to remedy mistakes created by the adoption of the Discovery Master's decision.

A. Due to the Change in the Litigation Schedule This Court Should Not Have Adopted the Discovery Master's Conclusion on the Balance of Equities.

In denying Lilly medical records, the Discovery Master relied on the fact that if this discovery was ordered, "the March 2008 trial date will have come and gone before anyone sees an actual patient record." Discovery Master Order, p. 7. This is no longer a concern. Since the Order, the State has admitted that, at a minimum, the Alaska-specific aspects of this case cannot be heard in March. As a result, a March 2008 trial date for Alaska-specific evidence has been, quite rightly, abandoned. *See* October 24, 2007 Status Conference Transcript, pp. 51-52. The State has proposed that the trial be bifurcated, which Lilly opposes, but, under either scenario, the trial of issues for which medical records would be most relevant will likely not take place for a year or more.

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The Discovery Master, at the time he considered these issues, could not have foreseen this change in circumstances. He believed that all aspects of the case would be tried in March 2008, and the schedule influenced his decision on the balance of equities. Discovery Master Order, p. 6. The Discovery Master also incorrectly assumed that this discovery would be too unwieldy. *Id.* In fact, however, there are at most only 500 individual Medicaid recipients at issue,[2] and Lilly has always stated it would accept some form of sampling of these medical records. Given the additional time for discovery, there is ample time for this kind of discovery. *Compare Foti v. Janssen Pharma., Inc.*, No. 04-3907-D, Consent Judgment at 2 (La. Dist. Ct. Apr. 10, 2007) (permitting discovery of 6000 patients' medical records).

B. The Discovery Master's Order Adopted by the Court Misconceived the Facts Regarding the Privacy of Medical Records.

To the extent that the Court based its ruling on the Discovery Master's conclusion that "[d]iscovery of the identity of Zyprexa users would be extraordinarily intrusive," Discovery Master Order, p. 6, it overlooked a solution offered by both parties. Both the State and Lilly agreed that the actual identity of any individual Zyprexa user is not necessary and could be redacted through the use of an independent third-party service. *See* Sept. 11, 2007 Motion Arguments Before the Discovery Master Transcript, p. 46. This proposal was rejected by the Discovery Master because of the time it would take to implement, Discovery

[2] *See* Response to Motion for Bifurcation, p. 9.

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Master Order, pp. 6-7, an issue that has been mitigated by the State's admission that the Alaska-specific part of the trial must be postponed.

C. This Court Failed to Consider That the Evidence Showing That Medical Records Are Relevant Is Uncontested.

Once the trial schedule and privacy issues are addressed, basic relevance issues must come to the fore. The primary reason medical records are relevant is that the State has brought a tort case alleging misrepresentations to prescribers and physical injuries to patients—the type of case in which medical records are *always* relevant. Even in the face of the competing equities identified by the Discovery Master, Lilly should have been allowed discovery of medical records. With these considerations sharply mitigated by the postponement of all or part of the trial, Lilly's entitlement to this discovery becomes evident.

Furthermore, the Discovery Master's conclusion regarding the relevance of medical records to challenging the State's statistical case was inconsistent with the evidence of record. The Discovery Master concluded that "Lilly doesn't need actual patient records to challenge [the State's Medicaid database]." Discovery Master Order, p. 7. This conclusion overlooks uncontested material facts established by Lilly's expert.

Lilly, through the affidavit of Dr. Beth A. Virnig, offered evidence regarding the relevance of medical records for challenging the State's statistical proof. Affidavit of Dr. Beth A. Virnig ¶ E.3. Lilly also showed that the State itself uses medical records when conducting audits to verify the accuracy of its Medicaid database. Campana Dep., pp. 226,

319-20. The State offered no competing or conflicting evidence. The Discovery Master's conclusion that medical records are not relevant was inconsistent with the uncontested evidence.

The Discovery Master's ruling regarding what evidence is relevant to challenging the State's use of database evidence is particularly problematic given that the State has not yet produced a complete, usable set of Medicaid data. Under these circumstances, the integrity and reliability of those data—the State's only evidence about what happened to patients in Alaska—is unknown. On this uncertain terrain, the ruling that medical records are not relevant to challenging the database was premature, and unsupported by the evidence.

CONCLUSION

For the reasons set forth above, Eli Lilly and Company respectfully asks this Court to reconsider its Order of November 14, 2007, denying discovery of medical records.

DATED this 26th day of November, 2007.

Attorneys for Defendant

PEPPER HAMILTON LLP
Andrew R. Rogoff, admitted *pro hac vice*
Eric J. Rothschild, admitted *pro hac vice*
3000 Two Logan Square, Suite 3000
Philadelphia, Pennsylvania 19103-2711
(215) 981-4000

LANE POWELL LLC

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

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Anchorage, Alaska 99503-2648
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I certify that on November 26, 2007, a copy of the foregoing was served by hand-delivery on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
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Anchorage, Alaska 99501-5911

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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 reviewed Lilly's Motion to Reconsider the Court's Order of November 14, 2007,

IT IS HEREBY ORDERED that plaintiff State of Alaska, shall file a response to the Motion to Reconsider by _____, 2007.

ORDERED this ____ day of _____, 2007.

_____
The Honorable Mark Rindner
Judge of the Superior Court

I certify that on November 26, 2007, a copy of the foregoing was served by hand-delivery on:

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

_____

005867.0038/162263.1

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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

Defendant Eli Lilly and Company's request for oral argument is GRANTED. Oral argument on Plaintiff's Memorandum in Support of Bifurcation and Defendant Eli Lilly and Company's Opposition in Response is set for _____, 2007, at _____ am/pm. Each party is granted ____ minutes.

ORDERED this ____ day of _____, 2007.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on November ____, 2007, a copy of the foregoing was served by hand and e-mail on:

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

009867.0038/162153.1

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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

Defendant Eli Lilly and Company's request for oral argument is GRANTED. Oral argument on Defendant Eli Lilly and Company's Motion for an Extension of Court-Ordered Deadlines is set for _____, 2007, at _____ am/pm. Each party is granted ____ minutes.

ORDERED this ____ day of _____, 2007.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on October 2, 2007, a copy of the foregoing was served by hand-delivery on:

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

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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

Upon consideration of Defendant Eli Lilly and Company ("Lilly")'s Motion for an Extension of Court-Ordered Deadlines and any response thereto, it is hereby ORDERED that:

1. The deadline for plaintiff State of Alaska to serve expert reports is extended to the date six (6) months following the State's service of complete Medicaid claims data upon Lilly.

2. The deadline for service of Lilly's expert reports shall be two (2) months after service of the State's expert reports.

3. All other dates set forth in the Routine Pretrial Order, dated January 10, 2007, including the October 29, 2007 deadline for service of written discovery and the March 3, 2008 trial date, are adjusted accordingly. A new scheduling order will be issued in due course.

ORDERED this _____ day of _____, 2007.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on October 2, 2007, a copy of the foregoing was served by hand-delivery on:

Eric T. Sanders, Esq., Feldman Orlansky & Sanders
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A B C

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

Upon consideration of Plaintiff's Memorandum in Support of Bifurcation and Defendant Eli Lilly and Company's Opposition in Response thereto, it is hereby ORDERED that:

The State's request for bifurcation is DENIED.

It is FURTHER ORDERED that Lilly's Motion for an Extension of all Court-Ordered Deadlines is GRANTED.

ORDERED this _____ day of November, 2007.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on November 9, 2007, a copy of the foregoing was served by hand-delivery and e-mail on:

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A B C

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

Eli Lilly and Company ("Lilly") has appealed the Order of the Discovery Master denying Lilly discovery of medical records and a complete production of the State's Medical database. Lilly has requested oral argument on this appeal. The Court concludes that oral argument is not needed.

The decision of the Discovery Master is affirmed. The Discovery Master has correctly balanced the competing interest in ruling that Lilly is not entitled to access individual patient records. Likewise, and in reliance on the agreement of the State to produce additional information regarding the Medicaid claims database and the ability of Lilly to renew its motion once the supplemental production is complete, the Court concludes that the decision of the Discovery Master denying, at this time Lilly's motion regarding the database was correct.

DATED at Anchorage, Alaska, this 14th day of November 2007.

MARK RINDNER
Superior Court Judge

I certify that on November 14, 2007 a copy was mailed to:
Sanders Jamieson
Hensley

Administrative Assistant

001545

A B C

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 Defendant's Appeal From Order of the Discovery Master is set for _____, 2007, at _____ am/pm. Each party is granted ____ minutes. This oral argument shall be held at _____.

ORDERED this ____ day of _____, 2007.

_____
The Honorable Mark Rindner
Judge of the Superior Court

I certify that on October 2, 2007, a copy of the foregoing was served by hand on:

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not used 11-1-07

A B C

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

Upon consideration of Defendant Eli Lilly and Company ("Lilly")'s Appeal From Order of the Discovery Master and any response thereto, it is hereby ORDERED that:

1. Lilly is entitled to production of medical records of Medicaid recipients for whom the costs of Zyprexa prescriptions were reimbursed under Alaska's Medicaid program. The State shall gather all such relevant medical records and produce them to Lilly; in the alternative, Lilly will serve subpoenas for medical records and a copy of this Order on healthcare providers, and said healthcare providers are required by this Order to produce all medical records requested by Lilly.

2. Lilly is entitled to production of the entire Medicaid claims database. Lilly's Commission of a Subpoena for access to the First Health database is hereby granted. In the alternative, Alaska will produce the full Medicaid claims database, including all data fields, to Lilly.

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ORDERED this _____ day of _____, 2007.

The Honorable Mark Rindner
Superior Court Judge

I certify that on October 2, 2007, a copy of the foregoing was served by hand on:

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A B C

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

FILED
STATE OF ALASKA
THIRD JUDICIAL DISTRICT
2007 NOV -9 PM 4:24
CLERK TRIAL COURTS
BY: DEPUTY CLERK

DEFENDANT LILLY'S REQUEST FOR ORAL ARGUMENT RE BIFURCATION

COMES NOW, defendant Eli Lilly and Company, by and through counsel, pursuant to Civil Rule 77(e), and requests oral argument on Plaintiff's Memorandum in Support of Bifurcation and Defendant Eli Lilly and Company's Opposition in Response.

DATED this 9th day of November, 2007.

Attorneys for Defendant

PEPPER HAMILTON LLP
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Eric J. Rothschild, admitted *pro hac vice*
3000 Two Logan Square
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By _____
Brewster H. Jamieson, ASBA No. 8411122
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A B C

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

OPPOSITION IN RESPONSE TO PLAINTIFF'S MEMORANDUM IN SUPPORT OF BIFURCATION

I. INTRODUCTION

For the better part of the last year, the State of Alaska ("the State") has championed its Medicaid database as the cornerstone of its case, arguing to this Court that it could be used in lieu of discovery from individual patients and prescribers to establish that Zyprexa® caused an increased incidence of diabetes in Alaska's Medicaid population. As this Court has recognized, the sufficiency of this statistical evidence to prove causation is a central, and potentially dispositive issue in this case. Now, however, the State has proposed a bifurcation plan that postpones consideration of the State's causation evidence until after a trial on other issues, mincing the case so that it can be tried bit-by-bit before several juries, in violation of the constitutional protections, and practical benefits, afforded by a single jury trial.

The State did not alight on this bifurcation procedure because of its merits, but as a direct result of its failure to produce its Medicaid database in time for the trial to take place as scheduled. Rather than regrouping to determine whether it can ever mount the case that it promised, the State has abruptly reformulated its proofs, claiming—falsely—that it can establish liability against Eli Lilly and Company ("Lilly"), including that Zyprexa and Lilly

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actions "were the *legal cause* of harm to the State . . . in the first phase of a bifurcation and *without needing any reference to the State's database*."[1]

In actuality, the most that the State could accomplish in the first trial is elicit advisory opinions from a jury about scientific questions and certain promotional activities, disconnected from any consequences for patients or the State. The State's proposal should be seen for what it is: an effort to construct a proceeding that might produce a partial "victory" that the State hopes will coerce a settlement from Lilly without ever proving causation or injury. What it will actually do is deter any resolution, by adding complexity and constitutional defects to this already unorthodox case.

II. BACKGROUND

At the Court's instruction, the State of Alaska has submitted a brief describing the bifurcation plan that it proposed during the status conference on October 24, 2007. The event that precipitated that proposal was Lilly's Motion for an Extension of Court-Ordered Deadlines, which was necessitated by the repeated false starts by the State in producing its Medicaid database. The State's Memorandum in Support of Bifurcation misleadingly suggests that Lilly is the agent of delay, having sought an extension "on the sole ground that Lilly's experts will need additional time to scrutinize a database of Medicaid records."[2] The State brazenly omits from its bifurcation brief that it has failed to timely produce its Medicaid

[1] Pl.'s Mem. in Supp. of Bifurcation 3 (emphasis added).

[2] *Id.* at 1.

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data, produced less data to Lilly than it had provided to its own experts, repeatedly misrepresented to Lilly and the Court that it had produced a complete, usable set of Medicaid data, and must now do over its data production.[3] When the Court asked when the State could produce the missing data, the State had no answer.[4] It still doesn't.

The State's solution to its production default is to have one trial using evidence developed in the federal multi-district litigation ("MDL") and postpone to a new trial—and a new jury—the presentation of evidence from its Medicaid database. In the first trial, the State claims that it can establish Lilly's liability by proving that (1) Zyprexa is defective, (2) Lilly failed to issue adequate warnings about Zyprexa's defects, and (3) Lilly's marketing and labeling of Zyprexa involved numerous unfair or deceptive acts.[5]

The State argues that its proposed bifurcation constitutes nothing more than the "obvious use" of Rule 42(b) to sever liability from damages,[6] suggesting that all aspects of liability, including causation, can be tried in the first phase of the trial, without reference to its Medicaid claims data.[7] This abruptly reformulates the method of proof that the State had promised to the Court in its Memorandum Describing Its Claims and Proofs, which argued

[3] *See generally* Lilly's Mot. for an Extension of All Court-Ordered Deadlines.

[4] Status Conference Tr. 4:17 to 5:16, 6:6 to 7:24, Oct. 24, 2007 (Mr. Sanders: "You know, in terms of an exact deadline for when this data will be provided to [Lilly], I don't know . . . .") (Exh. A).

[5] Pl.'s Mem. in Supp. of Bifurcation 3. The State has represented to Lilly that it will stipulate to dismissal of its Fraud and Negligent Misrepresentation claim (Third Claim for Relief).

[6] *Id.* at 7.

[7] *Id.* at 3.

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that Medicaid claims data were necessary—and sufficient—to prove causation.[8] Now the State claims that it can prove causation without even the aggregate claims data, but has not described what evidence it will use in its place. The State's motion also does not address when other evidence relating to liability will be presented, including: (1) evidence that the State has not changed its reimbursement practices, or taken any other action, since it discovered the alleged health risks of Zyprexa and the alleged improper marketing by Lilly; (2) testimony by Alaska prescribers about how they choose mental health medications for their patients; and (3) evidence about the mental health and medical conditions of individual Medicaid recipients.

III. ARGUMENT

A. Standards for Bifurcating Litigation.

Alaska Civil Rule 42(b) provides: "The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy may order a separate trial of any claim . . . or of any separate issue . . . always preserving inviolate the right of trial by jury . . . ." The Alaska rule is identical to Federal Rule of Civil Procedure 42 and, therefore, federal precedents should be considered.[9]

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[8] Pl.'s Mem. Describing Its Claims and Proofs 8-11.

[9] Alaska courts frequently recognize the similarities between the two sets of rules and examine federal decisions interpreting the federal counterpart to guide their decisions. *See, e.g., MacDonald v. Riggs*, 166 P.3d 12, 17-18 (Alaska 2007) (examining federal decisions and federal treatises examining Federal Rule of Civil Procedure 13 because it is identical to Alaska Civil Rule 13); *Martin v. Coastal Villages Region Fund*, 156 P.3d 1121, 1127 (Alaska 2007) (same respecting Alaska Civil Rule 65(a)); *Williams v. Engen*, 80 P.3d 745, 747-48 (Alaska 2003) (same respecting Alaska Civil Rule 27).

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The Alaska Supreme Court has interpreted the Rule several times over the past twenty-five years, and has reasoned that proposed separate trials would neither advance convenience nor expedite the case when the issues sought to be separated shared overlapping issues of fact.[10] Bifurcation is the exception, not the norm, as it infringes on an important aspect of the judicial process—the traditional role of the factfinder to make a determination on the basis of the case presented in its entirety.[11] Many of the issues in the litigation are

[10] *Domke v. Alyeska Pipeline Serv. Co.*, 137 P.3d 295, 303-04 (Alaska 2006); *Miller v. Sears*, 636 P.2d 1183, 1192 (Alaska 1981); *see* Fed. R. Civ. P. 42(b) advisory committee's note (stating that "separation of issues for trial is not to be routinely ordered").

[11] *See Kos Pharms, Inc. v. Barr Labs, Inc.*, 218 F.R.D. 387, 391 (S.D.N.Y. 2003) (inconveniences and inefficiencies in dual proceedings weigh against separation of trials, and for those probable adverse effects to be overcome, circumstances justifying bifurcation should be particularly compelling and prevail only in exceptional cases); *Monaghan v. SZS 33 Assoc.*, 827 F. Supp. 233, 246 (S.D.N.Y. 1993) ("the fundamental presumption which favors the trial of all issues to a single jury and underlies the assumption of Rule 42(b) that bifurcation, even in personal injury actions, is reserved for truly extraordinary situations of *undue* prejudice"); *Kimberly-Clark Corp. v. James River Corp.*, 131 F.R.D. 607, 608 (N.D. Ga. 1989) ("[T]he court should remain mindful of the traditional rule of the factfinder; i.e., to make an ultimate determination on the basis of a case presented in its entirety."); *see also ABB Indus. Sys., Inc. v. Prime Tech, Inc.*, 32 F. Supp. 2d 38, 43 (D. Conn. 1998) ("[S]eparation of issues for trial is not to be routinely ordered. . . . [W]here there is a significant overlap in the evidence pertaining to the claims to be separated, bifurcation will not serve judicial economy."); *Marisol v. Guiliani*, 929 F. Supp. 662, 693 (S.D.N.Y. 1996) ("Bifurcation . . . is a procedural device to be employed only in exceptional circumstances."); *Mangabat v. Sears Roebuck & Co.*, No. 92-1742, 1992 WL 211561, at 2 (E.D. Pa. Aug. 26, 1992) ("bifurcation is an extraordinary measure to be used where it is clearly economical"); *Malone v. Pipefitters' Assoc. Local Union No. 597*, No. 87-C-9966, 1992 WL 73520, at 1 (N.D. Ill. Mar. 30, 1992); *Brown v. Advantage Eng'g, Inc.*, 732 F. Supp. 1163, 1170-71 (N.D. Ga. 1990); *Marshall v. Overhead Door Corp.*, 131 F.R.D. 94, 98 (E.D. Pa. 1990); Jack B. Weinstein, *Routine Bifurcation of Jury Negligence Trials: An Example of the Questionable Use of Rule Making Power*, 14 Vand. L. Rev. 831, 833 (1961) (bifurcation interferes with the role of the jury).

inextricably intertwined and should be presented to a single jury in the same proceeding. Courts regularly recognize that partitioning inextricably intertwined issues can prejudice a party's ability to protect its rights,[12] which may rise to the level of a constitutional violation if a party is deprived of its ability to put forth all of its defenses.[13]

Moreover, should any element of a claim be resolved against Lilly by the first jury, the practical effect may be to impermissibly shift the burden of proof to Lilly for the second trial. If the first jury finds against Lilly on any element or claim, the second jury, which will be instructed about the first jury's findings in a vacuum, will likely place the burden on Lilly to disprove that Zyprexa caused harm to the Alaska Medicaid population. This impermissible advantage will deny Lilly its constitutional right to a fair, impartial jury and a meaningful opportunity to be heard.[14]

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[12] *See Insolia v. Philip Morris, Inc.*, 186 F.R.D. 547, 551 (W.D. Wis. 1999) (partitioning issues that are inextricably linked would prejudice the defendants' ability to protect their rights effectively); *see also Windham v. Amer. Brands, Inc.*, 565 F.2d 59, 71 (4th Cir. 1977) (noting that courts may not "deny or limit a litigant's right to offer relevant 'intertwined matter,' whether addressed to the issue of violation or that of injury and damage").

[13] *See Philip Morris USA v. Williams*, 127 S. Ct. 1057, 1063 (2007) (noting that due process guarantees that a party may put forth all of its defenses)

[14] *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 429 (1981); *Johnson v. Celotex Corp.*, 899 F.2d 1281, 1284-85 (2d Cir. 1990); *Windham v. Am. Brands, Inc.*, 565 F.2d 59, 71 (4th Cir. 1977).

For all of these reasons, the overwhelming majority of courts have rejected aggregated, bifurcated trials of the nature that the State proposes.[15] The State has not cited a single case supporting bifurcation, an implicit concession that the circumstances where bifurcation is allowed are easily distinguished from the State's proposal.

B. The Court Will Not Promote Any Efficiencies by Allowing This Case to Proceed to Trial Without Considering the Reliability of the State's Aggregate Causation Case.

Faced with a postponement of the trial entirely of its own making, the State has importuned the Court to allow it do *something* during the scheduled March trial period, a result that would reward the State and punish Lilly for the State's failure to meet its production obligations. The State argues that such a proceeding will result in substantial

[15] *See, e.g., Kos Pharms, Inc. v. Barr Labs., Inc.*, 218 F.R.D. 387, 393 (S.D.N.Y. 2003) (rejecting bifurcation because it would cause delays, inconvenience, and additional litigation costs); *Wilson v. Sundstrand Corp.*, No. 99 C 6944, 2003 WL 21878738, at *1 (N.D. Ill. Aug. 8, 2003) (denying bifurcation of liability and damages, noting that bifurcation is not the norm and that other judicial management techniques are available to courts); *In re Diamond B Marine Servs., Inc.*, No. CIV.A. 99-951, 2000 WL 37987, at *2 (E.D. La. Jan. 14, 2000) (denying bifurcation because of overlapping issues related to damages, causation, and liability); *ABB Indus. Sys., Inc. v. Prime Tech. Inc.*, 32 F. Supp. 2d 38, 43 (D. Conn. 1998) (denying bifurcation because multiple proceedings would require duplication of testimony and evidence); *Ake v. Gen. Motors Corp.*, 942 F. Supp. 869, 878 (W.D.N.Y. 1996) (denying separate trials because issues would overlap both proceedings); *THK Am., Inc. v. NSK Co. Ltd.*, 151 F.R.D. 625, 633 (N.D. Ill. 1993) (denying bifurcation because of inefficiencies); *Sunenblick v. Harrell*, 145 F.R.D. 314, 317 (S.D.N.Y. 1993) (denying bifurcation because the moving party did not demonstrate judicial economy); *Monaghan v. SZS 33 Assoc.*, 827 F. Supp. 233, 245 (S.D.N.Y. 1993); *Mangabat v. Sears Roebuck & Co.*, No. 92-1742, 1992 WL 211561, at *2 (E.D. Pa. Aug. 26, 1992); *Malone v. Pipefitters' Assoc. Local Union No. 597*, No. 87-C-9966, 1992 WL 73520, at *1 (N.D. Ill. Mar. 30, 1992); *Brown v. Advantage Eng'g, Inc.*, 732 F. Supp. 1163, 1170 (N.D. Ga. 1990); *Marshall v. Overhead Door Corp.*, 131 F.R.D. 94, 98 (E.D. Pa. 1990).

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efficiencies and no unfairness to Lilly. In fact, the framework proposed by the State will not achieve efficiency at all, because it leaves the most important questions unresolved until the second trial.

When this case began, the State touted its Medicaid claims data as the foundation of its case, the evidence that it would use to prove "generic" causation.[16] It strenuously resisted the discovery of any other evidence about the health outcomes of Alaska Medicaid recipients, meaning that, under the State's theory of the case, the database would be the only evidence of whether anything happened to Alaska Medicaid recipients because they used Zyprexa. The Court recognized the threshold question of whether the State could fulfill its burden on causation using its claims database, and established a briefing schedule to address its legal viability. At the conclusion of that briefing, the Court determined that it could not resolve the issue on the record presented, and permitted the State to "develop the statistical evidence that it intends to use at trial."[17] However, the Court recognized that using Medicaid claims data to prove causation remained a threshold issue in the case, to be addressed again through *Daubert/Coon* and summary judgment motions, which would "depend on a evidentiary record that has not yet been developed."[18]

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[16] Pl.'s Mem. Describing Its Claims and Proofs 9.

[17] Order Re: Pl.'s Claim of Proof 4-5.

[18] *Id.* at 4.

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If the State's bifurcation proposal is accepted, this case may go to trial in March with the evidentiary record still not developed, or tested by motions. There could be nothing more inefficient than conducting a several-week trial on generalized issues if the State's data-dependent case that it was harmed by Lilly is not methodologically reliable, legally sufficient, or even factually correct. If the State cannot demonstrate an increase in disease incidence attributable to Zyprexa, the Court, the parties, and a jury will have been subjected to a lengthy trial, in a case that never should have been filed.

The State may have already apprehended this last possibility. The data produced to date, while incomplete, reveals that of the 1040 Zyprexa users that have been diagnosed with diabetes and/or been treated with an anti-diabetic medication between 1996 and 2006, fully half (521) had been diagnosed with diabetes or taken a diabetic medication before their first recorded Zyprexa use, making Zyprexa causation impossible.[19] More cases of pre-existing diabetes will likely be revealed when the State produces pre-1996 data, and enrollment data. Application of the minimum exposure rule used in the Guo article (3 months or 3 prescriptions) will eliminate more cases.[20]

[19] *See* Guo et al., *Risk of Diabetes Mellitus Associated with Atypical Antipsychotic Use Among Medicaid Patients with Bipolar Disorder: A Nested Case-Control Study*, 27 Pharmacotherapy 29 (2007), the article relied upon by the State as the template for its own methodology. (Exh. B). Pl.'s Mem. Describing Its Claims and Proofs 10-11.

[20] *Id.*

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The State has also recognized that its maximum recovery for diabetes treatment is limited to the extra cases found among Zyprexa users, relative to the expected baseline rate in an appropriate control group.[21] However, the State has not even identified what the appropriate control group is, or how the baseline rate will be determined,[22] much less that any increased incidence has occurred.

In summary, the actual damage to the State—under its own theory—is unknown, and may be negligible or non-existent. This uncertainty eviscerates what the State describes as its "most powerful argument . . . that bifurcation will greatly increase the likelihood of an expeditious and economic settlement."[23] Having failed to compile the data that were supposed to demonstrate increased evidence of medical injuries, the State could not have demonstrated that it has been injured even to its own satisfaction, much less to any degree that would provide a basis for Lilly to consider a settlement.

Furthermore, the State is suggesting that Lilly might settle the case before many of its major legal challenges are addressed. While the State argues that bifurcation will benefit Lilly by giving it an opportunity to get the case dismissed in the first trial, it will deprive Lilly of an opportunity to have the case dismissed *without any trial at all.* Moreover,

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[21] Pl.'s Mem. Describing Its Claims and Proofs 8-9.

[22] Pl.'s Resps. to Lilly's Second Set of Interrogs. Nos. 41, 52. (Exh. C).

[23] Pl.'s Mem. in Supp. of Bifurcation 10.

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subjecting Lilly to the radical bifurcation procedure proposed by the State will multiply the legal issues available on appeal, making settlement even less likely.

C. The State Has Proposed a Radical Bifurcation Scheme That Splits Proof Of Liability Into Two Phases.

Although bifurcation of trials is not commonplace, its most frequent uses are to split liability from damages,[24] or punitive damages from other aspects of the case.[25] Recognizing this, the State has based its argument in support of bifurcation on the false premise that the proceedings can be neatly separated into liability and damages. The State asserts that the Medicaid data "is relevant only to a single issue: the quantity of damages."[26] This contention is impeached by the State's own, earlier description about how it would prove its case. The State explained to the Court that general causation, an element of liability, would be established by using its Medicaid claims data to show that there was a higher incidence of diabetes among Zyprexa users than an appropriate control group. It now represents to the Court that the Medicaid data are only relevant to damages, a reformulation that can only be attributed to expediency, not legal merit. If the State has different evidence to prove that Lilly's actions caused medical injuries to Alaska Medicaid recipients, and financial harm to the State, it has not revealed it.

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[24] *See e.g., Princeton Biochems, Inc. v. Beckham Instruments, Inc.*, 180 F.R.D. 254, 257-59 (D.N.J. 1998).

[25] *See, e.g., Mattison v. Dallas Carrier Corp.*, 947 F.2d 95, 110 (4th Cir. 1991).

[26] Pl.'s Mem. in Supp. of Bifurcation 11.

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The State cannot resolve liability in a first trial if its database causation evidence is not presented. At best, the first proceeding would address whether Lilly engaged in misconduct generally in its marketing of Zyprexa, but not whether any such conduct influenced Alaska prescribers, or resulted in bad health outcomes for Alaska Medicaid recipients. Similarly, the first proceeding might address whether Zyprexa is associated with increased rates of diabetes and other conditions, but not whether it actually did cause an increase in Alaska.

The State argues that its Unfair Trade Practices Act ("UTPA") claim for penalties does not require proof of causation and actual damages. But the proof the State acknowledges it needs, that Lilly promoted Zyprexa off-label to Alaska physicians,[27] does require proof of the alleged improper communications, including how physicians perceived the communications,[28] none of which is contemplated by the first phase proposed by the State. In addition, the State has asserted a UTPA claim for actual damages that does require proof of causation. No efficiency will be achieved by trying the UTPA claim once to recover civil penalties, and then over again for actual damages.

Moreover, if the first jury is going to be asked to deliver a verdict on Lilly's liability, due process requires that Lilly be afforded the opportunity to present every available

[27] *Id.* at 6.

[28] *State v. O'Neill Investigations, Inc.*, 609 P.2d 520 (Alaska 1980).

defense and litigate every issue related to liability.[29] If Lilly is not provided with the opportunity to analyze the full Medicaid database before the first trial, and develop testimony from Alaska prescribers, it will not be able to develop critical evidence for the jury's consideration, including the reasons other than Zyprexa that Alaska Medicaid recipients developed diabetes, and the reasons other than Lilly marketing that Alaska prescribers chose to prescribe Zyprexa to their patients.

D. The State's Proposal Bifurcates Proof of Individual Elements of Its Causes of Action.

The State's bifurcation proposal does not simply separate elements of liability—it even cleaves the proof of individual elements. For example, the State claims that it can establish in the first trial that Lilly's warning was inadequate. But the "adequacy of the warning is assessed, not 'in the air,' but in the specific circumstances of the case at hand."[30] The adequacy of a warning cannot be determined without tying the warning to a particular prescribing physician, treating a particular patient, during a particular period of time.[31] Of

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[29] *Philip Morris USA v. Williams*, 127 S. Ct. 1057, 1063 (2007); *Lindsay v. Normet*, 405 U.S. 56, 66 (1972); *United States v. Armour & Co.*, 402 U.S. 673, 682 (1971); *Am. Surety Co. v. Baldwin*, 287 U.S. 156, 168 (1932).

[30] *Lindsay v. Ortho Pharm. Corp.*, 637 F2d 87, 92 (2d Cir. 1980).

[31] *Shanks v. The Upjohn Co.*, 835 P.2d 1189, 1200 (Alaska 1992); *Lindsay v. Ortho Pharm. Corp.*, 637 F2d 87, 92 (2d Cir. 1980) ("[a] warning need be given only when the situation calls for it" (quotation omitted)); *Strasser v. Transtech Mobile Fleet Serv., Inc.*, 613 N.W.2d 142, 155 (Wis. 2000) (ruling that, because of the plaintiff's knowledge of danger, "[i]n the circumstances of this case, Transtech's failure to warn Strasser about the absence of safety treads in the new ladders was not negligence").

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paramount importance is "the actual state of knowledge of the prescribing physician, . . . the nature of the illness or condition which prompted the prescription, and the impact of any of the warnings in those circumstances . . . ."[32] The adequacy of the warning is judged not just by what was in the FDA-approved label, but also by what the prescribing physician actually knew from a variety of sources – some under the control of Lilly (such as discussions with sales representatives, approved promotional pieces, and "Dear Doctor" letters), and some outside Lilly's control (meetings, conversations with colleagues, and medical literature).[33]

Furthermore, the adequacy of the warning is not a static issue; it changes over time, as the warning itself changes, and as the information known to Lilly and available to the medical community changes.[34] The State has not explained how one jury would decide the adequacy of the warning at different points in time, and then a second jury would apply the first jury's verdict to individual prescriptions in the second trial. Trying the State's failure-

[32] *In re Tetracycline Cases*, 107 F.R.D. 719, 733 (W.D. Mo. 1985) (citations omitted).

[33] *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 92 (2d Cir. 1980); *In re Tetracycline Cases*, 107 F.R.D. 719, 733-34 (W.D. Mo. 1985).

[34] *See Beyette v. Ortho Pharm. Corp.*, 823 F.2d 990, 992-93 (6th Cir. 1987) (noting that warnings to the medical community change over time as new side effects to a device become apparent); *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 91 (2d Cir. 1980) (stating that warnings should change due to safety information learned through research, adverse reaction reports, and scientific literature); *In re Ford Motor Co. Vehicle Paint*, 182 F.R.D. 214, 220 (E.D. La. 1998) (noting that defendant's knowledge and conduct was not uniform over the period of time at issue, and that defendant's conduct needed to be assessed as it related to each plaintiff); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1148 (D. Or. 1989) (noting that warnings to the medical community should change as knowledge of a medication's side effects changes).

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to-warn claim without any consideration of actual prescriptions written guarantees accomplishing nothing because an abstract finding could *never* resolve whether the actual warning given to a prescriber was inadequate at a fixed time in light of the medical community's and the presciber's knowledge at that time, as required by Alaska law.[35]

The State may argue that it will demonstrate the impact on prescribers of Lilly's alleged failure with aggregate, rather than individualized evidence. But it has never explained how it would do that, even in the most superficial terms. This is yet another example of the infirmities in the State's method of proof, which must be directly addressed, not conveniently bypassed, before any trial takes place.

The State's proposal would also result in its evidence about whether Zyprexa *can* cause diabetes being presented in the first trial, and whether it *did* cause diabetes in the second trial. Courts have consistently rejected proposals for separate trials using this approach, because the causation questions are "inextricably intertwined."[36]

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[35] *Shanks v. The Upjohn Co.*, 835 P.2d 1189, 1200 (Alaska 1992).

[36] *In re Agent Orange*, 818 F.2d 145, 165 (2d Cir. 1987) (rejecting trial of "generic causation" in the class action setting because "generic causation and individual circumstances concerning each plaintiff and his or her exposure to Agent Orange thus appear to be inextricably intertwined, and class action would have allowed generic causation to be determined without regard to those characteristics and the individual's exposure"); *see, e.g., In re Fibreboard Corp.*, 893 F.2d 706, 712 (5th Cir. 1990) (rejecting proposal in a class action setting that "general causation" issue be tried because "commonality among class members on issues of causation and damages can be achieved only by lifting the description of the claims to a level of generality that tears them from their substantively required moorings to actual causation and discrete injury"); *In re Paxil*, 212 F.R.D. 539, 546-47 (C.D. Cal. 2003) (noting that "[t]he theory and the benefits of bifurcation, when placed in actual practice, will prove to be ephemeral" where plaintiffs sought to bifurcate general causation (continued . . .)

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The State also claims that it can resolve its UTPA claims for civil penalties in the first trial by presenting "evidence that Lilly's marketing efforts were not limited to [its approved] uses."[37] But, just like the failure-to-warn claim, the UTPA claim is not satisfied by marketing "in the air." As the State recognizes, it must demonstrate that Lilly violated Alaska's UTPA *in Alaska*, and the number of violations.[38] Any claim that Lilly engaged in misleading promotional activity with prescribers will depend, in part, on the prescribers' testimony about whether they were misled; certainly Lilly's defense will include that evidence.

E. The Same Evidence Will Be Presented in Both Trials.

No matter how neatly the State proposes to parse this case, it cannot avoid the presentation of the same voluminous and complicated scientific, regulatory, and marketing evidence to two juries.[39]

(. . . continued)
from specific causation); *In re Ford Motor Co. Vehicle Paint*, 182 F.R.D. 214, 220 (E.D. La. 1998) (noting that conducting a phased trial to establish general causation would have little if any significance because proof of specific causation was also necessary); *Arch v. Am. Tobacco Co.*, 175 F.R.D. 469, 488 (E.D. Pa. 1997) (same); *Kurczi v. Eli Lilly & Co.*, 160 F.R.D. 667, 677 (N.D. Ohio 1995) (same); *Ikonen v. Hartz Mountain Corp.*, 122 F.R.D. 258, 265 (S.D. Cal. 1988) (finding that bifurcating general causation from specific causation in the class-action context is not useful because the issues are inextricably intertwined); *see also Hamm v. Amer. Home Prods.*, 888 F. Supp. 1037, 1039 (E.D. Cal. 1995) (rejecting bifurcation because of jury management problems).

[37] Pl.'s Mem. in Supp. of Bifurcation 5.

[38] *Id.* at 6.

[39] *See In re Tetracycaline Cases*, 107 F.R.D. 719, 734 (W.D. Mo. 1985) ("of course, to the extent that such an evidentiary replay is required, most of the benefits of the . . . proceeding would be negated").

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The State has explained that, in a first trial to establish design defects and failure to warn, its experts "will testify about the deleterious health conditions that arise from Zyprexa's side effects."[40] This expert testimony will be based entirely on published scientific literature, as demonstrated by the MDL expert reports of Frederick Brancati, David Goff, and William Wirshing, which the State intends to rely upon in this matter. That same scientific literature will have to be presented again to the second jury as evidence of what prescribers knew about health outcomes associated with Zyprexa, and when they knew it, and to assess the risk-benefit determinations that they had to make. In addition, experts who will evaluate Alaska Medicaid data will necessarily have to discuss the scientific literature regarding antipsychotics and metabolic conditions, to sensibly articulate to the second jury why an increased incidence of diabetes amongst Zyprexa users in the Alaska Medicaid population (if it exists) can or cannot be deemed causal. The second jury would also have to have a firm grasp of this information to understand points of cross examination.

Regulatory evidence, including communications with the FDA, Zyprexa labeling changes, and Lilly's warnings to the medical community must be presented again.[41] Lilly would present this evidence to the second jury in the context of the adequacy of Zyprexa's

[40] Pl.'s Mem. in Supp. of Bifurcation 4.

[41] The State's failure-to-warn claim requires that it prove that an inadequate warning proximately caused injury to Alaska Medicaid recipients. *See Shanks v. The Upjohn Co.*, 835 P.2d 1189, 1200 (Alaska 1992); *Clary v. Fifth Ave. Chrysler Center, Inc.*, 454 P.2d 244, 247 (Alaska 1969).

A B C

warning to frame the information available to individual prescribers, from a variety of sources, regarding Zyprexa's alleged side effects, before and during the periods that they prescribed Zyprexa to Medicaid recipients.

Evidence of alleged off-label promotions presented in the first trial related to the State's UTPA claim would also have to be presented again. For the State to receive actual damages under UTPA, it has to demonstrate that it suffered an ascertainable loss as a result of the alleged off-label promotion, which will, among other things, require it to show that the promotion actually resulted in a prescription being written.[42] This will require a linkage between the alleged improper marketing and an action by a prescriber in Alaska, which would have to take place in the second trial.

The assertion that the second trial will require consideration only of the Medicaid data rests on the State's convenient evasion of the fact that, between Lilly's marketing and the Zyprexa label, and the health outcomes of patients, there is a learned intermediary, the prescriber, whose decision-making process will be evidence in the case. Since the State has no plan for determining the effect of Lilly's marketing and the Zyprexa warning on

[42] *See* Alaska Pattern Jury Instructions, Consumer Protection Act 10.01A, 10.01B, 10.03B, 10.04.

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prescribers in the first trial, the effect will have to be considered in the second trial, requiring the reintroduction and reconsideration of extensive evidence from the first trial.[43]

IV. CONCLUSION

The only way to determine whether Lilly harmed the State of Alaska is to find out what happened to Zyprexa prescribers and Zyprexa users in Alaska, the evidence of which resides in medical records, medical claims data, and prescriber testimony. Holding a trial on generalized issues of Zyprexa's effect profile and Lilly's marketing practices, without knowing whether there is even a prima facie case that Alaska Medicaid recipients were injured by Zyprexa, is a waste of the parties' and judicial resources, and a violation of Lilly's constitutional rights. The most expeditious use of resources is to continue working on the question that the Court recognized as primary at the outset: What evidence is relevant to deciding whether Lilly harmed the State?

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[43] Not only will the re-presentation of evidence be confusing and inefficient, but it may give rise to a constitutional violation. Federal courts addressing bifurcation plans have found them to be unconstitutional under the Reexamination Clause of the Seventh Amendment if they result in two juries examining the same issues of fact. *See, e.g., Castano v. American Tobacco Co.*, 84 F.3d 734, 750-51 (5th Cir. 1996) (rejecting a motion to try "core liability" issues followed by a trial of individual class members because the of the high risk of reexamination of issues, which would violate the Seventh Amendment); *In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1303 (7th Cir. 1995) (Posner, J.) (granting mandamus to reverse a trial court's bifurcation plan because overlapping issues was a "looming infringement of Seventh Amendment rights;" "How the resulting inconsistency between juries could be prevented escapes us"). Although the Alaska Constitution does not contain the same explicit reexamination prohibition as the Seventh Amendment to the U.S. Constitution, the Alaska Supreme Court has invoked the prohibition against reexamination. *See Evans v. State*, 56 P.3d 1046, 1051 (Alaska 2002).

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Accordingly, Lilly requests that the Court deny the State's Motion for Bifurcation, and grant Lilly's Motion for an Extension of all Court-Ordered Deadlines, which will allow the parties to develop the evidence that will determine whether this case should go to trial at all, and, if so, to try the case in one proceeding before a single jury.

DATED this 9th day of November, 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

STATUS CONFERENCE
BEFORE THE HONORABLE M. RINDNER

Pages 1 - 56
Wednesday, October 24, 2007
2:00 P.M.
Anchorage, Alaska

Court Reporter and Transcriptionist:
Diane M. Bondeson
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EXHIBIT A
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B C

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EXHIBIT A
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B C

MR. ROTHSCHILD: Sure. Your Honor, the request for a status conference was made by the State after Lilly filed a motion for extension of all the court-ordered deadlines. And the primary basis for that is that the evidence that the State is relying upon to prove its case, the Clinton and Medicaid claims data, has not been fully produced to Lilly. So neither party today has the data that it needs for its experts to analyze and to prepare this case for trial.

The State has admitted this. The Discovery Master has ordered that the State make a new production of Medicaid claims data. I understand the State to be making efforts to extract that, but as of today's date, we don't have that data, and we don't know when we'll be receiving it.

THE COURT: Okay. So, Mr. Sanders, do you have a characterization of why this delay has been requested or do you disagree with that? I mean, is there information that the State needs to produce that hasn't been produced in order to move this along?

MR. SANDERS: There is additional information that we intend to produce.

THE COURT: Okay. So then what are the

time lines going to be for getting that information so that everybody can then do the work that they need to do, and what's the effect of that going to be on deadlines and the trial date?

MR. SANDERS: Okay. If I could just back up. I did ask for the status conference, and the reason for that is they asked for an extension of all these deadlines. They didn't ask for an extension of the trial, and I assume that that really was what their intent was, although they didn't state it for some reason. So let's -- I just said let's call this what it's supposed to be, which is a motion to vacate the trial date.

And if that's being contemplated, I want to know that sooner rather than later because of these deadlines that are fast approaching.

THE COURT: Well, then let me just ask. I mean, is the effect if I grant your motion to set back all the trial dates really going to be to set off the trial date?

MR. ROTHSCHILD: It is, Your Honor, and it actually was specifically requested. It's in our proposed order. And we don't have the data yet, and we don't know when we're going to get it. We really need a period similar to what was contemplated when

this case was first scheduled, six months or so, to get this data, analyze it and prepare the expert reports, and certainly the trial dates would have to be shifted accordingly, and we in fact did request that in our proposed order.

THE COURT: So then what's everybody's best estimates of when the information that needs to be gathered is going to be gathered and what effect this will have on all the other dates and what that means for a rational trial date?

MR. SANDERS: Okay. Here's what -- here's my observation. If I understand what the complaint is, the complaint is all with respect to damages. It has nothing to do with liability.

And so what we would propose is -- we've gotten the -- we've gotten Lilly's expert witness list. They have 19 experts. And I can't go through and identify which are on damages and which are on liability, but obviously many of them are on liability because they say they're consistent with their expert reports in the MDL litigation.

So I think that it's unrealistic to think that Lilly is going to try this case in ten days on liability and damages. Probably more realistic is we're looking at ten days from Lilly just on

liability alone, but --

So what I'm saying is if the complaints that they're expressing here today all go to the area of damages, why can't we go ahead with the liability trial we have scheduled for March. We think we can put our case on in less than the ten days we propose for our entire case. I don't know -- I'll let Lilly have the ten days they had proposed before for liability. We'll try the liability case.

If we're correct, then that will be -- will resolve liability and causation and address damages, if there is liability, and causation at a later time. And if Lilly's position is correct -- if I understand it, they're saying there is no liability or causation issues. If they're right, then we're done, and they don't have to worry about all this damage information.

So what I would propose is we keep the liability trial, so we try liability and damages. We would vacate the trial date insofar as it applies to damages. If -- and I think I'm willing to go this far with them. You know, in terms of an exact deadline for when this data will be provided to them, I don't know, but I think that what our -- what we're willing to do -- because one of the complaints they

have in their pleadings were that the State is using some novel scientific methodology that we haven't explained to them yet so they can't prepare their reports.

Now, this is kind of a common theme the court hears all the time in cases, that: We don't know what their theory is. We can't prepare for it. We need to see their experts first.

So they propose one of two things. Either that reports be staggered, we produce ours first, they get to study them, and then they get to issue their reports. Or that we produce them simultaneously, and they produce rebuttal reports.

I think -- we're prepared in good faith to concede that we would give them our damage reports.

THE COURT: Damage or liability?

MR. SANDERS: Damage reports. The liability is -- they know all about liability. All these reports have already been exchanged in the MDL. So there is no secrets on the liability. They know what our theory of liability is. We know what their defenses are.

The only question on this case is -- the only mystery they're posing in the pleadings are about damages. We don't know how their damages are

Risk of Diabetes Mellitus Associated with Atypical Antipsychotic Use Among Medicaid Patients with Bipolar Disorder: A Nested Case-Control Study

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Study Objective. To quantify the risk of diabetes mellitus associated with atypical antipsychotics compared with conventional antipsychotics in managed care Medicaid patients with bipolar disorder.

Design. Retrospective nested case-control study.

Data Source. Integrated seven-state Medicaid managed care claims database from January 1, 1998–December 31, 2002.

Patients. Two hundred eighty-three patients with diabetes (cases) and 1134 controls matched by age, sex, and the index date on which bipolar disorder was diagnosed.

Measurements and Main Results. Cases were defined as those having an *International Classification of Diseases, Ninth Revision* diagnosis of diabetes or those receiving treatment with antidiabetic drugs. Both case and control patients had at least a 3-month exposure to either conventional or atypical antipsychotic agents or three filled prescriptions related to treatment for bipolar disorder. Of the 283 cases, 139 (49%) received atypical antipsychotics (olanzapine, risperidone, quetiapine, ziprasidone, and clozapine) and 133 (47%) were prescribed conventional antipsychotics. To compare the risk for new-onset diabetes associated with atypical versus conventional antipsychotics, we conducted a Cox proportional hazard regression, in which we controlled for age; sex; duration of bipolar disorder follow-up; use of lithium, anticonvulsants, antidepressants, and other drugs; and psychiatric and medical comorbidities. Compared with patients receiving conventional antipsychotics, the risk of diabetes was greatest among patients taking risperidone (hazard ratio [HR] 3.8, 95% confidence interval [CI] 2.7–5.3), olanzapine (3.7, 95% CI 2.5–5.3), and quetiapine (2.5, 95% CI 1.4–4.3). The risk for developing diabetes was also associated with weight gain (HR 2.5, 95% CI 1.9–3.4), hypertension (HR 1.6, 95% CI 1.2–2.2), and substance abuse (HR 1.5, 95% CI 1.0–2.2).

Conclusion. Olanzapine, risperidone, and quetiapine are all associated with development or exacerbation of diabetes mellitus in patients with bipolar disorder. When prescribing therapy for this patient population, metabolic complications such as diabetes, weight gain, and hypertension need to be considered.

Key Words: diabetes, bipolar disorder, atypical antipsychotics, managed care, Medicaid.

(Pharmacotherapy 2007;27(1):27–35)

Traditionally, mood stabilizers such as lithium, divalproex, and carbamazepine have been the primary agents used to treat bipolar disorder. Although conventional antipsychotics also have

been prescribed to treat acute mania, long-term maintenance use of these agents is limited due to their intolerable adverse events, including akathisia, extrapyramidal symptoms, and tardive dyskinesia. Atypical antipsychotics (aripiprazole, clozapine, olanzapine, quetiapine, risperidone, and ziprasidone) are generally regarded as having lower risk for causing extrapyramidal symptoms than conventional antipsychotics; they have been used with increasing frequency in the treatment of bipolar disorder since the mid-1990s.[1–4] This trend may reflect the antimanic or mood-stabilizing properties of atypical antipsychotics and their favorable tolerability profiles compared with conventional agents.[5–7] Recent clinical trials suggest that antipsychotic augmentation might be efficacious for treatment of bipolar depression.[7–9] Unfortunately, atypical antipsychotics are associated with metabolic complications that place patients at risk for weight gain, altered glucose metabolism, dyslipidemia, myocarditis, and cardiomyopathy.[10–13]

The increased risk for diabetes associated with atypical antipsychotics may reflect direct effects of these drugs on β-cell function and insulin action.[10, 11] Several published studies, including a number of retrospective cohort studies, have shown associations between the development of diabetes or glucose intolerance and the atypical antipsychotics clozapine, olanzapine, and risperidone in patients with schizophrenia.[14–23] A research group reported hazard ratios (HRs) for diabetes risk of 1.1–1.2 in Veterans Affairs patients who received atypical antipsychotics.[24] Two groups in the United Kingdom found that atypical antipsychotics were associated with HRs for diabetes of 4.7–5.8.[24, 25] An analysis based on the World Health Organization's adverse drug reaction database found that these agents had an HR for diabetes as high as 10.22.[26] Several cases of diabetic ketoacidosis and diabetes associated with atypical antipsychotics have been reported among adult[27] and pediatric[28, 29] patients with bipolar disorder. Although atypical antipsychotics are widely used to treat mania, their association with diabetes onset has not been adequately quantified in patients with bipolar disorder.[30]

Not only is the Medicaid program the dominant payer for mental health services in the United States,[31] but the number of Medicaid enrollees in managed care organizations has increased since the mid-1990s.[32] Studies using Iowa and California Medicaid claims databases have found that patients with schizophrenia exposed to clozapine or olanzapine were at increased risk for type 2 diabetes.[33, 34] Yet, very little information exists about the risk of diabetes associated with antipsychotic drug use among patients with bipolar disorder in the managed care Medicaid population.

We hypothesized that atypical antipsychotics would present a different risk for diabetes than conventional antipsychotics. Our objectives were to investigate the association between atypical antipsychotics and diabetes mellitus in patients with bipolar disorder in the managed care Medicaid population and compare it with the association between conventional antipsychotics and diabetes in the same patient population. In assessing the risk for diabetes, we controlled for key covariates such as age, sex, and psychiatric and medical comorbidities, as well as concomitant drugs that affect patients' risk for hyperglycemia.

Methods

Data Source

Our data source was a multistate managed care claims database (PharMetrics, Watertown, MA). The database covered over 45 million individuals enrolled in managed care organizations with 70 health plans, including seven state Medicaid managed care programs, in four U.S. regions: Midwest (34.1%), East (15.6%), South (23.9%), and West (26.4%).[35] The database included each patient's date of enrollment and pharmacy, medical, and institutional claims. Each medical claim was recorded with accompanying diagnostic codes from the *International Classification of Diseases, Ninth Revision* (ICD-9) that justified

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the medical service. This geographically diversified claims database provides a large quantity of health information pertaining to the Medicaid population. The use of Medicaid or managed care claims databases for pharmacoepidemiologic studies has been well documented.[14, 23, 24, 33, 34]

Study Design

We used a retrospective nested case-control (population-based case-control) design. Claims data from January 1, 1998–December 31, 2002 (5 calendar years) were reviewed. To protect patient confidentiality, we deleted patient names, insurance plan identification numbers, and other patient identifiers from the claims database. Randomized patient numbers and patients' birth years were used for identification and calculation of age. The research project was approved by the University of Cincinnati Medical Center's institutional review board.

Study Cohort Identification

As shown in Figure 1, from 1998–2002 a total of 48,965 managed care Medicaid patients had at least one diagnosis of an affective disorder (ICD-9 code 296.xx) or cyclothymia (ICD-9 code 301.13). We excluded 4841 patients with schizophrenia (295.xx), 30,624 patients with depression only (296.2x and/or 296.3x), and 29 patients aged 65 years or greater during the study period. These exclusions enabled us to assess patients with bipolar disorder while avoiding confounding due to patients who had schizophrenia and/or depression or who were eligible for both Medicare and Medicaid. The final cohort consisted of 13,471 patients with bipolar disorder indicated by any of the following ICD-9 codes: 296.0, 296.1, and 296.4–296.8. Because less than 0.1% of the study group had cyclothymia, patients with that disorder were not categorized separately.

In keeping with other published retrospective cohort studies,[15–25] we selected a cohort of patients who had a minimum of 3 months of exposure to atypical or conventional antipsychotics or at least three filled prescriptions related to treatment of bipolar disorder during the study period. Incident cases of diabetes were identified by either the earliest diagnosis of ICD-9 code 250.xx or treatment for diabetes after the first identified use of antipsychotics. The date for the first diabetes diagnosis or first use of antidiabetic drugs was defined as the diabetes index date. To ensure that we were identifying incident cases of diabetes, we checked medical and prescription claim records for any diagnosis or treatment of diabetes before the diabetes index date. Patients were rejected as cases if they had a prescription for oral antidiabetic agents before the diabetes index date. The oral antidiabetic agents identified were sulfonylurea drugs (acetohexamide, glipizide, glyburide), a biguanide (metformin), thiazolidinediones (pioglitazone, rosiglitazone), α-glucosidase inhibitors (acarbose, miglitol), and the new drugs repaglinide and nateglinide.

The index date of bipolar diagnosis was the first date of diagnosis indicated by designated ICD-9 codes for bipolar disorder during the study period. For each case we matched five controls according to age at bipolar diagnosis index date (standard deviation of 5 yrs), sex, and the month and year of diagnosis of bipolar disorder. Controls meeting the matching criteria were selected at random using SAS, version 8.0 (SAS Institute Inc., Cary, NC), software. Controls were selected from a population of patients who had been diagnosed with bipolar disorder but were not diagnosed with or treated for diabetes at any time during the study period. Because the

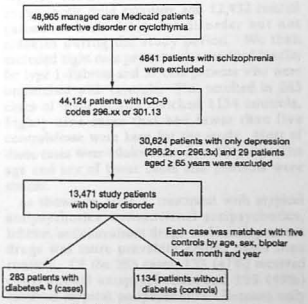

Figure 1. Patient flow diagram of incident cases of diabetes mellitus and controls from patients with bipolar disorder in the United States managed care Medicaid population, 1998–2002. [a]Incident cases of diabetes were identified by either earliest diagnosis of *International Classification of Diseases, Ninth Revision* (ICD-9) code 250.xx or treatment for diabetes. [b]Eighty-nine case patients with fewer than five matched controls were included in the analysis.

month and year of bipolar diagnosis were part of the matching criteria, the calendar time distributions of the bipolar index date were the same for both cases and controls.

Drug Use and Covariates

We classified antipsychotics as either conventional or atypical. The atypical antipsychotics were olanzapine, risperidone, quetiapine, ziprasidone, and clozapine. Aripiprazole was not included in this analysis as it was not available during the study period. The conventional antipsychotics were haloperidol, chlorpromazine, fluphenazine, loxapine, molindone, perphenazine, thioridazine, trifluoperazine, thiothixene, and pimozide. Other antipsychotics, such as thioxanthenes (flupenthixol, zuclopenthixol), pipotiazine, and methotrimeprazine were not included in this study because they were not available in the United States.

Published reports indicate that some drugs elevate blood glucose levels in some patients. Thus, our analysis incorporated data on administration of any of the following drugs during the study period: α-blockers (e.g., doxazosin, prazosin, terazosin), β-blockers (e.g., atenolol, betaxolol, bisoprolol), thiazide diuretics (e.g., chlorothiazide, chlorthalidone, polythiazide), corticosteroids (e.g., methylprednisolone, hydrocortisone), phenytoin, oral contraceptives containing norgesterol, and valproic acid.[30,36,37]

For both cases and controls, all prescription drug claims for treatment of bipolar disorder and diabetes were abstracted and reviewed. The follow-up period began with each patient's first bipolar diagnosis date and ended with the index date of diabetes, the end of the study period, or the end of the patient's enrollment in the managed care Medicaid program, whichever came first. We used dichotomous variables to indicate whether a patient had received concomitant drugs known to be associated with diabetes or hyperglycemia. All drug claims were identified by national drug codes.

In addition to drugs known to affect the risk of diabetes, we adjusted the analysis for psychiatric comorbidities (alcohol abuse, substance abuse disorder, personality disorder, anxiety disorder, and impulse-control disorder) and medical comorbidities (hypertension, weight gain, arthritis, cerebral vascular disease, chronic obstructive pulmonary disease, dyslipidemia, and coronary heart disease. The ICD-9 codes were used to identify comorbid conditions from either hospital or clinical encounters.

Statistical Analysis

All analyses were performed with SAS, version 8.0. Descriptive statistics were used to explore patient demographics and drug use categories. The age of each patient was simply the age at bipolar diagnosis. We conducted the Cox proportional hazard regression to assess the risk for diabetes associated with antipsychotic drugs due to the consideration of time-to-event with censoring and covariates. We determined hazard ratios for each risk factor with 95% confidence intervals. Patients taking conventional antipsychotics were the referent group in our comparison of diabetes risk among patients.

Results

Table 1 summarizes the characteristics of the study population. During the 5-year study period (1998–2002), of the 13,471 managed care Medicaid patients with bipolar disorder, 1730 (13%) had at least one prescription for atypical antipsychotics, 1918 (14%) had prescriptions for conventional antipsychotics, 1048 (8%) for lithium, 3013 (22%) for anticonvulsants, and 4011 (30%) for antidepressants.

The first cohorts we selected consisted of 323 case patients who developed diabetes after the bipolar index date and after their first antipsychotic drug exposure and 12,432 control patients who had bipolar disorder but not diabetes during the study period. We then excluded eight case patients who received insulin for type 1 diabetes and 32 case patients who were unmatched with controls. This resulted in 283 cases of diabetes and matched 1134 controls. Eighty-nine cases that had fewer than five controls/case were kept for the study. Most of those cases were adults older than 50 years. The age and sex of these cases and controls were similar.

As shown in Table 1, treatment with atypical antipsychotics, conventional antipsychotics, lithium, anticonvulsant drugs, and antidepressant drugs was more prevalent among cases than controls. Of the 283 cases, 133 (47%) received conventional antipsychotics, and 139 (49%) received atypical antipsychotics. Because only five patients (< 2%) received more than one atypical antipsychotic during the study period, we did not categorize this patient group.

Compared with patients receiving conventional antipsychotics, the risk for diabetes was greatest among patients taking risperidone (HR 3.8, 95% CI 2.7–5.3), olanzapine (HR 3.7, 95% CI

Table 1. Characteristics of the Study Patients

Characteristic	No. (%) of Patients	
	Cases (n=283)	Controls (n=1134)
Age (yrs)		
≤12	5 (1.77)	25 (2.20)
13–17	10 (3.53)	50 (4.41)
18–34	70 (24.73)	329 (29.01)
35–49	129 (45.58)	562 (49.56)
50–64	69 (24.38)	168 (14.81)
Sex		
Female	227 (80.21)	916 (80.78)
Male	56 (19.79)	218 (19.22)
Psychotherapeutic drugs[a]		
Lithium	153 (54.06)	119 (10.49)
Anticonvulsants[b]	164 (57.95)	289 (25.48)
Atypical antipsychotics	139 (49.12)	164 (14.46)
Olanzapine	51 (18.02)	79 (6.97)
Quetiapine	18 (6.36)	20 (1.76)
Risperidone	65 (22.97)	61 (5.38)
Ziprasidone	2 (0.71)	3 (0.26)
Clozapine	3 (1.06)	2 (0.18)
Antidepressants	174 (61.48)	374 (32.98)
Conventional antipsychotics	133 (47.00)	213 (18.78)
Other concomitant drugs[a]		
β-Blockers	63 (22.26)	86 (7.58)
α-Blockers	4 (1.41)	7 (0.62)
Corticosteroids	78 (27.56)	171 (15.08)
Thiazide diuretics	30 (10.60)	38 (3.35)
Oral contraceptives	9 (3.18)	17 (1.50)
Valproic acid	1 (0.35)	8 (0.71)
Phenytoin	5 (1.76)	18 (1.59)
Psychiatric comorbidities[c]		
Alcohol abuse	22 (7.77)	147 (12.96)
Substance abuse	41 (14.48)	146 (12.87)
Anxiety disorder	150 (53.00)	445 (39.24)
Impulse-control disorder	5 (1.76)	22 (1.94)
Personality disorder	21 (7.42)	65 (5.73)
Medical comorbidities[c]		
Hypertension	130 (45.94)	194 (17.11)
Weight gain	79 (27.92)	90 (7.94)
Arthritis	16 (5.65)	30 (2.65)
Chronic obstructive pulmonary disease	41 (14.49)	71 (6.26)
Cerebral vascular disease	15 (5.30)	27 (2.38)
Coronary heart disease	11 (3.88)	5 (0.44)
Dyslipidemia	8 (2.83)	5 (0.44)

[a]Some patients received more than one drug.
[b]Anticonvulsants were divalproex and carbamazepine.
[c]Some patients were diagnosed with more than one comorbid condition.

2.5–5.3), quetiapine (HR 2.5, 95% CI 1.4–4.3), and the anticonvulsants divalproex and carbamazepine (HR 1.6, 95% CI 1.2–2.1; Table 2). These data were obtained in a process that controlled for the covariates of age, sex, and duration of follow-up; use of lithium, anticonvulsants, and antidepressants; concomitant drugs (not related to bipolar disorder); and psychiatric and medical comorbidities. In addition, patients whose bipolar disorder was coupled with substance abuse, hypertension, and/or weight gain had a significantly higher risk for diabetes than their counterparts.

Discussion

This multistate, population-based, nested case-control study examined the risk of diabetes

associated with use of antipsychotics in Medicaid patients with bipolar disorder. After controlling for personal risk factors and concomitant drug use, we found that patients receiving atypical antipsychotics for bipolar disorder are at increased risk for diabetes. Our findings add to the body of observational evidence indicating that certain atypical antipsychotics may be associated with an increased risk for diabetes among patients with bipolar disorder.[27–29] It is unclear, however, whether the diabetes in the study population is due to the use of atypical antipsychotics versus the underlying condition of bipolar disorder versus characteristics of the Medicaid population, such as low socioeconomic status, poor overall physical health, unhealthy lifestyles, and poor access to health care services.

Atypical antipsychotics are generally regarded as having less potential for causing extrapyramidal symptoms and a higher serotonin:dopamine receptor affinity compared with conventional antipsychotics.[11, 12] Recent literature indicates that clozapine, olanzapine, and risperidone are more likely to be associated with diabetes (indicated by diabetic ketoacidosis and an atherogenic lipid profile) than other atypical agents.[14, 28, 29, 38, 39] One possible mechanism for hyperglycemia is impairment of insulin resistance, which may occur because of weight gain or a change in body fat distribution or by a direct effect on insulin-sensitive target tissues.[2, 10, 11]

Our findings are comparable to data from published pharmacoepidemiologic studies of patients with schizophrenia.[14, 23–25] For example, reported HRs for diabetes in patients with schizophrenia were 1.2–5.8 for olanzapine and 1.1–2.2 for risperidone.[14, 23–25, 33] These values can be compared with the HRs we obtained for the same drugs in patients with bipolar disorder: HR 3.7 (95% CI 2.5–5.3) for olanzapine and 3.8 (95% CI 2.7–5.3) for risperidone (Table 2). After controlling for comorbidities, personal risk factors, and concomitant drugs, we also found that quetiapine increases the risk for diabetes in patients with bipolar disorder (HR 2.5, 95% CI 1.4–4.4). Although quetiapine has been linked to diabetes in case reports,[40–43] earlier studies have failed to confirm this association.[33] This may be due to their small sample sizes or lack of control for confounding variables.[44] The HRs associated with clozapine (HR 2.9, 95% CI 0.9–9.6) and ziprasidone (HR 4.3, 95% CI 1.0–18.9) in our study were large, but they were not statistically significant. This might be due to the small number of patients in our study who received either clozapine or ziprasidone. Long-term data from large, randomized, controlled trials are needed to more explicitly examine the association between diabetes and various atypical antipsychotic drugs.

As shown in Table 2, in addition to antipsychotic use, diabetes risk is also associated with weight gain and hypertension. As the literature indicates, olanzapine, clozapine, and risperidone are associated with weight gain,[13, 45, 46] hyperlipidemia, and hypertriglyceridemia, all of which are independent risk factors for heart disease.[14, 47, 48] Our findings of elevated HRs for weight gain and hypertension make it likely that the incident cases of diabetes we identified were associated with metabolic syndrome. Our data also show that patients with substance abuse have a heightened risk for diabetes. It is possible that these patients might have less healthy lifestyles, poorer drug compliance, or poorer access to health care services than patients without substance abuse.[49, 50] Poor drug compliance might lead to drug overdose, which could increase the risk for diabetes in this population.[33]

Our study had several limitations. Children, women, and low-income populations are overrepresented in the Medicaid population. Thus, our findings might not be indicative of the general population. We inferred drug use from automated pharmacy claims data. Although baseline drug use differed between cases and controls, we tried to adjust for these differences with the Cox proportional hazard model. Because of the retrospective nature of a claims database review, we could not assess individual patients with regard to severity of bipolar disorder, socioeconomic class, lipid profiles, fasting glucose concentrations, or changes in body mass index related to weight gain.

Moreover, data on patients' ethnicity were missing when PharMetrics (data vendor) collected medical claims information from participating managed care organizations. Another concern is that clinicians may have prescribed one drug versus another based on patients' specific symptoms. We attempted to reduce this potential confounding bias by adjusting for known concomitant drugs and comorbidities. We also included dyslipidemia and coronary heart disease as comorbidities, as these provide a rough proxy for patients at high risk for diabetes. It is possible that we underestimated the prevalence of diabetes due to our study's limited time window, changes in

Table 2. Hazard Ratios for Diabetes Risk

Variable	Hazard Ratio[a]	95% CI
Pyschotherapeutic drugs		
Conventional antipsychotic	1.000	1.000
Olanzapine	3.664	2.542–5.281
Quetiapine	2.476	1.427–4.296
Risperidone	3.771	2.699–5.269
Ziprasidone	4.297	0.976–18.923
Clozapine	2.872	0.862–9.575
Lithium	1.016	0.729–1.416
Anticonvulsant[b]	1.571	1.153–2.140
Antidepressant	1.138	0.842–1.538
Other concomitant drugs		
β-Blocker	1.329	0.960–1.839
α-Blocker	0.669	0.235–1.907
Corticosteroid	1.048	0.775–1.417
Thiazide diuretic	1.254	0.807–1.947
Oral contraceptive	1.766	0.829–3.761
Valproic acid	0.359	0.049–2.640
Phenytoin	0.428	0.167–1.098
Psychiatric comorbidities		
Alcohol abuse	0.623	0.390–0.996
Substance abuse	1.491	1.033–2.152
Anxiety disorder	1.257	0.963–1.640
Impulse-control disorder	0.499	0.183–1.360
Personality disorder	1.096	0.673–1.783
Medical comorbidities		
Hypertension	1.636	1.208–2.216
Weight gain	2.516	1.876–3.375
Arthritis	0.920	0.535–1.582
Chronic obstructive pulmonary disease	1.289	0.865–1.921
Cerebral vascular disease	1.223	0.702–2.129
Coronary heart disease	1.134	0.588–2.188
Dyslipidemia	1.844	0.813–4.182

CI = confidence interval.
[a]Model for age, sex, bipolar follow-up months, use of drugs, psychiatric and medical comorbidities.
[b]Anticonvulsants were divalproex and carbamazepine.

managed care enrollment, and the fact that some mental services may not have been billed to patients' managed care organizations. Finally, we identified comorbid conditions by diagnostic codes without considering the contribution of drugs to weight gain, hypertension, cerebral vascular disease, and other disorders.

Despite the above limitations, our study adds to the limited literature about diabetes risk in patients with bipolar disorder in managed care Medicaid programs. It provides useful information on disease management strategies in terms of selection of mood stabilizers and consideration of relevant comorbidities for patients with bipolar disorder, especially the managed care Medicaid population. Atypical antipsychotics provide great benefit to a wide variety of individuals with psychiatric disorders; nevertheless, they have a constellation of adverse effects related to increased risk for weight gain, diabetes, and dyslipidemia.[10,11]

Conclusion

The atypical antipsychotics olanzapine, risperidone, and quetiapine are consistently associated with increased risk for diabetes in patients with bipolar disorder after adjustment for relevant risk factors. Metabolic complications are a clinically important issue for patients receiving antipsychotic therapy. The choice of olanzapine, risperidone, or quetiapine for a specific patient with bipolar disorder should involve consideration of each agent's risks and benefits, with attention to comorbid conditions relevant to the patient's risk for diabetes. Thus,

the propensity of an antipsychotic agent to induce or exacerbate diabetes is a critical consideration in the selection of an agent to treat bipolar disorder.

Acknowledgment

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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 RESPONSES TO DEFENDANT'S SECOND SET OF INTERROGATORIES

Pursuant to Rule 33 of the Alaska Rules of Civil Procedure, Plaintiff, the State of Alaska, provides the following Answers to Defendant's Second Set of Interrogatories. The State makes notice that Interrogatories 39-54 relate to the nature and extent of the State's damages arising from Defendant's conduct in this case. Discovery regarding these issues is not complete. Therefore, the State specifically reserves the right to supplement and amend these responses as provided by the applicable rules of procedure. Additionally, many responses to these Interrogatories will be contained within Plaintiff's experts' reports to be produced at a later date.

INTERROGATORIES

INTERROGATORY NO. 39: Identify each and every medical condition the treatment of which you have paid for that you contend was caused by Zyprexa.

FELDMAN ORLANSKY & SANDERS
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ANSWER: The State's response to this interrogatory will be part of its expert disclosures and accompanying reports related to its proof of damages in this case. As such, the State fully reserves the right to supplement this interrogatory. The State has paid for the treatment of diabetes and diabetes-related conditions including, but not limited to: all diabetes, diabetic conditions, pancreatitis, weight gain, dislipidemia and related sequalea and secondary injuries.

INTERROGATORY NO.40: Identify by ICN each and every Medicaid claim you contend you would not have paid for or reimbursed but for the Medicaid recipient's ingestion of Zyprexa.

ANSWER: The State's response to this interrogatory will be part of its expert disclosures and accompanying reports related to its proof of damages in this case. The included ICN's will be all ICN's associated with the medical conditions referenced in Interrogatory No. 39, above. By way of further response, in order to completely and accurately answer this question, further data is being extracted for the State Medicaid database.

INTERROGATORY NO. 41: Do you contend that, compared to another population of individuals, the Alaska Medicaid recipients who ingested Zyprexa had a higher incidence of any of the medical conditions identified in response to Interrogatory No. 1? If so, for each condition, identify that comparison population of individuals, and state the criteria by which you have defined that population.

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ANSWER: Yes. By way of further response, The State's response to this interrogatory will be part of its expert disclosures and accompanying reports related to its proof of damages in this case.

INTERROGATORY NO. 42: In response to Lilly's Interrogatory No. 18 (First Set), you contend that you paid for "unnecessary Zyprexa prescriptions" as a result of Lilly's alleged wrongful conduct. Identify the criteria by which you define Zyprexa prescriptions as unnecessary.

ANSWER: The State objects to this interrogatory in that it seeks the mental impressions, conclusions, opinions and/or legal theories of the attorneys in this litigation. Subject to and without waiving any objections, the State will prove at the trial of this case that Defendant deceptively and illegally marketed Zyprexa in Alaska, and that all prescriptions occurring during the time of that conduct or potentially resulting from that conduct were unnecessary.

INTERROGATORY NO.43: Identify by ICN each prescription reimbursed by Alaska that was unnecessary.

ANSWER: See Answer No. 42 above.

INTERROGATORY NO. 44: Identify every medicine you contend is an "equally efficacious and safer alternative" (as you have used that phrase in response to Lilly's Interrogatory No. 19 (First Set)) to Zyprexa for Zyprexa's FDA-approved schizophrenia indication.

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INTERROGATORY NO. 51: For each medical condition identified in response to Interrogatory No. 1, describe the criteria you are using to determine that a Medicaid recipient developed that condition.

ANSWER: The State is using ICD-9 Codes and other health codes such as revenue codes, HCPCS, procedure codes, and / or codes associated with prescriptions for drug products utilized to treat medical conditions listed in Interrogatory No. 39 above.

INTERROGATORY NO. 52: For each medical condition identified in response to Interrogatory No. 1, describe the criteria you are using to identify Medicaid recipients who will be considered when comparing incidence rate of that medical condition in Zyprexa users versus the comparison population identified in response to Interrogatory No. 3 ("the comparison population"), including, but not limited to:

a. time on Zyprexa;

b. time on any medication used to define the comparison population;

c. date of first Zyprexa prescription;

d. date of first prescription of any medication used to define the comparison population;

e. time between first Zyprexa prescription and diagnosis of the medical condition;

f. time between first prescription of any medication used to define the comparison population and diagnosis of the medical condition;

g. time between first Zyprexa prescription and first prescription of any medication being used as evidence that the Medicaid recipient has the medical condition;

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h. time between first prescription of any medication used to define the comparison population and first prescription of any medication being used as evidence that the Medicaid recipient has the medical condition;

i. time between last Zyprexa prescription and diagnosis of the medical condition;

j. time between last prescription of any medication used to define the comparison population and diagnosis of the medical condition;

k. time between last Zyprexa prescription and first prescription of any medication being used as evidence that the Medicaid recipient has the medical condition;

l. time between last prescription of any medication used to define the comparison population and first prescription of any medication being used as evidence that the Medicaid recipient has the medical condition;

m. time between date of Medicaid enrollment and first Zyprexa prescription;

n. time between date of Medicaid enrollment and first prescription of any medication used to define the comparison population; and

o. time between date of Medicaid enrollment and first event used to establish that the Medicaid recipient has any of the medical conditions identified in response to Interrogatory No. 1.

ANSWER: The State's response to this interrogatory will be part of its expert disclosures and accompanying reports related to its proof of damages in this case. Further, answers to many of these subparts may be found in the data previously produced by the State or data which is forthcoming.

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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

IT IS HEREBY ORDERED that defendant Eli Lilly and Company's Unopposed Motion for Extension of Time is GRANTED. Defendant Eli Lilly and Company shall file its reply to plaintiff's Memorandum in Support of Bifurcation by November 9, 2007.

ORDERED this 6th day of November, 2007.

The Honorable Mark Rindner
Superior Court Judge

I certify that on November 6, 2007, a copy of the foregoing was served by fax and mail on:

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

009867.0038/162099.1

I certify that on 11/9/07 a copy of the above was mailed to each of the following at their addresses of record:

Jamieson Sanders
Administrative Assistant

001591

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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'S UNOPPOSED MOTION FOR EXTENSION OF TIME

COMES NOW defendant Eli Lilly and Company, by and through its counsel, Lane Powell LLC, and requests that this Court grant an extension of time to November 9, 2007, to file its reply to plaintiff's Memorandum in Support of Bifurcation. Eric Sanders, counsel for plaintiff State of Alaska, does not oppose this extension of time.

DATED this 6th day of November, 2007.

Attorneys for Defendant

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LANE POWELL LLC

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

I certify that on November 6, 2007, a copy of the foregoing was served by fax and mail on:

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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

MEMORANDUM IN SUPPORT OF BIFURCATION

After a lengthy hearing on the subject in January 2007, this court set to begin on March 3, 2008.[1] Now, ten months later, defendant Eli Lilly and Company has asked the court to vacate the trial date and impose a six-month delay on the sole ground that Lilly's experts will need additional time to scrutinize a database of Medicaid records that is relevant only to a single issue: the quantity of damages that the State should be allowed to recover for harm caused specifically in Alaska by Lilly's drug Zyprexa.[2]

The State is willing to accommodate Lilly's request for more time to study the database, but it is adamantly opposed to Lilly's unwarranted request for an across-the-board delay of trial. Instead, the State has moved to bifurcate—to put Zyprexa and

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1 *See* Routine Pretrial Order, dated January 10, 2007.

2 *See* Defendant Eli Lilly's Motion for an Extension of Court-Ordered Deadlines, filed Oct. 2, 2007.

Lilly's representations about it on trial in March as previously scheduled, while reserving the only issue related to the database (the magnitude of the harm that Lilly's actions and Zyprexa have caused to Alaska's Medicaid population) for a separate damages trial to take place later.[3] 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.

The State's proposed bifurcation addresses any legitimate need for additional time that Lilly may possess, while simultaneously serving the interests of expedition, convenience, and judicial economy. Because bifurcating trial will cause no prejudice and impose no additional burdens on Lilly, separate trials should be ordered.

ARGUMENT

This court's power to bifurcate trial stems from Alaska Rule of Civil Procedure 42(b). Rule 42(b) invites the court to order a "separate trial of any . . . issue" whenever separate trial would be "conducive to expedition and economy" or "further[] . . . convenience":

> The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim, cross-claim, counterclaim, or third-party claim, or of any separate issue or of any number of claims, cross-claims, counterclaims, third-party claims, or issues, always preserving inviolate the right of trial by jury as declared by the Alaska Constitution and Statutes of Alaska.[4]

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[3] *See* Log Notes of Status Hearing held Oct. 24, 2007.

[4] ALASKA RULE OF CIVIL PROCEDURE 42(b) (emphasis added).

The bifurcation proposed by the State would separate issues of liability from damages and forward each of the interests identified in the Rule.

I. THE STATE'S THRESHOLD LIABILITY CASE DOES NOT DEPEND ON ANY ANALYSIS OF THE STATE'S MEDICAID DATABASE AND COULD BE JUDICIOUSLY ESTABLISHED AT A SEPARATE TRIAL IN MARCH 2008.

The State intends to pursue claims that are based on three bedrock principles of liability: (1) that manufacturers may be held liable for design defects in their products, (2) that manufactures may be held liable for failing to provide adequate warnings, and (3) that businesses operating in Alaska may be assessed civil penalties and held liable for engaging in unfair or deceptive trade practices.[5] As applied to this case, the State will establish Lilly's liability by proving: (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. While quantification of the harm caused to the State by Lilly's defective product and failure-to-adequately warn claims will likely depend on expert analysis of the State's Medicaid database, the State's initial demonstration of Lilly's threshold liability will not; that Zyprexa and Lilly actions were the legal cause of harm to the State can be decided in the first phase of a bifurcated trial without making any reference to the State's database.

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[5] *Cf.* Complaint at ¶¶ 28-55.

A. Proof that Zyprexa is Defective and that Lilly Failed to Issue Adequate Warnings About Zyprexa's Defects Will Be Established Without Reference to the State's Medicaid Database.

The essence of the State's design-defect and failure-to-adequately-warn claims will be that Lilly failed to warn Alaska physicians of the dangers associated with Zyprexa use: increased glucose levels, elevated cholesterol, and excessive weight gain. The State can establish these claims without recourse to its Medicaid database or proof of specific damages.

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. Previously deposed Lilly employees will be called by the State to demonstrate that Zyprexa causes harmful side effects; that Lilly knew about the side effects; and that Lilly failed to share its knowledge with physicians or the FDA. Lilly's employees will also testify as to the reasons for this failure.

The State's experts will testify about the deleterious health conditions that arise from Zyprexa's side effects (including diabetes and hyperglycemia) and that Lilly knew, or should have known, that Zyprexa engenders significant health risks in its users.

Finally, evidence of Lilly's labeling of Zyprexa will conclusively demonstrate Lilly's failure to warn of these risks. The labeling that Lilly initially provided with Zyprexa warned only that diabetes was infrequent. When Lilly changed Zyprexa's labeling in 2004, the company inaccurately claimed that the increased risk of diabetes and

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hyperglycemia caused by Zyprexa was comparable to other atypical antipsychotics. Recently, Lilly again changed Zyprexa's labeling and has now finally acknowledged that Zyprexa use results in all three of the harmful side effects that will be emphasized by the State. Lilly now acknowledges that Zyprexa causes increased glucose levels (both generally and in comparison to competitor drugs), elevated cholesterol, and significant weight gain. Thus, Lilly has already admitted the essential truth of the State's liability case related to design defect and failure to warn, and the issues are ripe for trial in March.

B. Proof that Lilly Engaged in Unfair and Deceptive Trade Practices Will Be Established Without Reference to the State's Medicaid Database.

The essence of the State's Unfair Trade Practices Act claim will be that, in addition to the failings already described, Lilly improperly promoted Zyprexa for uses which were not appropriate or approved by the FDA. The State's Unfair Trade Practices claim, too, can be conclusively established without any recourse to the State's Medicaid database or proof of specific damages.

To prove that Lilly improperly overpromoted Zyprexa, the State demonstrate Zyprexa's approved uses and present evidence that Lilly's marketing efforts were not limited to those uses. Experts will testify about the risks of Zyprexa and the reasons why the drug should have been limited to its intended and approved users. Lilly employees will then testify as to how Lilly ignored those risks and sought to maximize Zyprexa's market by pushing uses which were unapproved and unsafe.

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Together, the evidence will show that Lilly sought to increase its competitive advantage by concealing Zyprexa's risks, providing inadequate warnings, and over-promoting its use. A jury may impose liability under Alaska's Unfair Trade Practices Act without determining the extent of the damage actually caused by Lilly's unfair acts. Importantly, none of the requirements for finding a violation of Alaska's UTPA require a showing of either actual damages or causation,[6] and the State is empowered to impose civil penalties on Lilly for each communication that it made in Alaska that was "capable of being interpreted in a misleading way."[7]

The civil-penalty portion of the State's Unfair Trade Practices claim can therefore be entirely resolved without any reference to the State's Medicaid database.

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[6] *See* AS 45.50.471 and ALASKA PATTERN CIVIL JURY INSTRUCTIONS art.10.

[7] *See Odom v. Fairbanks Memorial Hosp.*, 999 P.2d 123, 132 (Alaska 2000):

> An act or practice is deceptive or unfair if it has the capacity or tendency to deceive. Actual injury as a result of the deception is not required. . . . All that is required is a showing that the acts and practices were capable of being interpreted in a misleading way.

(internal quotation marks omitted and emphasis added). *See also* AS 45.50.551(b):

> In an action brought under AS 45.50.501, if the court finds that a person is using or has used an act or practice declared unlawful by AS 45.50.471, the attorney general, upon petition to the court, may recover, on behalf of the state, a civil penalty of not more than $5,000 per violation.

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II. BIFURCATION WILL ENSURE THAT THIS LITIGATION STAYS ON COURSE, INCREASE THE LIKELIHOOD OF SETTLEMENT, AND SPARE THIS COURT AND THE PARTIES FROM ANY UNNECESSARY EXPENSE.

The court's broad discretion to order bifurcation under Rule 42(b) exists to promote speedy and efficient resolution of cases while providing justice to the parties involved.[8] To that end, courts and commentators alike have noted that separating issues of liability from issues of damages is one "obvious use" of the rule:

> The separation of issues of liability from those relating to damages is an obvious use for Rule 42(b). Logically, the existence of liability must be resolved before damages are considered. Moreover, the evidence pertinent to the two issues is often wholly unrelated and there is no efficiency in trying them together. Thus it is not surprising that federal courts, in many kinds of litigation, have ordered liability and damages tried separately[.][9]

Because liability is dispositive of damages, separating liability from damages can lead to significant reductions in both the length and cost of trial. Commentary on the use of Federal Rule of Civil Procedure 42(b) often underscores that resolution of a first liability trial can lead to significant time and cost savings either by (1) eliminating the need for the damages trial altogether, and/or (2) encouraging settlement:

> [S]everence of certain issues for separate trial under Federal Rule of Civil Procedure 42(b) can reduce the length of trial, particularly if the severed issue is dispositive of the case, and can also improve comprehension of the

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[8] *Cf.* 9 CHARLES ALAN WRIGHT AND ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2381 *History and Purpose of the Rule*, p.427 (3ed. 1995) ("[The] objective is to give the court broad discretion to decide how cases on its docket are to be tried so that the business of the court may be dispatched with expedition and economy while providing justice to the parties.").

[9] *Id.* at § 2390, p.502.

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issues and evidence. Severance may permit trial of an issue early in the litigation, which can affect settlement negotiations as well as the scope of discovery.[10]

Both are strong possibilities in this case.

A. Bifurcation Promotes the Interests of Expedition, Party Convenience, and Judicial Economy Potentially Eliminating the Need for a Damages Trial.

One obvious advantage of the approach advocated by the State is that it may eliminate the need for a damages trial altogether. If Lilly shows that it is not liable under the State's theories, both the parties and the court will be spared great time and expense.

The State alleges that Zyprexa is defective in that it causes weight gain and increased blood glucose and cholesterol levels. The State claims that Lilly failed to sufficiently warn of this, and instead overpromoted the drug. If true, these facts prove that Lilly is liable for a defective product and violations of the Unfair Trade Practices Act. Otherwise, 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

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[10] MANUAL FOR COMPLEX LITIGATION (FOURTH) § 11.632 *Separate Trials* p.122 (2004). *Cf.* 9 CHARLES ALAN WRIGHT AND ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2388, p.476 (3ed. 1995):

> If a single issue could be dispositive of the case or is likely to lead the parties to negotiate a settlement and resolution of it might make it unnecessary to try the other issues in the litigation, separate trial of that issue may be desirable to save the time of the court and reduce the expenses of the parties.

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State's Medicaid database or present much of the expert testimony that they presently anticipate offering in this case.

B. Bifurcation Promotes the Interest of Convenience by Simplifying the Parties' Trial Efforts and Avoiding Jury Confusion.

Bifurcation will also benefit this litigation even if Lilly is unable to escape liability in a preliminary trial. Bifurcation will simplify the parties' trial coordination efforts and ward off the potential for jury confusion.

Duplication of witnesses between the two phases of the trial would be almost nonexistent. The parties would need to call any actuaries, statisticians, or economists in the first trial to address the extent of the damage that Lilly has allegedly caused to the State because those experts would be relevant only to damages.

The greater benefit that bifurcation would bring to this case is that it would avoid 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.[11] Bifurcation ensures that evidence related damages will not improperly influence the jury's liability determination,

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[11] *See id.* at § 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").

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.[12]

C. Bifurcation Promotes the Interests of Expedition and Judicial Economy By Encouraging Settlement.

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; 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.

There is therefore good reason to suspect that Lilly may settle this case if this court holds the parties' to their agreed-upon March 2008 trial date. Indeed, Lilly's own counsel, in a hearing before this court on January 8, 2007, acknowledged that the likelihood of settlement increases as the parties get closer to March:

> I know on behalf of defense counsel we will make every effort to settle the case. I assume that if the case is still active at the end of the year, I'm sure we'll have serious negotiation[s] . . .

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[12] The jury charged with determining the State's damages would not need to be composed of members of the jury that determined liability. *See id.* at § 2391 *Separate Juries*, p.513.

Further, if the parties have not settled this matter prior to the first phase of trial, a trial on liability will surely increase the likelihood of settlement before the start of the damages trial. If a jury finds Lilly liable, then the parties will have a better understanding of their respective positions and enjoy similar views of Lilly's exposure, making settlement more likely. Thus, even if liability is proven, the parties and the Court may still avoid having to try the issue of damages.

D. Bifurcation Will Not Prejudice Either Party.

Finally, it must be emphasized that the State's request for bifurcation will not prejudice either party. Indeed, rather than causing any harm to Lilly, bifurcation may actually operate in its favor.

Beyond the fact that (as noted above) bifurcation generally assists defendants in their effort to avoid liability, a trial in March should benefit Lilly in this case: after years of litigation in the MDL involving the production of millions of documents and the deposition of numerous experts and Lilly employees, it is Lilly who should actually be *more* prepared than the State to go to trial in March. Lilly's counsel is and has long been fully aware of the issues surrounding failure to warn, design defect, and overpromotion, and each of these threshold issues is national in scope. The thousands of consolidated suits being tried in MDL litigation have already led to an exhaustive, nation-wide investigation of the implications of Lilly's actions, and Lilly has participated fully in that

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effort. The witnesses who have been deposed in the MDL will be available to testify in March and the State's bifurcation request imposes no new burdens whatsoever on Lilly.

In addition to advancing the interests of expedition, convenience and judicial economy, bifurcation is therefore also eminently fair and should be ordered in this case.

CONCLUSION

The State will be prepared to present its liability case in March. To prove its case, the State will show that Zyprexa is defective, that Lilly failed to issue adequate warnings about Zyprexa's defects, and that Lilly engaged in numerous unfair trade practices in Alaska. No part of the State's liability case will require reference to the State's Medicaid database.

The State's proposal for bifurcation addresses any legitimate need for additional time that Lilly may possess, while simultaneously serving the interests of expedition, convenience, and judicial economy by strongly encouraging settlement and potentially eliminating the need for trial on damages altogether. Because bifurcating trial will cause no prejudice and impose no additional burdens on Lilly, this court should grant the State's request.

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Dated this 1st day of November 2007.

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I hereby certify that a true and correct copy of the foregoing messenger
Memorandum in Support of Bifurcation was served by email and ~~mail~~ on:

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

By Peggy S Crowe
Date 11/1/07

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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-06-5630 CIV

FILED
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THIRD DISTRICT
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ERRATA TO PLAINTIFF'S MEMORANDUM IN SUPPORT OF BIFURCATION

The State of Alaska hereby files corrected pages 1 and 5 of its Memorandum in Support of Bifurcation. The first sentence on page 1 in the original memorandum is missing two words and should read ". . . this court set the trial to begin on March 3, 2008." The first sentence in the last paragraph on page 5 is missing one word and should read ". . . the State will demonstrate Zyprexa's approved uses . . . ."

DATED this 2nd day of November, 2007.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY_____
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AK Bar No. 7510085

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I hereby certify that a true and correct copy of the foregoing **Errata to Plaintiff's Memorandum in Support of Bifurcation** was served by mail / messenger / facsimile on:

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Barry Boise, via email (boiseb@pepperlaw.com)
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By Peggy S. Crowe
Date 11/2/07

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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

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After a lengthy hearing on the subject in January 2007, this court set the trial to begin on March 3, 2008.[1] Now, ten months later, defendant Eli Lilly and Company has asked the court to vacate the trial date and impose a six-month delay on the sole ground that Lilly's experts will need additional time to scrutinize a database of Medicaid records that is relevant only to a single issue: the quantity of damages that the State should be allowed to recover for harm caused specifically in Alaska by Lilly's drug Zyprexa.[2]

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hyperglycemia caused by Zyprexa was comparable to other atypical antipsychotics. Recently, Lilly again changed Zyprexa's labeling and has now finally acknowledged that Zyprexa use results in all three of the harmful side effects that will be emphasized by the State. Lilly now acknowledges that Zyprexa causes increased glucose levels (both generally and in comparison to competitor drugs), elevated cholesterol, and significant weight gain. Thus, Lilly has already admitted the essential truth of the State's liability case related to design defect and failure to warn, and the issues are ripe for trial in March.

B. Proof that Lilly Engaged in Unfair and Deceptive Trade Practices Will Be Established Without Reference to the State's Medicaid Database.

The essence of the State's Unfair Trade Practices Act claim will be that, in addition to the failings already described, Lilly improperly promoted Zyprexa for uses which were not appropriate or approved by the FDA. The State's Unfair Trade Practices claim, too, can be conclusively established without any recourse to the State's Medicaid database or proof of specific damages.

To prove that Lilly improperly overpromoted Zyprexa, the State will demonstrate Zyprexa's approved uses and present evidence that Lilly's marketing efforts were not limited to those uses. Experts will testify about the risks of Zyprexa and the reasons why the drug should have been limited to its intended and approved users. Lilly employees will then testify as to how Lilly ignored those risks and sought to maximize Zyprexa's market by pushing uses which were unapproved and unsafe.

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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-06-5630 CI

ORDER GRANTING EXTENSION TO FILE MEMORANDUM ON BIFURCATION

IT IS HEREBY ORDERED that the State of Alaska's Unopposed Motion for Extension of Time to File Memorandum on Bifurcation is GRANTED. The State shall have a one-day extension to November 1, 2007, to file its memorandum on bifurcation.

IT IS FURTHER ORDERED that Eli Lilly shall have until November 8, 2007, to file its response to the State's memorandum on bifurcation

DATED this 2 day of November 2007.

BY THE COURT

Mark Rindner
Superior Court Judge

I certify that on 11-2-07 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

OCT 31 2007

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001610

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

UNOPPOSED MOTION FOR EXTENSION OF TIME TO FILE MEMORANDUM ON BIFURCATION

Plaintiff, State of Alaska, by and through its counsel, Feldman Orlansky & Sanders, requests that this Court grant it a one-day extension to November 1, 2007, to file its memorandum on bifurcation. Brewster Jamieson, the attorney for defendant, Eli Lilly and Company, does not oppose this extension. At the same time, the parties agree that Eli Lilly shall be granted a one-day extension to November 8, 2007, to file its response to the State's memorandum.

DATED this 31st day of October, 2007.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

for BY _____
Eric T. Sanders
AK Bar No. 7510085

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& SANDERS
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GARRETSON & STEELE
Matthew L. Garretson
Joseph W. Steele
Counsel for Plaintiff

RICHARDSON, PATRICK, WESTBROOK
& BRICKMAN, LLC
H. Blair Hahn
Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of **Unopposed Motion for Extension of Time to File Memorandum on Bifurcation and [proposed] Order** were served by facsimile and mail 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 Peggy S Crowe
Date 10/31/07

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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 reviewed the defendant's Motion for Nonresident Attorney for Permission to Appear and Participate, as well as all responses thereto;

HEREBY ORDERS that John F. Brenner of Pepper Hamilton LLP, 3000 Two Logan Square, Philadelphia, Pennsylvania 19103-2799, phone number 215-981-4000, may appear and participate as attorney for defendant in the above-captioned action in association with Brewster H. Jamieson.

DATED this 24 day of October, 2007.

The Honorable Mark Rindner

I certify that on October 22, 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

000867.0038/161950.1

I certify that on 10-25-07 a copy of the above was mailed to each of the following at their addresses of record:

Sanders Jamieson

Administrative Assistant

001613

LANE POWELL LLC
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

MOTION OF NONRESIDENT ATTORNEY FOR PERMISSION TO APPEAR AND PARTICIPATE

Pursuant to Alaska R. Civ. P. 81(a)(2), defendant moves to permit John F. Brenner of Pepper Hamilton LLP, 3000 Two Logan Square, Philadelphia, Pennsylvania 19103-2799, phone number 215-981-4000, to appear and participate as attorney for defendant in the above-captioned action. Mr. Brenner, as shown by the attached certificate, is a member in good standing of the Bar of the State of New Jersey and is not otherwise disqualified from practicing law in the State of Alaska.

Applicant will be associated with Brewster H. Jamieson, ASBA No. 8411122, of Lane Powell LLC, whose address is 301 West Northern Lights Boulevard, Suite 301, Anchorage, Alaska 99503-2648, phone number 907-277-9511, and who is authorized to practice in this court and the courts of this state. Brewster H. Jamieson consents to this association.

Pursuant to Civil Rule 81(a)(2)(D), proof of payment of the fee required to be paid to the Alaska Bar Association is also attached.

DATED this 22nd day of October, 2007.

LANE POWELL LLC
Attorneys for Defendant

By _____
Brewster H. Jamieson, ASBA No. 8411122

I certify that on October 22, 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

_____

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

Supreme Court of New Jersey

Certificate of Good Standing

This is to certify that **JOHN F BRENNER** (No. **017121980**) was constituted and appointed an Attorney at Law of New Jersey on **December 18, 1980** and, as such, has been admitted to practice before the Supreme Court and all other courts of this State as an Attorney at Law, according to its laws, rules, and customs.

I further certify that as of this date, the above-named is an Attorney at Law in Good Standing. For the purpose of this Certificate, an attorney is in "Good Standing" if the Court's records reflect that the attorney: 1) is current with all assessments imposed as a part of the filing of the annual Attorney Registration Statement, including, but not limited to, all obligations to the New Jersey Lawyers' Fund for Client Protection; 2) is not suspended or disbarred from the practice of law; 3) has not resigned from the Bar of this State; and 4) has not been transferred to Disability Inactive status pursuant to Rule 1:20-12.

Please note that this Certificate does not constitute confirmation of an attorney's satisfaction of the administrative requirements of Rule 1:21-1(a) for eligibility to practice law in this State.

In testimony whereof, I have hereunto set my hand and affixed the Seal of the Supreme Court, at Trenton, this **18TH** day of **October** , 20 **07**

Stephen W. Feinen
Clerk of the Supreme Court

453a

001615

ALASKA BAR ASSOCIATION
P.O. Box 100279, Anchorage, Alaska 99510-0279
(907) 272-7469

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001616

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

ORDER GRANTING REQUEST FOR STATUS CONFERENCE

IT IS HEREBY ORDERED that plaintiff's request for a status conference on the trial date is GRANTED. A state conference shall be held on the 24th day of October, 2007, at 2:00 p.m., before the Judge Mark Rindner, at the Alaska Court System, 825 West 4th Avenue, Anchorage, Alaska, in the Courtroom 403.

DATED this 15 day of Oct, 2007.

Mark Rindner
Superior Court Judge

FELDMAN ORLANSKY
& SANDERS
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I certify that on 10-15-07 a copy of the above was mailed to each of the following at their addresses of record: faxed
E. Sanders B. Jamieson

Administrative Assistant

001617

P. 01

TRANSACTION REPORT

OCT-15-2007 MON 03:47 PM

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DATE	START	RECEIVER	TX TIME	PAGES	TYPE	NOTE	M#	DP
OCT-15	03:46 PM	92762631	15″	1	SEND	OK	259	
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			TOTAL :			30S PAGES: 2		

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

ORDER GRANTING REQUEST FOR STATUS CONFERENCE

IT IS HEREBY ORDERED that plaintiff's request for a status conference on the trial date is GRANTED. A state conference shall be held on the 24th day of October,

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

REQUEST FOR STATUS CONFERENCE ON THE TRIAL DATE

After conferring with the parties, the Court issued a Routine Pretrial Order in this case on January 10, 2007. The Order established the date the trial would commence (March 3, 2008) and all the usual pretrial deadlines.

On October 2, 2007, Eli Lilly and Company ("Lilly") filed a 23-page motion which "seeks a six-month extension of all Court-imposed deadlines in this action . . . ." Curiously, Lilly did not request a new trial date.

It is apparent that if any of the pretrial deadlines are extended more than one month, the present trial date will no longer be viable. Therefore, Lilly is really asking not only for a change in the deadlines, but also another date to commence trial.

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There is no good reason to ignore the real question: should the March 3, 2008 trial date be changed? If the answer to this question is "yes," Lilly's motion is moot.

Based upon the foregoing considerations, the State requests that the Court schedule a status conference to determine whether the trial date should be moved and, if so, what new deadlines shall be imposed. Because the deadline to serve written discovery is October 29, 2007, and the deadline for producing expert reports is November 12, 2007, the State requests that the conference be held as soon as possible.

DATED this 12th day of October, 2007.

FELDMAN ORLANSKY & SANDERS

BY _____
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AK Bar No. 7510085

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(843) 727-6500

Attorneys for Plaintiff, State of Alaska

Certificate of Service
I hereby certify that a true and correct copy of the foregoing **Request for Status Conference on the Trial Date** 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 Peggy S Crowe
Date 10/12/07

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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 GRANTING EXTENSION TO FILE OPPOSITION TO LILLY'S MOTION FOR EXTENSION OF COURT-ORDERED DEADLINES

IT IS ORDERED that the plaintiff's Motion for Extension of Time to File Opposition to Lilly's Motion for Extension of Court-Ordered Deadlines is GRANTED. Plaintiff shall have until October 26, 2007, to file its opposition to the Lilly's Motion for Extension of Court-Ordered Deadlines.

ENTERED this 15 day of October, 2007.

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,

Defendant.

Case No. 3AN-06-5630 CIV

MOTION FOR EXTENSION OF TIME TO FILE OPPOSITION TO LILLY'S MOTION FOR EXTENSION OF COURT-ORDERED DEADLINES

The State of Alaska, by and through its counsel, Feldman Orlansky & Sanders, requests that this Court grant it a two-week extension to October 26, 2007, to file its opposition to Eli Lilly's Motion for Extension of Court-Ordered Deadlines. The State has filed a request for status conference concerning the trial date and if a new date is set, Lilly's Motion for Extension of Court-Ordered Deadlines will be moot.

DATED this 12th day of October, 2007.

FELDMAN ORLANSKY & SANDERS

BY _____
Eric T. Sanders
AK Bar No. 7510085

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& SANDERS
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Mt. Pleasant, SC 29465
(843) 727-6500

Attorneys for Plaintiff, State of Alaska

Certificate of Service
I hereby certify that true and correct copies of Plaintiff's **Motion for Extension of Time to File Opposition to Lilly's Motion for Extension Of Court-Ordered Deadlines and [proposed] Order** were 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 Peggy S Crowl
Date 10/12/07

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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 RESPONSE TO DEFENDANT ELI LILLY AND COMPANY'S APPEAL FROM ORDER OF THE DISCOVERY MASTER

Eli Lilly and Company ("Lilly") has appealed the Discovery Master's Order of September 24, 2007, regarding various motions to compel filed by the parties. Lilly has failed to articulate any error committed by the Discovery Master in arriving at his rulings. This Court should affirm the Discovery Master's reasoned order.

I. INTRODUCTION

In the Order Re: Plaintiff's Claims of Proof, this Court observed that "[b]oth parties, if necessary, may request that the Court or the Discovery Master impose appropriate limitations on discovery pursuant to Civil Rule 26(b)(2), Civil Rule 26(c) or

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other applicable civil rules."[1] Lilly sought in discovery the individual medical records of Medicaid recipients, setting forth a variety of arguments regarding the possibility that such records might provide relevant information Lilly needed. The State responded that Lilly had not met what should be a substantial showing of need when balanced against the important privacy interests at stake and the significant burdens to the litigation that would result from allowing the discovery.

Disclosure of individual medical records subjects a population of individuals, many of whom have serious mental illness, to unnecessary and intrusive discovery. As important as the intrusion this discovery would visit upon a sensitive population of Alaska citizens is, equally important is the burden the discovery would visit upon the litigation itself. As recognized by the Discovery Master, it would require discovery of the medical records of as many as 700 individuals.[2] Such discovery would result in an exponential increase in both the time and cost required to litigate this case, and ultimately result in an unrealistically burdensome endeavor that would effectively end the State's meritorious lawsuit.

---

[1] *State of Alaska v. Eli Lilly and Company,* Case No. 3AN-06-05630 CI, Order dated July 31, 2007, at 5.

[2] Discovery Master Order: State's First Motion to Compel, Lilly's Motion to Compel and Lilly's Motion for Commission of Subpoena at 6 (hereinafter "DM Order").

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Due to the importance of these issues, the parties submitted hundreds of pages of briefs and exhibits and engaged in hours of oral argument in front of the Discovery Master.[3] Indeed, the Discovery Master spent over 25 hours considering the parties' arguments and reaching his decision. After this extensive briefing and argument by the parties, and careful consideration of the arguments by the Discovery Master, he issued a lengthy and thoughtful order addressing each of the contested issues. Nevertheless, Lilly has filed the instant appeal, and has reiterated its previous arguments in an effort to receive a different ruling based on the same facts and circumstances previously presented to the Discovery Master.

II. ARGUMENT

The Discovery Master correctly recognized that the State has brought this lawsuit on its own behalf and for its own damages, not as a subrogation action or an action claiming by and/or through any individual Medicaid recipients.[4] As such, the State's burden is to demonstrate causation in this population of individuals, not causation in any specific individual. Regardless, the Medicaid data the State is providing in discovery allows Lilly to identify specific Medicaid recipients (though not by name) and contains

[3] *See* Exhibit A, Transcript of Oral Argument September 11, 2007.

[4] DM Order at 1-2.

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much of the individual information, including confounding information, Lilly claims it needs.

While Lilly argued the data is deficient in certain areas, by virtue of missing or allegedly incorrect data, the Discovery Master correctly concluded Lilly could freely and effectively challenge the admissibility and sufficiency of the State's evidence based on those deficiencies.[5] Lilly did not demonstrate how access to individual records would reliably or substantially advance the cause of curing deficiencies in the data, at least when balanced against the intrusiveness of the discovery and the burden it would present. The Discovery Master appropriately struck this balance.

The Discovery Master correctly found that the discovery Lilly seeks would present a substantial intrusion into sensitive and private medical information of nonparties to this litigation.[6] He further found that the discovery would impose unworkable burdens on the litigation itself.[7] While the Discovery Master considered each argument proffered by Lilly in support of its position, he appropriately found Lilly failed to demonstrate a substantial and compelling need for medical records sufficient to overcome these interests.

---

[5] DM Order at 5-6.

[6] DM Order at 6.

[7] DM Order at 6-7.

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As for Lilly's request for the State's *entire* Medicaid claims database, this database covers the entire Alaska Medicaid population. This is a population that exceeds 100,000 individuals, and contains millions of pieces of information. Much of that data is not remotely relevant to the inquiries either party must make in this litigation. Regardless, the State agreed to produce the data Lilly's expert said was missing, to the extent it exists, and has taken steps to do so. (Hence, the scope of this production was specifically designed by Lilly's own expert, not by the State.) Based in part upon that plan, the Discovery Master denied Lilly's motion regarding the database.[8] Importantly, the order further provides that Lilly has the right to renew its motion for the *entire* database if it has reason to once the supplemental production is complete.

Lilly has made no better showing on these issues to this Court than it did to the Discovery Master, and Lilly has failed to point to any error in the Discovery Master's order. Lilly simply disagrees with the decision. The true nature of Lilly's objection to the order is that Lilly is fundamentally opposed to the nature of this case. Lilly seeks to turn a trial between two parties into a trial of hundreds of nonparties. This is not an undertaking required to obtain information necessary for Lilly's defense, but an effort to make justice for the State unobtainable as a practical matter, without years of protracted discovery and litigation at a cost that no plaintiff can afford. The Court should not allow

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[8] DM Order at 8.

Lilly to use extraordinary and unnecessary discovery demands to deny the State justice in this case.

III. CONCLUSION

For the foregoing reasons, and those apparent from the pleadings, exhibits and arguments before the Discovery Master, the State respectfully requests the Court affirm the Master's order.

Dated this 10th day of October, 2007.

FELDMAN, ORLANSKY & SANDERS

BY _____
Eric T. Sanders
Alaska Bar No. 7510085

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Counsel for Plaintiff, State of Alaska

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Certificate of Service
I hereby certify that a true and correct copy of **Plaintiff's Response to Defendant Eli Lilly and Company's Appeal From Order of the Discovery Master** 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 Peggy S Crowl
Date 10/10/07

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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

A-P-P-E-A-R-A-N-C-E-S

DISCOVERY MASTER:
Judge Dan A. Hensley (Retired)
1036 West 22nd Avenue
Anchorage, Alaska 99503
(907/277-7354)

For the Plaintiff:
Eric T. Sanders
FELDMAN ORLANSKY & SANDERS
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David L. Suggs
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Christiaan Marcum
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APPEARANCES (continued)

Barry H. Boise
Eric J. Rothschild (Appearing telephonically.)
George Lehner (Appearing telephonically.)
PEPPER HAMILTON
3000 Logan Square
Philadelphia, Pennsylvania 19103-2799
(215/981-4591)

Court Reporter:
Diane M. Bondeson
PACIFIC RIM REPORTING
711 M Street, Suite 4
Anchorage, Alaska 99501

ANCHORAGE, ALASKA; TUESDAY, SEPTEMBER 11, 2007
11:00 A.M.
-o0o-

DISCOVERY MASTER: All right. Good morning. We're on record in State of Alaska vs. Eli Lilly and Company. This is Dan Hensley, the discovery master, and this is arguments on various discovery motions.

Let's take roll. For the plaintiffs here live are Eric Sanders, Joe Steele, Christiaan Marcum, David Suggs. Nobody on the telephone.

For the defendants, present, Barry Boise, Brewster Jamieson, Andrea Girolamo-Welp. And on the telephone, Eric Rothschild and George Lehner.

And for you folks on the phone, could you hear me okay?

MR. ROTHSCHILD: Yes. Thank you, Your Honor.

MR. LEHNER: Yes.

MR. BOISE: George and Eric, before you speak, can you just identify who was speaking, for the court reporter and the benefit of those other than Dave and I who know your voice well enough.

DISCOVERY MASTER: There is a number of issues pending. I'd kind of like -- I know you've

organized your arguments. I would -- if you can, I'd like to cut to the chase and have you address early the argument about access to patient records and, in addition, the status of discovery of the State's claims database.

I understand that since the motions were filed the State has done some supplementing on that. I understand -- or at least it appears to me that the defendants are dissatisfied. I think some of that dissatisfaction arises over the crux issues that we have to deal with today, but maybe some of that other dissatisfaction doesn't.

So I'd like to address what you all think -- I'd like you to address early in your arguments what you all think the status of that discovery is related to the issues that aren't covered by the other significant issue, access to patient records.

In terms of order of argument -- couple motions filed by the State, we have some filed by the defense. Some of the issues are crossovers. So we'll start with the State, we'll go to the defense, then we'll go back to the State and then we'll go to the defense. And then, unless there is more that we have to say, we'll stop there.

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.

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.

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

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.

In the Medicaid population, the State is required to pay for everybody on the roulette wheel, so the State has got to pay for zero, double zero, triple zero and so on. It doesn't matter what their names are. It could be Mr. Smith, it could be Mr. Jones, it could be Mr. Whatever. It doesn't matter what their names are. What matters is we had to pay for four more than we should have had to pay for. We don't need to know their names because we're not going to give them any money. So that is the exercise that we are involved in in this particular deal. So we don't need to know their names, and Lilly doesn't need to know their names.

The way that this works is that it can be very difficult and it is an additional step to try to figure out whether a particular person, Mr. Jones' diabetes was caused by Zyprexa, whether Mr. Jones' heart disease was caused by the fact that he smokes, whether Mr. Jones' lung cancer was caused by the fact that he smokes.

If you look, however, at large numbers, what you will see is that if you introduce tobacco into a Medicaid population, you will get a lot more heart disease in addition to the background rate. And if you introduce Zyprexa into a Medicaid

population, you will get diabetics in addition to the background rate.

Whether a specific person's diabetes was caused by the drug does not make any difference. It's the increase over the background rate.

So to do this scientifically, you don't need the person's name, and you probably don't need their medical records.

Now, if the Court wants to entertain the idea that all right, maybe there is some information in the medical records, as suggested by Dr. Virnig, that would be useful, let me address how that ought to be done. The issues are many and varied, and they become exceedingly difficult if you want to involve particular people's names.

The obvious reason for that is that we're talking about people who are taking powerful antipsychotic medications. Those people, under the Alaska Constitution and under HIPAA, have a right of privacy that by definition needs to be invaded as little as possible. So the way to do it, if it were to be done, is to produce a de-identified set of medical records or charts.

Now, our position very clearly is it does not need to be done because the exercise we're

involved in is the same kind of scientific exercise that Lilly engages in and the authors of pharmacotherapy on the Zyprexa engaged in. But setting that aside and saying, "All right. How are we going to be minimally invasive here," which I think is clearly what's called for, the answer to that is if Lilly finds this information to be vital to their defense, then what ought to be done is essentially an escrow agent ought to be set up.

There are many firms that engage in getting medical records and putting them in electronic format. They could be hired. They would be possessed of the names. They would go out and get the medical records, they would do the de-identifying them, and then they would provide them to Lilly in the de-identified form. At minimum, names would need to be removed, Social Security numbers would need to be removed, and perhaps there are other things that might need to be addressed.

Once you get past that and you say, all right. For reasons that have not been presented to me, as the referee in this matter, that is, the need for the names -- see, the way I look at it is this. The process we're involved in here is a process of science. It is a scientific question whether you

need the names or not.

Now, we have the good doctor's declaration, and she could have said, presumably if she believed it, "I need the names for something." But currently there is no scientific evidence before you that suggests the necessity for individual identities. In fact, quite the contrary.

If you look at the pharmacotherapy article that Lilly has submitted to you, the individual identities are not there, and they didn't know them. If you look at Dr. Virnig's declaration, she does not suggest that they need individual identities.

Let me point this out. They are saying that they need the individual identities because they need to take depositions. And they say they need to take depositions before they even know what's in the people's medical records.

What is really going on here is that this is an effort to shut down this litigation. The shutting down of the litigation for four years will -- it's basically this. You know, Lilly's monitor here is four more years. Why? Because the patent on Zyprexa expires in four years, and the longer that we can be delayed and the more expensive it can be made, the better to protect the Zyprexa

franchise.

Any defendant can shut down any plaintiff's litigation. Allstate's got enough money to shut down every whiplash plaintiff. The medical malpractice insurers have got enough money to shut down all the malpractice plaintiffs. If you let them run amok and go out and take 700 depositions, they're going to put us out of business and leave us without a remedy.

So the real thing that is being played for here is essentially a checkmate move where we go out, we get the names of the individual Zyprexa users and we depose them, and we depose them forever.

Let me suggest that there are a couple of problems here that they seem to have conveniently forgotten. Thing No. 1 is this: If they subpoena the patient's physicians and try to take their depositions, they will be invading the physician/patient privilege. There is no waiver of the physician/patient privilege, and every one of the physicians who goes about telling things about his patient in addition to the medical records is going to be liable for that to the patient.

Number 2. The patient has not waived the physician/patient privilege, and the patient can show up, and you can ask them all the questions you want

about his medical history, and he doesn't have to answer one of them because a subpoena does not a privilege waive. So you can subpoena me to my deposition, but if I have a Fifth Amendment privilege, I have a Fifth Amendment privilege. You can subpoena me to my deposition, and if I have a doctor/patient privilege, I have a doctor/patient privilege.

There is no waiver of physician/patient in any law that I'm aware of. There is no waiver as to the doctor, and there is no waiver as to the patient. And as far as I can tell, the doctors and the patients showing up for their depositions should tell the lawyer at the deposition to pound sand. "I don't have to talk about this," and they shouldn't. So I don't think any of that is going anywhere.

Furthermore, the question is if you have the de-identified medical records, what in addition would you need to know to what is in the de-identified medical records? Well, I read this affidavit very carefully, and what the good doctor is saying is the information that we need would be, if it's anywhere, in the patient's chart. Right? Doesn't say you need the names, doesn't say you need the depositions, doesn't say you need anything in

addition to the patient's chart.

And you can identify discrete individuals on the chart. So this little problem they have about we need to know the patient's name from the Medicaid database, we know what the discrete individuals are. If they want to look at discrete individuals, and this would be a rational way to proceed if you were really interested, is what you would do is you would say let's identify discrete individuals from the Medicaid database whose medical records we think we need to look at. Because out of the group of people that are there, out of the -- well, you know, there is 700-plus diabetics that we've been able to identify and maybe down to less than that. Which of the medical of the 700 do you need to look at their medical records.

In some cases, undoubtedly what you need to know will be a part of the Medicaid records. Perhaps in other cases, if people looked at them and looked at the discrete individual and said, "This is what we know from the database. Let's look at these medical records, and here's why we need to," then that could be arranged.

So my suggestion would be if the Court is going to go down this path, we start with Lilly

identifying the names of discrete individuals, the patient identifier of discrete individuals whose medical records they think they need to see, have the de-identified medical records gathered by an appropriately neutral source, and then they can look at them, and then they can say whatever they want to say after that.

I cannot see anything right now before the decision maker that would allow you to intelligently say there is some basis here for needing the names of these people. It simply is not necessary, and there is no evidence before you that says that it is.

So that would be the route that I would go down. If you don't want to go down that route and you want to say, "All right. We're going to give them the names of these people," then of course there are orders that would need to be fashioned and notice that would need to be given.

Alaska being Alaska, I think that these people would have to receive notice that their records are sought, and Alaskans being Alaskans, there is going to be a hue and cry the like of which we've never seen.

And furthermore, before we ever give them the names, I think that the State and the lawyers for

the State would need to have an agreement by Lilly to defend and indemnify them for the lawsuits that inevitably will follow because some of these people are going to be mad as wet hens about this issue.

So if you're going to go down that route, then what's going to have to happen is you're going to have to fashion a very careful and very limited order that justifies the invasion that we're talking about of these people. That is, we're going to give them names and therefore give Lilly access to the people.

If Lilly has got access to these people, that's going to create no end of problems, and I don't know what the justification would be for the order. In other words, I don't know -- if I was trying to write it myself as the referee, I don't know what I would put in there as to how I am basing my position: This is why I have to give them the name of Mr. Jones and Mr. Smith and Mr. Sanders and so on. I just don't see it.

And so I suggest that at this point in time, if we're going down the medical records road, we do it de-identified. We identify which of the discrete individuals they think they need. We look at those. The doctors can tell us whether what they

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.

So a large part of what Mr. Steele has argued has already been argued, and certainly the State is, you know, subject to motions for summary judgment and like, free to proceed, but so is Lilly free to proceed in defending itself, and Lilly doesn't choose to defend itself using solely statistical methods and solely epidemiology.

Moreover, the medical records are essential to start to test the accuracy of what's in this database in the first place. We've already been told it's only as good as what's coded, and there are a lot of procedure codes that aren't in there. A person may go in for seven procedures and only one seems to be listed or two listed in the database. So there is an incomplete nature to the database that needs to be tested, as well.

Whether Zyprexa causes diabetes and whether there is this background risk or excess risk needs to be examined, and Mr. Steele would acknowledge this by looking at confounding factors, looking at whether perhaps the diabetes preceded the ingestion of the Zyprexa. Is there a temporal relationship? Were there other medications, such as beta blockers, which would help explain or be an alternate cause for those issues? These are all scientific issues where the

way to examine it is to get a full picture of a person's medical history.

But that's not their only claim. Their claim also is that Lilly inappropriately marketed the product and that there were prescriptions for Zyprexa for off-label uses; that patients were given medications to which there was no benefit. Well, certainly the database isn't going to tell you whether a patient benefited or not from medication.

Certainly the fact that going to the medical history and saying that they have failed on virtually every other medication but seem to do better on Zyprexa would certainly give you an indication there.

So Lilly's defense is going to be centered on yes, you do need to prove specific causation; yes, it is important why the doctor wrote the prescription; it is important what the cause of the diabetes are. And that is why there is a compelling need for medical records.

We are very sensitive to the arguments about patients' rights here. And in our briefing we suggested, Lilly suggested that we get some form of de-identified medical records, that the State has the right under the Medicaid contract it has with the

enrollees to obtain medical records. And if the State wants to go through the burden of de-identifying to protect its interests, that Lilly is in favor of that process. And we went further and said, to meet the doomsday scenario painted by Mr. Steele that we're going to take 700 plaintiffs' depositions, we said before we take a single deposition of a person who is suffering from mental illness, we're going to come back to you and say here is the type of people we need to depose.

But before we can even begin to make the judgment as to depositions of prescribers or plaintiffs, we need, A, a fuller database so we can make the assessment of medical records that we absolutely need, and we need additional medical records.

And there is only one other case I'm aware of that's proceeded in this fashion. The State of Louisiana has sued an atypical antipsychotic manufacturer, Jansen, Johnson and Johnson, over a Lilly competitor product, Risperdal, espousing similar theories, and we attached the court's order in that case.

There was a dispute as to whether medical records are obtainable in that litigation, and HIPAA

concerns and privacy concerns were raised, and the court entered an order, said yes, you're entitled to at least a sampling of medical records, and ordered a sampling of 6,000 parties. Ultimately resolved on 6,000 medical records to be produced in that litigation.

And at a minimum, we would see a sampling of those medical records to begin with. As it's going to take time to collect all of them anyway, let's get started on a sampling of those that -- on Zyprexa, those not on Zyprexa, so we can start to unpeel what is really going on here and start to look at specific people, whether it be by name or number, and understand what this case is all about.

We think we are entitled to the medical records for each enrollee here ultimately to test it, but this has to be done in some incremental fashion. There is only so many that can be collected in a period of time, and we need to start this process so we can start to get this going.

I mean, even what we find from our experiences in the personal injury litigation, what we find is that a person -- medical records reveal preexisting diabetes. We see a patient that doesn't have schizophrenia by a coding mechanism, we go into

the medical records, and we realize they do have schizophrenia. It gives much insight into what is really needed to be done here. And we have, you know, proof of terrific efficacy of this product that is important for, we think, a jury to see here.

Now, while the State may want to ultimately try their case in some sort of mathematical model, epidemiological model, Lilly should be free to defend itself by showing the jury what this medication is and how it works and hear from perhaps recipients if later deemed appropriate, hear from doctors who actually prescribed the medication. Or, at a minimum, let's look at the medical records and let the records start to speak for themselves on these issues that are really at issue here.

So from Lilly's perspective, we see a compelling need in order to, A, be able to test the accuracy of the data we're getting; B, to tell the full story, as we're told there is corrupt data prior to 1996. So if a patient had diabetes prior to 1996, we're never going to know that. They may have entered the system, and someone didn't check that box. And C, we want to be able to show on a case-by-case basis why this causation theory of epidemiology just doesn't hold water when it's put to

the challenge of actually being tested by medical records and the real-life facts that exist in this patient population.

The State is undoubtedly seeking millions, tens of millions, hundreds of millions. I don't know what the ultimate claim here is going to look like. And there is certainly some cost to this litigation, undoubtedly. Certainly the product liability litigation has gone forth where we looked and received medical records and were able to make assessments based on those. And from Lilly's defense perspective, it's essential that we have the same opportunity here.

DISCOVERY MASTER: I have a question about the Los Angeles -- L.A. I wrote.

MR. BOISE: Louisiana.

DISCOVERY MASTER: That's Louisiana?

MR. BOISE: Yes, sir.

DISCOVERY MASTER: Maybe I'm missing something, but my impression from reading that material was that, 1, it was -- the court issued a consent decree; and 2, at best it was based on a fairly brief decision by a judge or magistrate without -- I didn't see the background material on that that analyzed the arguments you all are making.

In fact, I saw -- at least a comment said of course they're entitled to the records, and you went on with a consent -- somebody went on with a consent decree. Is there some more background in there that I'm missing?

MR. BOISE: Yeah, there is. And my understanding of the consent decree under Louisiana law is that it was -- this was a very much contested motion, and if we're able to get the briefing from both sides of that issue to prove to Your Honor that this was very much a contested issue, we could certainly provide that.

DISCOVERY MASTER: I don't doubt it was contested. I guess my question is the basis for the decision. I don't see the basis for the decision in the materials that you gave me. Is there a basis, articulated basis for the decision?

MR. BOISE: We have the opinion is what we understand --

DISCOVERY MASTER: All right.

MR. BOISE: -- you know, to be the basis. I mean, our basis for the request is certainly the compelling need to understand what's really going on here.

DISCOVERY MASTER: To the extent I'm asked

to be persuaded by a decision in that case, at least, unless I missed something, I didn't see a very articulated basis for the underlying decision that led to the consent decree. I guess that's the proposition I'm positing, and maybe somebody can tell me if I missed something, I'll go read it.

MR. BOISE: That's the opinion that the court issued.

DISCOVERY MASTER: All right.

MR. BOISE: Certainly extensive briefing on the topic, if that's something of interest to Your Honor. I mean, the issues there are not dissimilar to here, though, in that there was opposition to it, that there were HIPAA concerns raised, and those issues were dismissed in albeit a short order. But I've been assured by the parties in that litigation that that was not a consented litigation in that regard. I know the State has made that claim in the briefing, but I think it's belied by the record.

And I don't know if they've made a representation that they've spoken to the counsel in that case and what the issues were, but my understanding from counsel in that case was that it was a very much contested issue.

MR. ROTHSCHILD: And Judge Hensley, this is

Eric Rothschild. Barry is right. There is extensive briefing, and there is extensive argument on the record about these issues. I do think that the consent judgment and what reasoning you find there is the most complete description of what the Court says. There is quite a bit of lead-up to it.

DISCOVERY MASTER: All right. Thank you. Did you have more?

MR. BOISE: If you have questions.

DISCOVERY MASTER: Go back to Mr. Steele.

MR. STEELE: Sure. Let me address just very briefly the "Judge Rindner has already ruled." I'm sorry. With all due respect to these guys, that's nonsense. When Mr. Rogoff was up here and we had our motion on the law of the case, at the end of that motion I said to Judge Rindner, "With all due respect, before we begin talking about the invasion of these people's privacy, we're going to have to have a hearing on the subject."

And Judge Rindner said, "Yes, I understand it is a very serious matter, and there will have to be a hearing on the subject."

I would stipulate, and I'm sure they probably will too, that if you, for example, wished to ask Judge Rindner if he has ruled on that subject

and you wished to ask him if what I say, is it true, that you would be welcome to --

DISCOVERY MASTER: Hold on a second. If you want to get your guy back on.

MR. BOISE: No, we can continue. Thank you, though.

DISCOVERY MASTER: I thought maybe we lost him.

MR. BOISE: If we lost him, he'll come back.

DISCOVERY MASTER: But listen, I read what Judge Rindner said, and I have my own view of what Judge Rindner said. So you don't all have to tell me what you think he said. I have my own view.

MR. STEELE: Did you read, though, the hearing that we had with Mr. Rogoff on the issues of law?

DISCOVERY MASTER: Yes.

MR. STEELE: Okay. Do you recall the discussion at the end of the hearing on that issue?

DISCOVERY MASTER: I read that.

MR. STEELE: Okay. Good. All right. So moving on to the next point, Mr. Boise's point about did they have diabetes pre-Zyprexa. That is answered by the Medicaid database. Were they on beta

blockers, that is answered by the Medicaid database. As I have said, most of the things they want to know are in the Medicaid database, and that fact, of course, is demonstrated by the fact that the two examples that Mr. Boise can come up with are both things that are covered in the Medicaid database.

The idea that Medicaid studies don't hold water, that this isn't the way to do it, that's really going to be bad news back at Lilly because I can tell you -- for example, one of the ways that Lilly used --

DISCOVERY MASTER: Let me interrupt you.

MR. STEELE: Yeah.

DISCOVERY MASTER: I don't think the question is whether epidemiological studies are not valid scientific studies. I think the question is what are valid ways of challenging epidemiological studies.

MR. STEELE: I think that's exactly right. Okay. But the first question is -- in other words, what they're saying is they didn't agree with you. In other words, Mr. Boise didn't say what you just said. If Mr. Boise is saying what you just said, then I agree with you.

Let me address the challenging part of it,

though. The challenging part of it really has got to be addressed in two ways: No. 1, can they be so challenging as to put us out of business? Right? Because anybody can do that to anybody if you're a multibillion dollar corporation. No. 2, what is the need for the information, right?

It may be true that in defending my whiplash cases, the defense lawyer, I would like to have all of the medical records of all of the witnesses to Mr. Smith running the red light. It may be true that I want to depose everybody that they know to see if they are a chronic liar. But that doesn't mean I get to do it.

Judge Rindner limited our discovery in this case so as not to unduly burden Lilly. So we've got our ten depos, and we've got our limitations on discovery. And what I'm suggesting is that they should not be allowed to be so invasive as to be able to put us out of business, and they should not be allowed to be so invasive as to unduly burden people who do not need to be unduly burdened.

DISCOVERY MASTER: Mr. Boise.

MR. BOISE: Okay. First of all, the response to the epidemiology. I'm not suggesting epidemiology doesn't have a place in science. The

question is what is its place in the courtroom to prove the claims, and more importantly, or equally importantly, what is a fair way to defend against those claims and present an alternate story or an alternate presentation to the claim that Zyprexa has done these horrible things. And I think -- all I've represented what Judge Rindner ruled was that Lilly, subject to Rule 26 obligations, is not limited in how it's going to defend its case. That's all I was suggesting by the order, and I think that's what the plain language says there.

DISCOVERY MASTER: Judge Rindner ruled that he decided he wasn't going to decide that at this point.

MR. BOISE: Ultimately declined -- well, yeah, ultimately decided --

DISCOVERY MASTER: Leave that to someone else.

MR. BOISE: He ultimately declined whether that theory will be adequate. He declined to rule on that for sure. He went on to say, I think -- and I'll take your heat. I won't debate what the order says. I'll leave it there.

Mr. Steele challenged me to come up with items that are not in the database. Diabetes family

history. Pretty important. Not in the database. There is allegations of weight gain associated with this medication and history of weight gain and what obesity -- what's the role of obesity. Not in the database. Being able to show whether a patient had diabetes prior to 1996. Not in the database. What other -- whether they had all these other medications, whether they ultimately were coded properly is a very open question.

The database is only as good as what it possibly can be, and it wasn't designed, and it's certainly not implemented to be a form of -- a source of this type of evidence. It's help running Medicaid program.

Medical records is what -- are used to assess whether -- a medical history, which is crucial to our claims. Whether a patient felt better on this medication versus another medication isn't in the database. You know, certainly Lilly's defense is going to be this is a terrific medication that helps people; that the Alaskans should hear that part of the story, too, that they're not going to hear through some statistical analysis.

There is more examples, and Dr. Virnig certainly presented a few more as to, you know, the

need, you know, for medical records. We have argument and briefing in addition to the affidavit which lays it out in fuller detail as well.

So the issue really is will Lilly be denied the right to present its case in a manner which will show the medical issues in a way other than epidemiology, or is Lilly forced to defend its case in the sole theory that plaintiffs have chosen to present their case.

And I'd submit it's fundamentally unfair to say that Lilly is limited to the manner in which the State has decided to pursue its claims; that ultimately this may be -- there is some burden associated with that that I think is -- certainly should be considered. And if the burden is it's costly for the State to collect the medical records, well, then in that situation, give us the names, and we'll go out and subpoena them.

If the issue is, well, that's not satisfactory because we want to protect the privacy interests and we need to do the de-identifying and that's the burden, well, that's the burden. I mean, we're prepared to collect the medical records on our own, at our expense, have them subject to a protective order, take all effort and respect with

those records and not contact a single person about their medical history without coming back to this Court.

We're willing to take every step necessary to make this not a burden on the individuals, and not a burden on the State, for that matter, and address the needs in any way that will allow us to get the records that we think are just essential to defending ourselves.

MR. STEELE: Let me just address that last point.

DISCOVERY MASTER: Okay. Address the last one, and have one last word as well. Go ahead.

MR. STEELE: Sure. The burden of getting the medical records, Lilly wants the medical records. If the medical records are to be gotten, they should bear the burden of it. The way that it is done is -- the way that it should be done is the way that it is always done. There are many services that go out and are in the business of collecting medical records. They can do that in electronic format.

The way to do it is to give that service, as an escrow holder, the names of the people so that only they will have them, and we can all be assured they won't go somewhere that they shouldn't, and then

they can collect and de-identify the records. That's how it should be done.

MR. BOISE: We made that proposal.

DISCOVERY MASTER: Is the beef who's going to pay for it if you go that way?

MR. STEELE: Sure. They should pay for it.

MR. BOISE: For the process of collecting? We're perfectly well to go out and hire a medical collection service and go out for the burden of collecting those records. Whether -- you know, who pays for the de-identifying process, if the State is going to pay for the process of document collection and those issues and there is going to be fee sharing along the way, I think it should be subject to discussion as to how the burden of production ultimately is done, or further order from the Court.

DISCOVERY MASTER: You want to take 10, 15, and then we'll move on to other issues?

(Recess held.)

DISCOVERY MASTER: On the record. And we have -- on the phone, who do we have?

MR. LEHNER: This is George Lehner.

MR. ROTHSCHILD: And this is Eric Rothschild.

DISCOVERY MASTER: Okay. Go ahead, Mr. Steele.

MR. STEELE: One thing that our side wanted to point out as sort of a general frame around all of this discussion is that one of the things that Judge Rindner has very clearly ruled on is that we have a March trial date. And a concern that we have, I think, with respect to all of the things that we're discussing here today is that we proceed consistent with the wishes of Judge Rindner and that we fashion our approach to completing the discovery in a way when it -- so that it can be accomplished within those time frames. I think that that's -- I know that that's very important to us, that we remain on schedule, and we are willing to, at least within our power, to expedite that which we can do to move things forward. So I just wanted to put that frame around our discussion.

DISCOVERY MASTER: Would you like to respond or add to the frame there, Mr. Boise?

MR. BOISE: Just to add to it, you're familiar with the history here of the Judge's desire and then declination to cut to the chase on what the proofs would look like. And really in earnest discovery began when the Judge ruled on August 1 as

to what the claims were going to look like or not look like or opted, as is his ultimate prerogative, not to rule. And Lilly is looking for an opportunity to defend itself, and if it takes more time to do that, that might be a consequence of the fact it takes more time in a hugely complex case.

We are willing to make the efforts to do what we can to speed the process along. We're sitting here still without workable data, and that's just the reality of where we sit.

DISCOVERY MASTER: All right. Thank you. Let's move on to the other issues, and although so far it seems to me that arguing issues discrete issue by discrete issue has worked pretty well, so let's continue with that unless you all want to frame this some other way. And we'll go ahead with the State's motions first, and then if there are other issues after the State has covered them, Mr. Boise can do that.

But what are you going to do -- Mr. Suggs has taken the lead seat here. What are you going to address, Mr. Suggs?

MR. SUGGS: Our First Motion to Compel.

MR. BOISE: Your Honor, just one point. I think it might be helpful. In essence we reverse

argued Lilly's motion on the database and medical records, allowing the State to go first, and I felt that was very helpful because ultimately some issues through meet and confer and otherwise were resolved, which narrowed the dispute and I think greatly shortened the argument.

To the extent that I can maybe tick through some of the issues in the State's First Motion to Compel, I'm happy to do that if you think it would be likewise useful.

DISCOVERY MASTER: You mean things that you think will reduce the dispute?

MR. BOISE: Correct.

DISCOVERY MASTER: Problem with that, Mr. Suggs?

MR. SUGGS: Well, usually when I bring a motion, I like to argue it first.

DISCOVERY MASTER: Well, if Mr. Boise is going to tell you what you don't have to argue.

MR. SUGGS: Okay.

DISCOVERY MASTER: If he limits his comments to that, why don't you go forward.

MR. SUGGS: Let me ask this. Is there anything that you're offering in addition to what was in your response?

MR. BOISE: I think so, yeah.

MR. SUGGS: Okay. Let's hear it.

MR. BOISE: I think so. I mean, the -- I guess I'm first addressing Plaintiff's First Motion to Compel, and the first category, and I'm on page, you know, 2 of that motion where there is a number of interrogatories and requests for production that have been grouped together where the State asks for the names of individuals that communicated with the Alaska Medicaid program, representatives of other public payers and representatives of any formulary interactions, as well as representatives of the Executive or Legislative branch.

And the areas -- and then it goes on for categories of information about interactions with patient advocacy, the APA, TMAP and CNS, and I think where we can narrow the dispute is Lilly has identified two names and will identify other names of representatives that dealt with the Alaska Medicaid program and produce their files. There is one more name in particular that we understand and are ready for production.

We still dispute the representatives of, quote, other public payers. This has been about Medicaid information.

DISCOVERY MASTER: Don't make your argument. Just tell me what's off the table.

MR. BOISE: Fair enough. Off the table. So public payer still on table. Interactions with Alaska formulary we would treat as off the table, that we would give you the identity of the individuals that dealt with the Alaska formulary decisionmakers. Employees of the Executive and Legislative branch to the extent not included in that would still be on the table and would be still subject to the motion to compel.

On the patient advocacy groups, the APA and CNS, Alaska-based individuals that dealt with those organizations we would take off the table. To the extent that it's seeking information beyond that or seeking information regarding TMAP, we would say it's still on the table.

MR. SUGGS: I'm not sure I understand. So of the four bullet points on page 4 of our motion, you're willing to give us the discovery request on the first two but not the last two, or did I misunderstand?

MR. BOISE: For the first, second and fourth bullet point, we're prepared to give you the information from the Alaska-based folks, the people

who deal with Alaska on these issues. Since we think there are none for the third bullet point, the TMAP reference, that would be not. Would be still on the table.

MR. SUGGS: Well, okay. Then I -- so you're -- the important caveat here with respect to those items on the page 4 is that you're only prepared to give us the names of Alaska-based folks who deal with those areas?

MR. BOISE: We'll give you the names of Alaska-based folks that deal with those areas and produce documents, whether from those or others, that reference, refer to interactions with Alaska.

DISCOVERY MASTER: Okay. Anything else, Mr. Boise?

MR. BOISE: Yeah. On page 7, there is interrogatories that deal with call notes.

MR. SUGGS: Excuse me. Can I interrupt here? What I would suggest is that we deal with these chunks first, and this first chunking, he's already addressed that. And he's now getting into part B of our motion, and I would suggest that we can probably keep things more under control if we deal with these in chunks. Would that be acceptable?

DISCOVERY MASTER: You want to argue them

in chunks?

MR. SUGGS: Yes.

DISCOVERY MASTER: That's fine.

MR. SUGGS: Okay. Okay. Our first set of requests there which are noted on the -- do you have our brief there?

DISCOVERY MASTER: Yes, I do.

MR. SUGGS: Okay. On page 2, continuing on page 3. Now Mr. Boise indicates that they are willing to give us the information regarding representatives of Alaska Medicaid program and also our request regarding communications with members of any organization, committee or authority responsible for determining which prescription drugs will be on any Alaska formulary, pharmaceutical and therapeutics list or preferred drug list.

Now, are you also offering to give us not only the names but their -- and their documents?

MR. BOISE: Yes.

MR. SUGGS: Okay. And will you also give a description that we asked for in our interrogatory as to where those folks fit in in the chain of command? Because part of our interrogatory was to identify those individuals with those responsibilities and to identify for us where they fit in the reporting

relationship from that person up to the chief executive officer of the company.

MR. BOISE: Certainly we can answer the interrogatory that gives their reporting structure. We take it all the way up to the CEO. I think we can talk about on whether, you know -- but through their organizational structure, their direct reports and their second reports above that so you have a point of perspective I don't have any objection to.

MR. SUGGS: Okay. So then the things that we're left with in that first chunk on page 2 and 3 of our motion was the same categories of information regarding their contacts, communications with representatives of other public payers and the executive branch.

It would be our position that we're entitled to that information as well. The relevance of these discovery requests regarding those categories is apparent. Our Complaint includes claims for failure to warn, fraud, misrepresentation and unfair trade practices. Evidence that Lilly misled public payers and representatives of the State regarding risks and benefits of Zyprexa is relevant to those claims.

Then with respect to the other four, the

other category on page 4 of the motion, there are the four bullet points over there. I have a concern with what Mr. Boise said that he was only offering to give us the names and the documents from those individuals who are Alaska-based. For example, with the Comprehensive Neuroscience Organization, that is not an Alaska organization. It's a national organization. And part of the thrust of our discovery there has to deal with -- if I can find the document here. Has to deal with a product that they put out that was referred to as the Expert Consensus Guideline Series where -- which is described on their Web page as utilizing a unique content --

(Off record.)

MR. SUGGS: Comprehensive Neuroscience puts out a product called Expert Consensus Guideline Series, which they describe on their Web page -- and I can give you a copy of their Web page here. Which they describe as utilizing unique content, development, methodology that harnesses the unbiased expertise of prominent thought leaders in neuropsychiatry.

They publish these consensus guidelines, and to the extent that Lilly had a hand in providing misleading information to Comprehensive Neuroscience

that was included in those guideline series, we think that's relevant information that we ought to be entitled to.

And I seriously doubt that they had somebody who was based in Alaska making those communications with Comprehensive Neuroscience. If there were such communications, it was probably with somebody back at headquarters in Indianapolis. And if in fact such misrepresentations and misleading information was provided to them and it went out on a national basis, it could have an impact in Alaska even if the communications didn't occur here in Alaska.

The same is true with respect to the discovery regarding the Texas Medication Algorithm Project, and I should probably take a moment to describe for you what that is. I have another document I can hand up to you here that will help illustrate the relevance of this, Your Honor.

I'm handing you an e-mail which is dated June 28, 2004, to John Lechleiter, who was the president and chief operating officer of Eli Lilly. And the subject of this e-mail is: FYI. Linkage of Lilly with Texas Federal Mental Health Initiatives. And it notes -- it attaches a press report from 2004

noting that President Bush planned to unveil a sweeping mental health initiative that recommends screening for every citizen and promotes the use of expensive antidepressants and antipsychotic drugs favored by supporters of the administration.

On the following page it notes that the new freedom initiative, according to a progress report, seeks to integrate mentally ill patients fully into the community by providing services in the community rather than the institutions, the British Medical Journal reported, and critics say the plan protects the profits of drug companies at the expense of the public.

This Texas Medication Algorithm Project was a program held up as a model medication treatment plan that illustrates an evidence-based practice that results in better consumer outcomes. But the Texas project sparked controversy when a Pennsylvania government employee revealed state officials with influence over the plan had received money and perks from drug companies who stand to gain from it.

And at the bottom of the second page, they note that Eli Lilly, manufacturer of Zyprexa, one of the drugs recommended in the plan, has multiple ties to the Bush administration.

This Texas Medication Algorithm Project was basically a publication that came out recommending the use of various types of antipsychotic drugs under particular conditions and recommending how and when the drugs would be used.

To the extent Lilly provided -- well, that TMAP project was then published and could have influenced people here in -- prescribers here in Alaska, and we believe we're entitled to discover what information Lilly provided to TMAP and how they tried to influence the drafting of those guidelines.

And again, that would be something which was probably not done by someone based in Alaska but rather by someone based back at Lilly headquarters in Indianapolis.

Similarly, the American Psychiatric Association also publishes guidelines for treatment of psychiatric conditions, and we believe that Lilly may have again provided information to the American Psychiatric Association that may have influenced how they wrote up their recommendations for Zyprexa. And to the extent that was done, it could influence prescribers here in Alaska, but I'd seriously doubt that people based in Alaska would have been the ones having those communications.

So this is an instance where we're seeking discovery not just purely related to the conduct and activities in Alaska but with respect to activities that may have influenced prescribing behavior of physicians in Alaska, as in states all around the country.

DISCOVERY MASTER: All right. Mr. Boise.

MR. BOISE: My turn for that chunk?

DISCOVERY MASTER: Yup.

MR. BOISE: Okay. The first argument surrounding allegations of misrepresentation or fraud to public payers. We asked the State interrogatories and asked the State do you have any evidence of fraud, who made the misrepresentation, was there any allegation of misrepresentation to a State agency as the State would be uniquely qualified to know whether any statements, let alone misrepresentations, were made, and we were told they are aware of none. And that was really the basis for -- you know, for the statement about, well, you know, that really isn't the scope of their claim.

And when you look at their Complaint and the allegations even in their Complaint, it's not speaking in terms of direct fraud on a State public payer, whoever those public payers may or may not be.

So that was -- that was a big part of the response to not agreeing, I guess keeping it on the table, any interactions with public payers in Alaska.

As far as the other category in this chunk as to the Executive and Legislative branch, again there is no allegation of interactions there or no connection or effort to connect up any communication with any employee of any Alaska Executive or Legislative branch to this process. To the extent it involves medical decision making, formulary access, those type of issues, we're agreeing to produce those interactions, but a broad interrogatory or document request that seeks any interaction with any legislature or any employee of any legislature or executive we think is just not linked to any fact or allegation in this case.

There is also reference to CNS and what Mr. Suggs had handed up to you about CNS. We asked does Alaska use CNS, and what we understood and what we have in an interrogatory response is that there is one specific program that Alaska uses regarding a CNS project. Are there any algorithms? No. There is just this BPRS - I may have the initials wrong. I can get them right for you - is the CNS product used.

So again, the extent that there is a CNS

product used in Alaska and there is fair discovery on that, we understand that, but broad allegations of, you know, we're curious about what your interactions might have been with a nationwide organization concerning products not utilized in Alaska we think is beyond the pale.

It's worth noting here that at virtually every hearing before Judge Rindner, there is concerns expressed by the Judge, and ones that you should be mindful - I hope you're mindful of, too - are that of keeping this litigation focused on Alaska. The plaintiff's lawyers here have other interests as well. They have other states as clients as well. They have other actions against Lilly, both personal injury litigation as well as other state attorney generals action, and we're very sensitive to the notion of keeping this litigation about this litigation.

And Judge Rindner at every hearing, and I can cite you to some testimony if it's of interest, has really focused on that issue and expressed that concern of keeping discovery pertinent to this litigation for use in this litigation and not opening it up to broader speculative efforts that may be of use where there is a tie to a state that's not

Alaska.

And, you know, TMAP is -- the Texas Medication Algorithm Project is an example of that as well. Alaska doesn't use that Algorithm in its decision making, in its Medicaid decision making, at least that's what their interrogatory responses reveal. There isn't an algorithm utilized, and issues concerning TMAP are beyond what is pertinent to Alaska.

MR. SUGGS: If I could briefly respond?

DISCOVERY MASTER: Yes.

MR. SUGGS: I think it will be helpful to look at the exact language of what we're asking in our interrogatory regarding communications with people in the executive branch.

Interrogatory No. 6 asked Lilly to identify any employee or agent of Lilly who was responsible for lobbying or communicating with any employee or representative of Alaska's Executive or Legislative branch of government - here is the key language - regarding the efficacy, benefits, risks or costs associated with the use of Zyprexa from October 1996 to the present.

We're not -- this is not a fishing operation, trying to find out what lobbying

relationships they have generally with Alaska. It's specifically with respect to the efficacy, benefits, risks or costs associated with the use of Zyprexa. It's clearly relevant to our failure-to-warn case, clearly relevant to our misrepresentation claims, clearly relevant with respect to what they knew about the risks and benefits of this product and what they were telling the public.

Also with respect to Comprehensive Neuroscience, again we see that this product here, these guidelines that they publish, are available on the Internet. That's how people get them. And the interrogatory specifically there says, "Identify any and all Lilly employees responsible for communicating with Comprehensive Neuroscience from October 1996 to the present regarding the development of Expert Consensus Guideline Series."

That's exactly what we're talking about here. Alaska prescribers could easily obtain this material from Comprehensive Neuroscience. It's not restricted in its availability by particular state. And to the extent -- and it's -- as I pointed out, they bill themselves as putting on an impartial consensus of expert opinion.

If in fact Eli Lilly was actively engaged

in providing material, then one could question the unbiased nature of that product that was being put out.

DISCOVERY MASTER: Your ordinary consumer, ordinary doctor argument is going to be, at least by your theory of the case, be presented by expert testimony?

MR. SUGGS: Yes.

DISCOVERY MASTER: And is there any expert testimony in the record that would indicate that the ordinary Alaska consumer would rely on comprehensive -- Alaska consumer doctor prescribing these medications would rely on any of these, TMAP, CNS?

MR. SUGGS: Not as of yet, Your Honor.

MR. STEELE: I'm quite certain there will be. We haven't gotten that far yet. Now that you mentioned it.

DISCOVERY MASTER: All right. Are you finished, Mr. Suggs?

MR. SUGGS: Yes.

DISCOVERY MASTER: Mr. Boise.

MR. BOISE: Just in brief response. There is no allegation of misrepresentations to the Legislature on the safety efficacy profile of Zyprexa

or the Executive branch or lobbying in any way, shape or form connected up to their claims. If there was a misrepresentation to the Medicaid agency or what Lilly knew about Zyprexa, that certainly has been the scope of exhaustive discovery that Mr. Suggs has helped lead and take, I think, just about every major deposition in the underlying litigation and the analysis of nearly 15 million pages of documents, getting to what Lilly knew on those issues. And I don't -- our objection is to looking at what was said in a lobbying effort or to an executive not connected up to this case.

DISCOVERY MASTER: The question is -- the answer may be no now, but it may be yes later. Is there any allegation that the Alaska Legislature or the Alaska Executive Branch, other than Medicaid, took any actions to influence the use of Zyprexa?

MR. SUGGS: Not that I'm aware of.

DISCOVERY MASTER: Unlike the allegations that are similar to the allegations made in the TMAP?

MR. SUGGS: Not that I'm aware of, Your Honor.

DISCOVERY MASTER: All right. Next chunk.

MR. SUGGS: Okay. Our next chunk, Your

Honor, calls for -- relates to interrogatory No. 4 and our corresponding request for production at No. 7, and these have to do with the identity of Lilly sales representatives in Alaska from October 1996 to the present. And also calls for production of a database of so-called call notes generated by those sales representatives.

Zyprexa went on the market in October of 1996, and the State is alleging that from the outset of marketing to the present Lilly has consistently failed to adequately warn about the risks of Zyprexa, engaged in fraudulent misrepresentations, and violated Alaska's Unfair Trade Practices Act.

We have requested the identities of Lilly's sales representatives in Alaska from October 1996 to the present, and I believe that the identities of those sales representatives and the documents in their possession relating to Zyprexa are clearly relevant to what was -- what information was provided to practicing physicians here in Alaska.

That discovery is clearly relevant to our claims for failure to warn, also with respect to our claims regarding misrepresentations, overpromotion, and violation of the Unfair Trade Practices Act.

It is the custom and practice of Lilly

sales representatives after each call that they make on a physician to prepare what they refer to as "call notes." And we've had several iterations of that database produced in the MDL litigation. I have one of them on my computer, and I think I can probably make this a lot clearer as to what we're asking and show its relevance if I can show that to you, your Honor.

MR. BOISE: As Dave knows, I've seen these before.

MR. SUGGS: Yup. This is -- the database is produced in an Excel format, so it's searchable. It shows the call date, the caller ID, the name of the physician. I'm sorry, the name of the sales rep over here in this column. The prescriber's name, first and last. The city, the state. And then they have over here something called "action," which, as I understand it, is -- to the extent there is a record in there, communication that the sales rep made to the doctor. And then there is another field over here called "reaction." And then follow-up, and then the other is the identifying production information of the MDL. One of our principal claims --

DISCOVERY MASTER: Is that it? Everybody

is standing up around here.

MR. SUGGS: Well, I'll come back to it to show you some more, but you can sit down for the time being.

One of our principal claims in this litigation involves our claim that Lilly began a program in 2000 of overpromoting the use of Zyprexa to primary care physicians. Although Zyprexa was indicated -- I'm not sure how familiar Your Honor is with the term "indication" in pharmaceutical litigation. It's a term of art. An indication is a section in the label that describes the particular uses of the drug which have been formally approved by the FDA, and if a -- it is improper and illegal for a drug company to promote the use of the drug for uses that are not listed in the indication section.

It is our claim that beginning in the fall of 2000, Lilly promoted the use of Zyprexa to primary care physicians who typically did not prescribe antipsychotics for their patients, and that they promoted the drug, instead of promoting it for schizophrenia, which was one of its approved indications, and also promoting it -- or promoting it for the acute manic phase of bipolar disorder, they promoted it for what they referred to as complicated

mood disorders.

They also referred to -- described Zyprexa to primary care physicians as being the safe, proven solution in mood, thought and behavioral disorders. And we have internal documents indicating that they said that mental orders (as spoken) is intentionally broad and vague, providing latitude to frame the discussion around symptoms and behaviors rather than specific indications.

And what they did to promote the drug this way was to develop what they called little patient exemplars, one of which was a -- one of their favorites was sort of an exemplar patient, fictional person referred to as Donna. And Donna was a person who they referred to as the prime example of someone having these complicated mood disorders. No way could this person have schizophrenia, and it's also clear that she did not fit the other legal indication for the drug, which was the acute manic phase of bipolar disorder.

We've seen in the MDL production of the call notes that if you do a search here for an action and you do a search for Donna, you come up with a lot of hits. I'm going to do a search right now. Somehow it seems to be a frozen hour glass here.

I'll have to do the search again here.

Okay. Here's one call note where they say Zyprexa -- this is in the action section of the database. So this is what the sales rep is telling the treating doctor. "Zyprexa improves behavior, mood and thought." Those are not indications for the drug. "Consider new patient type Donna with multiple symptoms, i.e., mushy middle. Zyp," stands for Zyprexa, "is truly broad-spectrum psychotropic properly framed, weight change and diabetes."

If you go to the next one. Zyprexa -- I'm sorry, it's the same one.

Zyprexa improves behavior, mood and thought. Consider new patient Donna with multiple symptoms. I.e, mushy middle. Zyprexa is truly broad-based psychotropic. Japanese label changes. Verbatim.

Zyprexa improves behavior, mood and thought. Consider new patient type Donna with multiple symptoms, i.e, mushy middle. Zyprexa is truly broad-based spectrum psychotropic. Same message he's giving there.

Donna on DVD. Showed the Donna DVD to these doctors. I feel these doctors were very responsive because I'm not sure they think Zyprexa

when they see this patient. All doctors said that they see these patients.

We watched the Donna DVD.

I mean, you can tell from these call notes just what they were telling the doctors here, and it's our represent -- our claim that every representation they made here about Donna was an example of off-label promotion. Under our unfair trade practices claim, we're entitled to discover all of the improper promotion that they made to all physicians regardless of whether the physician ultimately wound up making a prescription for Zyprexa or not. It's a violation of the Unfair Trade Practices Act to make a misrepresentation or to improperly promote a product in the state regardless of whether anybody buys it or not.

And that's essentially the thrust of our claim there, Your Honor.

DISCOVERY MASTER: Mr. Boise.

MR. BOISE: Okay. Thank you. As you can see from Mr. Suggs's presentation, there has been a substantial call note production already made to plaintiffs which certainly the State has access to. And in particular, there was 100,000 random call notes throughout the country that were produced, of

which a small number of them were Alaska-based call notes, a couple of hundred. In addition, to the extent that there were prescribers that prescribed Zyprexa and the claim is that diabetes was caused as a result of that prescription, call notes involving certain of those prescribers were also produced as part of the litigation.

DISCOVERY MASTER: In the MDL.

MR. BOISE: In the MDL or state court actions as well. What you have here, then, is if there was -- there is a mechanism that was set up to do some form of sampling of the total database. Now, what we've done in response to the plaintiff's motion, the State's motion, is say, "Okay. How many of those call notes can we isolate to Alaska?" And we've approximated that number to be about 40,000 of these entries. And what we have proposed is a similar system as to what we have utilized in other fora which is sampling method to extract a certain percentage of those, or to the extent that there are doctors that they believe have been deceived, we can identify those physicians and produce call notes for those doctors so we can get at what is really going on in that note.

A call note is not a verbatim record. It

is a jotting used by sales representatives to jog their memory in the short term. So it hardly reflects the full nature of any communication, and to get the full measure, certainly we would have to get some information around that communication above and beyond perhaps the call note.

What I heard today for the first time, which I think is interesting, is the emphasis really on Donna. And certainly the database is searchable, and we could, for example, search and produce the Alaska call notes that reference Donna or mushy middle or things of that nature --

MR. SUGGS: It's not just Donna.

MR. BOISE: -- and produce those terms. But if there is certain allegations that they're making they want us to look for, extract and produce, we are all for some reasoned approach.

Just so you get a fuller picture of mood, thought and behavior -- and this really ties to the database argument a little bit.

DISCOVERY MASTER: May I ask you a question before you continue?

MR. BOISE: Absolutely.

DISCOVERY MASTER: Do you object to producing the call notes other than overbroad and

burdensome? If you object to produce a random sample? Or tell me why you're not willing to produce them all.

MR. BOISE: The full data set? Yeah, the burden is in our history. And we have a long history of producing call notes in the litigation. It's about -- the review-and-produce time is about two minutes per call note of review time. So you can do the math for --

DISCOVERY MASTER: And you say there are 40,000 Alaskan?

MR. BOISE: Alaska call notes.

DISCOVERY MASTER: On Zyprexa?

MR. BOISE: Well, that could involve Zyprexa. We have to look at them to see whether they involve Zyprexa.

DISCOVERY MASTER: You have to look at them individually?

MR. BOISE: Yes.

MR. SUGGS: Your Honor.

DISCOVERY MASTER: I don't want to interrupt his argument. I'll let you respond when he finishes.

MR. BOISE: Yeah, and, you know, there is a lot of long discussion about, you know, how much

discovery of physicians is going to take place ultimately in this case. And certainly the extent that Lilly would pursue any physician's deposition, we would do what we have always done in the underlying litigation, is produce the call notes that associate with that physician. So those interactions are part of the discovery record, that we take it on a physician-by-physician basis. If there is more reasoned way to get at this to meet the State's needs short of 40,000, whether it's, you know, searching certain terms or not, we're willing to discuss that. We just have not had the opportunity to discuss whether anything short of this is even of interest.

Just so the allegation doesn't go unsaid, I know we're not trying the case before you today. Bipolar disorder for which Zyprexa is indicated is a mood disorder. So when the plaintiffs claim that if a doctor writes "mood" down in a record or "mood" somehow gets to a database, that that means it's nonindicated, we would say that's exactly why we need to look at medical record which would show the elements of bipolar disorder.

You know, it's a new disorder, and that's exactly what the Donna profile, to use the example, is going to. There is certainly a profile consistent

with bipolar disorder.

So we're willing to, on call notes, produce a subset, a reasonable subset, come up with some accommodation with the State to meet their needs.

As far as identifying the actual reps, we would be willing to extract from the call note database the reps that worked in Alaska and get that list of individuals to the State to take that off the table, as well.

As far as -- now, going forward in trying to collect all the files of all the people that ever worked in Alaska, we would suggest that that is unnecessary for a number of reasons.

The primary reason is -- again referring to a database production that Lilly has made in the underlying litigation that the State has access to. Mr. Suggs is pulling documents to show Your Honor today in many scores, which is highlighting the fact they've had discovery on many of these issues.

One issue where there has been extensive discovery, are there resources that are available to sales representatives. There is a database, which Mr. Suggs knows well, called Knowledge Management, or KM, which is the resource guide for which sales reps

can pull information to utilize in the field.

They have that centralized database and data source, and to go out and then to try to collect the pieces for a rep where they have the source from which they pull the information is duplicative and, you know, has largely been rejected in litigation as such.

So if there is a rep of interest, again, what we've done in the litigation is say, "Here's a rep we're really interested in. Let's talk about it. Let's see if their file is pertinent to the allegations that are made." And we in certain circumstances certainly produced those files. But to do whole-cloth "go and collect from the field information that's already been produced from the source" we think is inappropriate, and we think there are better ways to get at the call note database than what has been suggested.

MR. SUGGS: As part of our unfair trade practices claim, we're entitled to try and establish the communications that they had with all physicians in the state, not just particular physicians.

This call note database, they can sort this by state. So they can pull out all the Alaska with the click of a button, just like I did right there.

They can sort this out by state.

They claim that there is 40,000 records here. If you'll note here, there is about three or four entries that would fill a single page. So if you're talking about four entries per page, you're talking about 40,000 entries, you divide by four, that's about 10,000 actual pages. 10,000 -- there is about 2500 pages of documents in a banker's box. You're talking about four boxes' worth of documents here, is what we're talking about for the entire -- it's the equivalent in paper of this database with respect to the Alaska call notes.

They've represented in their pleadings it's going to take them 1300 hours to review that volume of material. It just doesn't -- just doesn't stand, Your Honor.

They also talk about privilege, review for privilege issues. I can't imagine that in these notes that are here that are a partial record of communications with the sales rep or the doctor, that there is going to be any privileged information or any work-product type information. And if that's an issue, we could have as part of the production a claw-back provision, which is something that's frequently employed in discovery of electronic

documents where if in fact as it turns out that there is some privileged matter that comes up, they can literally claw back that part of the information and redact that later on. But it shouldn't be held up for this 1300 hours of review of four boxes of documents.

I think this material, it's easily producible. It doesn't take that much time to review. With the claw-back provision, it can save a lot of that review time. And it's clearly relevant to our Unfair Trade Practices Act claims.

DISCOVERY MASTER: All right. Next chunk.

MR. SUGGS: Okay. The next chunk, Your Honor, has to deal with Interrogatory No. 7 and corresponding Request for Production No. 10. In those discovery requests we've requested the identities of those responsible for developing and implementing marketing programs to support access to Medicaid recipients and any documents regarding the same.

Their specific objection is based on their claim that the State is only entitled to discovery of Lilly's conduct directed specifically to physicians, and that's simply incorrect. Their communications

and activities aimed at access to Zyprexa by Medicaid or for promotion for the State's Medicaid population are central to our claims here.

A key element of our common law statutory claims is that Lilly's misconduct resulted in increased Medicaid expenditures, and these requests seek information and documents related to marketing programs that may have directly resulted in those increased expenditures. The information is clearly relevant to our claims, Your Honor.

DISCOVERY MASTER: Mr. Boise.

MR. BOISE: And we've agreed to produce the individuals that were responsible for implementing or communicating with the State Medicaid program for Alaska. And they can see their documents and what was actually done in Alaska as opposed to, you know, the broader issue of what was done in 49 other states.

MR. SUGGS: So this is one where you are giving us what we're asking?

MR. BOISE: We've agreed to produce the Alaska folks and search more broadly for references to marketing to Alaska Medicaid.

MR. SUGGS: Okay. Well --

DISCOVERY MASTER: Is that what you want?

MR. SUGGS: Sounds like they've agreed to give it to us.

DISCOVERY MASTER: That's all you want on 7 --

MR. SUGGS: Yup.

DISCOVERY MASTER: -- and 10, Interrogatory No. 7, RFP No. 10?

MR. SUGGS: Yeah. The next chunk, Your Honor, was Interrogatory Nos. 12 and 13 where we requested specific financial information on an annual basis related to the sales of Zyprexa both globally and in Alaska. They objected by saying that this was unduly burdensome and overbroad, but they failed to define their burden in relation to producing that information. And frankly, since Lilly is a publicly traded corporation, it's therefore required to maintain and periodically report similar information to that requested by the State. So we think their claim of undue burden is unfounded.

More importantly, Your Honor, the information is clearly relevant to the subject matter of this action. It's relevant to show state of mind and motive to engage in fraud, misrepresentation and unfair trade practices. And moreover, evidence of increasing financial gains after certain promotional

conduct complained of by the State was implemented. For example, the off-label promotion to primary care physicians is clear evidence of the result of that conduct.

DISCOVERY MASTER: Mr. Boise.

MR. BOISE: Lilly is a publicly traded company, and it does report publicly some of the types of information that plaintiffs seek and would be at least responsive to the allegation or the need to show some sort of motive. That is, there are net sales figures that are available on publicly available documents, and if Mr. Suggs can't locate them, I can certainly help him, where net sales would be shown for Zyprexa and other data that is sought.

What we've simply objected to was trying to -- you know, the actual request includes: What is the income before taxes, or what is the cost of products sold? I mean to engage in some form of accounting exercise to get at the very general issue that Lilly is a publicly traded company, that it's a for-profit company, and it publicly reports the types of information that is sought but not the specific information that is sought.

If the allegation is increase in sales yields, increase in revenue and there was increase in

sales over periods of time, Lilly doesn't object to producing the publicly available information where that information can be derived, or alternatively, suggest the State can pull it up today and see the net sales figures for the product.

MR. SUGGS: Well, we're not just asking for net sales figures. As you know, we're also asking for measures of profitability, and we're not just asking for the corporation-wide figures but also for the sales and profitability in Alaska.

MR. BOISE: To address the Alaska point, certainly the Medicaid sales is certainly something that we can produce or something that you already have access to. I don't know of a way beyond measuring Medicaid sales how to get out the issue of all sales in Alaska. The information is not kept in that way, it's not maintained in that way. But we certainly could give you a proxy, which would be Medicaid sales over time, and have no objection to doing so.

MR. SUGGS: Well, Your Honor, we think we're entitled to the profitability information, not just sales.

DISCOVERY MASTER: All right.

MR. SUGGS: Your Honor, our next chunk was

Interrogatory Nos. 19 and 20 and corresponding Requests for Production Nos. and 19 and 20. There we requested the identification of any civil or criminal investigations or actions involving Lilly and Zyprexa and the identities that involve Lilly employees or representatives and any corresponding witness statements, testimony or other related documents.

They have objected by asserting 14 of their general objections. They also assert attorney/client privilege and work-product protection, yet they failed to demonstrate how either concept applies to the particular information we're seeking.

Under Rule 26(d)(5) of the Alaska Rules of Civil Procedure, a party withholding information it claims is privileged has to make the claim expressly and describe the nature of the documents, communications or things not produced or disclosed in a manner that, without revealing the information itself privileged or protected, will enable other parties to assess the applicability of the privilege or protection.

They have not done that in this instance. They have not produced any information, not any sort of privilege log. They just had a blanket objection, "Well, this is all attorney/client privilege and work

product and therefore you can't have it."

DISCOVERY MASTER: Mr. Boise.

MR. BOISE: This is the clearest, the clearest possible example I can think of of attempting to get at information that is not about Alaska. In Lilly's public statements, in its public reporting, it certainly discloses certain other government investigations by other state entities, other state attorney generals, and those investigations involve actions and conduct within the borders of those states.

To give you some feel for this, there is a multi-state investigation by individual states that Alaska has expressly decided it does not want to participate in. And now what Alaska seeks is, "Well, what discovery or information did those other states get concerning conduct in their borders pursuant to a subpoena or a civil investigative demand?"

So Lilly cooperates with a government investigation involving the state of Illinois where it produces information responsive to Illinois information, and the price of that is somehow it gets subpoenaed or requested in the context of Alaska.

I think it's important to note that to the extent there is information that is otherwise

responsive to these requests, the fact that it's been produced elsewhere is no bar to us producing -- Lilly producing information to here. The question is does the broad category of everything ever produced to Illinois or everything produced to Ohio, or whatever state you want to pick, in itself responsive. And I think our brief lays out the cases as to why other investigations are not the subject, because -- there is a number of reasons.

I mean, first, states could investigate without a Complaint, and most do. So there is no -- there is no relevancy argument in responding to that information. Lilly can provide information around a wide variety of topics that involve -- in other state borders that involve those states. If it involved Alaska, we would produce it here. It doesn't involve Alaska.

This isn't calculated to lead to discovery of information concerning conduct in Alaska. It's calculated to lead to discovery of information that's responsive to other states.

There is no withholding of information if it involves the scope of these other discovery requests. It's just a scatter-shot attempt to collect other information that would help, perhaps,

the plaintiffs in pursuing other state attorney general representations, and that is just a huge concern here.

And I know Mr. Suggs doesn't agree with that or isn't concerned about that, but it is an absolute concern. We think the record bears it out as far as comments that Judge Rindner has made throughout. And if it's Alaska-based or otherwise responsive to any one of these discovery requests that's ordered to be produced, we certainly would produce the information. We're not withholding it because it's there. However, it's not calculated to lead to discovery of any information. It's calculated to pry into what other states are investigating.

MR. SUGGS: Your Honor, I can't imagine that these other investigations that are going on have solely to do with particular conduct in particular states. I mean, the fact of the matter is this type of litigation, yes, there is a state component, but you're also looking at what was going on back in Indianapolis, because the conduct of this company is clearly directed by the mothership back in Indianapolis.

Now, we've asked for this information

relating to these other investigations. They've made a bald assertion of attorney/client and work product privilege. Alaska Rules of Civil Procedure say that they have to make that claim expressly and they have to describe the nature of the documents, communications or things not produced or disclosed in a manner that allows people to make a determination of whether there is in fact a legitimate claim of privilege or work product. They simply haven't done that. They've just made a bald assertion, "Well, this is attorney/client privilege and work product."

DISCOVERY MASTER: I'm hearing a relevance argument today.

MR. BOISE: Correct.

DISCOVERY MASTER: Do you also have an attorney/client, work-product claim?

MR. BOISE: Well, certainly if there was -- if the information was -- depending upon how you interpret the request. If it called for attorney/client communication and was otherwise ordered produced, we would produce a privilege log. We are saying there is no circumstance where the information is producible in this form.

If there is conduct in Indianapolis, as Mr. Suggs would put it, and it's otherwise responsive

or pertinent to a request that Alaska has made, then it would be produced, but what they're trying to do is sweep well beyond that.

If the question is what did Lilly know about an XYZ topic, and the court determines that that topic is the proper subject of discovery, we would produce information responsive to that request irrespective of whether it was produced elsewhere, and the fact it was produced elsewhere is completely beside the point to anything pertinent here.

What I hear Mr. Suggs saying is he's not interested in anything that was state-specific, that he's only interested in broader statements of applicability. To the extent that the nonstate-specific data has been produced in a government investigation and has been requested here, otherwise we would produce it.

MR. SUGGS: Well, Your Honor --

DISCOVERY MASTER: Have you produced it?

MR. BOISE: Well --

MR. SUGGS: He can't represent that.

MR. BOISE: What's that? I can represent. I mean, certainly there has been discovery taken in the MDL where plaintiffs have access to information that has also been produced elsewhere, in other fora,

which would be part of a production. So the answer to that question would be the extent that it's been requested and sought, would we produce it? Yes. Have we produced it? Yes. What we're objecting to is producing, you know, the entirety of an investigation that by definition has nothing to do with Alaska. By definition, an investigation by Illinois has nothing to do with Alaska.

DISCOVERY MASTER: Unless they're investigating the same issues that are being investigated here and the things they're asking you for are similar to what's being asked for here by virtue of another discovery request.

MR. BOISE: And if it was, we would be producing it here in response to another discovery request. But what this discovery request is calculated to do is sweep beyond what Dave asked for in another discovery request and see what else other governments are asking the company, who is voluntarily cooperating with investigations, to produce in addition to what is otherwise sought.

If there is a request in here that calls for the production of information, we are not withholding that information merely because it was produced elsewhere. We would produce it in response

to this request.

If, hypothetically, Alaska call notes were sought in some other government investigation and you order Alaska call notes to be produced, we produced Alaska call notes, not because they were produced in another place but because they've been independently sought and either produced or objected to here.

The way in order to tailor discovery to this case is to tailor discovery to this case, not ask what's happened in other government investigations which are geared towards conduct within their borders.

MR. SUGGS: Well, Your Honor, one of the problems I have with what Mr. Boise says is he talks about, well, to the extent the documents deal with another -- regarding a particular subject matter, they've been produced. The MDL had the most bizarre document production I've ever seen. What's usually the case is you write document request interrogatories asking about particular subject matters. You say give me all the documents on subject X.

In the MDL, documents weren't produced that way. In the MDL, we had an order -- I was not part of this particular --

MR. BOISE: You were part of the team, sir.

MR. SUGGS: I was not responsible for the order that came out, but basically what the Court said in the MDL, the Special Master there ruled that Lilly only had to produce documents from, I believe it was 60 individuals.

MR. BOISE: It's more than that. It's much more than that.

MR. SUGGS: Well, in any event, it was not with respect to subject matter but with respect to the custodial files of particular individuals. So that's one problem that I have with what Mr. Boise says. I don't know that everything has been produced with regard to every subject matter that we're asking for.

And as I said before, I cannot believe, Your Honor, that these other investigations are focusing solely on what happened in Arkansas or Georgia or wherever. Simple reality of corporate life is that the policies are set at the top, direction is set from the top down. And to the extent that those other investigations have been -- have been able to unearth information regarding the conduct of Lilly at the corporate level and coming

out of Indianapolis that has an effect on states everywhere, including Alaska, we'd like to have that discovery. And if they claim that that material is privileged or work product, then they've got to comply with the Alaska Rules in terms of making a description of that.

MR. STEELE: Would it be possible for me to say something on this subject since I'm involved in the Utah litigation and the civil investigative demand there, so I know something about it.

DISCOVERY MASTER: All right.

MR. STEELE: And what I can say about it is this, and Mr. Boise and I of course have corresponded and talked about this subject. In terms of that which is being investigated in Utah, it is certainly broader than what in particular was done in Utah as Mr. Suggs suggests.

These policies that Lilly set with respect to how they were going to sell their drugs were nationwide policies, and while I will agree that Alaska and Utah are probably the first states that will secede from the Union, nevertheless, they are currently part of the United States, and the policies that were set that were prevalent throughout the United States are the subject of investigation by

Utah.

So as the Court suggested, these investigations are far broader than just what happened in a particular state.

MR. SUGGS: And, Your Honor, I should also point out, if you look at the particular language of our interrogatories, the scope of the information that we're asking for here is a lot narrower than portrayed by Mr. Boise.

Interrogatory No. 19 says, "Identify any civil or criminal investigations or actions of or against Lilly, including but not limited to any whistle-blower action or any state or federal government authority investigation or action related in any way to Zyprexa, including but not limited to any such investigation or action related to the marketing or promotion of Zyprexa."

It's asking them to identify the investigations. That's the extent of Interrogatory No. 19.

Interrogatory No. 20 says, "For any investigation or action identified in response to Interrogatory 19 above, identify any and all individual employees or representatives of Lilly involved in such investigation or action and state

for each, A, the role of the individual employee or representative of Lilly in the investigation or action; and B, whether the individual or representative of Lilly gave any statement or testimony, whether oral or in writing, including any deposition or sworn testimony, in the investigation or action."

So we're asking them to identify any witnesses who have been identified in those cases.

Now, to the extent we've got a list of those witnesses, we can then compare that with the list of people who were ordered to -- they were ordered to produce documents from in the MDL, and we can see if that is in fact a match or if there is other folks who it turns out have been involved in these other states' investigations from whom there has been material produced that was never produced in the MDL. This is a way of getting at that.

I can't see how it could possibly be burdensome or oppressive for them to identify the investigations that are ongoing and any employees who have been involved in that investigation.

DISCOVERY MASTER: Mr. Boise.

MR. BOISE: Yeah. So the request, and that includes -- the totality of your request on this

topic, then, is to identify the investigations and to give you the names of individuals that have testified in those investigations. Is that as I understand the request?

MR. SUGGS: Well, that's --

MR. BOISE: No documents?

MR. SUGGS: Interrogatories 19 and 20 are, and then the requests for production, let's see what those say.

MR. BOISE: And this maybe speaks to the absence of a meet and confer on this topic because I read it a little bit broader, and hence the need for objections, relevance and breadth and the like.

MR. SUGGS: Well, the Request for Production 19 calls for you to produce any documents that were produced in any civil or criminal investigational action identified in response to accompanying Interrogatory 19 which were not previously produced in the Zyprexa MDL.

And No. 20 is, "Produce copies of any statement or transcript of testimony by any individual identified in response to accompanying Interrogatory 19."

MR. BOISE: So you are still seeking -- can I ask a question of --

DISCOVERY MASTER: Yes.

MR. BOISE: I don't mean to be so informal. Are you still seeking information that is specific to the state? For example, Mr. Steele raises Utah. He asked for specific information about employees in Utah as part of your CID. Is that excluded from this request?

MR. SUGGS: Our interrogatories and document requests are what they are. We're asking you to identify the investigations, we're asking you to identify the individuals who are involved in those investigations, we're asking you to produce any documents that were not produced in the MDL, and we're asking you to produce any witness statements that have been taken in conjunction with any of those investigations.

MR. BOISE: I just heard your argument to say that if there is documents specific to a state, you're not interested to those in addition to the MDL. You are interested or not interested in -- for instance in Mr. --

MR. SUGGS: If it's --

MR. BOISE: Let me just finish.

MR. SUGGS: If it's with respect to a particular detail guy in Arkansas, I don't care about

that.

MR. BOISE: So as I understand the request, it is identify government investigations such as Mr. Steele's CID, identify individuals who have been deposed or who have given a statement --

MR. SUGGS: Right.

MR. BOISE: -- in those, and produce those documents to the extent they're not specific to, you know, a sales rep in that action or otherwise haven't been produced in the MDL?

MR. SUGGS: Correct.

MR. BOISE: Can I talk to my client about that? Because I don't think there is that much of a breach on -- in difference of opinion as --

DISCOVERY MASTER: Sure.

MR. BOISE: -- now I understand the request. So I'd ask just to table that for a little bit. I'll try to get ahold of someone perhaps at the end and get back to you, if I can, today shortly thereafter, but it's not that far from -- it addresses many of the concerns is what I would say.

DISCOVERY MASTER: All right. Next chunk, Mr. Suggs.

MR. SUGGS: The next chunk has to deal with their direct-to-position promotion in Alaska. And --

DISCOVERY MASTER: Numbers are?

MR. SUGGS: This would be Request for Production Nos. 4, 5 and 6, and basically this is requesting documents relating to communication between Lilly sales reps, Lilly thought leaders, that's in quotes, or consultants or any other Lilly-retained or paid medical doctor and any health care providers in Alaska.

Again, they're seeking to limit the production of such documents to if there is any physicians that we identify for it. We don't know what all physicians they promoted to here in Alaska. They clearly do.

Our claim for violations of the Unfair Trade Practices Act are not conditioned upon any particular physician actually writing a prescription for Zyprexa but only require proof that Lilly's conduct had the capability to mislead. Thus all of Lilly's communications to any physicians in Alaska with respect to Zyprexa is relevant and discoverable to our claims.

DISCOVERY MASTER: Mr. Boise.

MR. BOISE: Maybe I'm again a little bit unclear on what exactly is being sought. Maybe I read this broader than what was intended. You're

seeking Lilly's interactions with physicians in Alaska as opposed to Lilly's interactions with its own consultants.

MR. SUGGS: Request for Production No. 4 calls for the production of any and all documents relating to, referring to or embodying any communications between Lilly sales representatives and health care providers in Alaska from October 1996 to the present relating or referring to the efficacy, benefits, risks or costs associated with the use of Zyprexa.

MR. BOISE: And I believe those for sales reps would be call notes you're talking about.

MR. SUGGS: Well, it could be call notes, it could be any -- I don't know what materials you guys have. It's any and all documents relating to, referring to or embodying any communications between Lilly sales representatives and health care providers.

MR. BOISE: And just --

MR. SUGGS: Maybe it's a memo that the guy wrote to his regional sales manager. I don't know what it is. You guys have got the documents. I don't.

MR. BOISE: That would be the nature of the

objection, would simply be -- you know, to try to figure out over a ten-year period what was any communication ever made on the topic of Zyprexa is something that would -- I'm not sure how I would go about it.

MR. SUGGS: Well, I could start --

DISCOVERY MASTER: Hold on. Hold on. Hold on.

MR. BOISE: To the extent that there is a database which reflects those communications, that's the call note database that I think we've already discussed. So the objection would be --

DISCOVERY MASTER: Have you looked to see if there is that kind of information or have you tried to figure out how to find that kind of information?

MR. BOISE: Have I looked? No. Have I thought about and discussed how would I find that information? Yes. And I'm a little bit at odds on that. I don't know how I would go about it short of trying to locate every person that worked in Alaska as a sales representative and seeing whether they had any communication concerning the topic of Zyprexa and undertaking that type of path, and what we've said is that --

DISCOVERY MASTER: How about persons other than sales reps? Leaving aside have you looked, have you tried to figure out whether that kind of information exists and if so, how you can find it?

MR. BOISE: Sure. There is information about interactions with, quote, thought leaders, and we've produced in the MDL for prescribers that are pertinent to the action a portion of a database called TLPS, is the portion of the database or the extract as part of what we call case-specific discovery.

So if there is issues concerning a prescriber, there is certain data that we've produced as to that prescriber that are contained in certain data sources. That would include this thought leader partnership database, as well as call notes, as well as some other data points.

So yes, there is a -- there is a process for trying to get at interactions with physicians. The question is which physicians. What I'm hearing is any interaction with any Alaska physician --

MR. SUGGS: Any --

MR. BOISE: -- at any time.

MR. SUGGS: Exactly, because it could be a violation of the Unfair Trade Practices Act.

And Your Honor, there is really three different things here chunked together. One is communications between the sales reps and the doctors. Okay. They know who their sales reps were. They can go to -- they know which sales reps detail Zyprexa, and they can go to those sales reps, and they can say, "Give us your documents relating to communications that you had with the doctors that you detailed in Alaska."

The second aspect of this is Request for Production No. 5, which calls for documents referring -- pardon me, relating to, referring to or embodying any communications between any thought leaders, outside speakers or consultants retained or paid by Lilly, and health care providers in Alaska.

I mean, this is very focused on Alaska. They know who their thought leaders were. They know who their outside consultants were here in Alaska.

DISCOVERY MASTER: Got to help me. What's a thought leader?

MR. SUGGS: A thought leader is a guy -- is a doctor who is thought to be prominent in the field and who is respected in the community, and so that they would have -- they would hire these guys to go out and give presentations about how great Zyprexa

was. I don't know how many they had in Alaska doing that, but they certainly knew who they were and can dig up the documents relating to those people.

And the third aspect of this chunk is for them to produce documents relating or referring to any communications between any medical doctor that is a regular employee of Lilly and any health care provider in Alaska.

And they had a medical department that -- and people in the medical department that would respond to requests for information from physicians. And to the extent that there were letters from Lilly's medical department in Alaska going to physicians here in the state who were asking for information about Zyprexa, that's the subject of that request.

DISCOVERY MASTER: All right. Help me with -- what are your objections, now that you know?

MR. BOISE: Sure. I agree with Mr. Suggs. There is a way to get at requests made from Alaska physicians and what the response to that request would be. The question becomes what's the universe of physicians for that, what are the topics of inquiry. Is it any request on any topic for any purpose relating to Zyprexa or is it something else?

MR. SUGGS: Well, if you just look at the request for production. It says produce -- this is No. 6, "Produce any and all documents relating to, referring to or embodying any communications between any medical doctor that is a regular employee of Lilly," that would be an in-house guy, "and any health care provider in Alaska between October 1996 and the present," key language, "regarding the efficacy, benefits, risks or costs associated with the use of Zyprexa." We were very specific here.

MR. BOISE: Yeah. And --

MR. SUGGS: We want to know what this company was telling doctors here in the state about the risks and benefits of the drug, and we've gone at it several different ways with the sales reps, with the thought leaders, with the in-house medical guys. I think we're entitled to that information. They haven't given it to us, and they refuse to give it to us.

MR. BOISE: Well, no. What we have said in our response of his briefing is that this is the type of information that we produce for specific prescribers of interest. You claim prescribers have been the subject of some fraudulent conduct. There is research that we can do and undertake on a

prescriber basis that would get to the issues that Mr. Suggs is addressing, and we certainly --

DISCOVERY MASTER: Can you do it for every physician in Alaska, not limited to prescribers of interest, if that's the -- I mean, that's a difference of opinion you all have. Can you do it if he prevails?

MR. BOISE: Can we do it? Yes as to certain topics that he's talking about. Yes -- and by topics, I should be more clear. Not all data is maintained going back for all years. So there may be limits to what the call center data source has and what's available.

I think - I'm not sure - I could answer the question it goes back to '99 time frame. That's true for many of the data sources. So that would be one limiting factor. But with that caveat aside, certainly those databases could be searched and information could be extracted as to communications with Alaska physicians on requests for medical information by Lilly employees. That's something that we are capable of doing. It's just done on a -- it has to be done on a person-by-person basis.

Call notes we've talked about and what those interactions would be.

As far as getting at what the -- what any consultant ever said to any physician, I don't know how I would get at that information. I just don't know how that would be captured. I haven't seen that. There is not a data source, there is not a place to go to say, "Okay. This is the communication that was made," other than if it was reflected in, you know, one of these other sources.

DISCOVERY MASTER: How about thought leaders?

MR. BOISE: That's what I've just addressed. A thought -- the thought leaders is a bit of an odd term, actually. I mean, I think Mr. Suggs' definition is a reasonably fair one. The question is can we get at a physician's -- consultant, perhaps. Not really a thought leader. Let me push beyond the definitions.

I think what he's asking for is is there someone who is paid by Lilly to go out and present information to Alaska physicians, and, you know, who are those people and what have they said, is what I understand.

MR. SUGGS: Yeah. What are their documents? Are there any documents relating or referring to or embodying those communications?

MR. BOISE: And, you know, who those people are that would be based in Alaska, I just don't know how I would get at that information as it was sought. You know, I could find out and report back promptly, but, I mean, certainly the -- as I looked at the issues in the past, and I've been involved in discovery in this case from the very beginning, I haven't seen a way to get at that, but I'm not prepared to represent to you that it's not possible should it be ordered.

MR. SUGGS: What I'm hearing is that apparently no attempt was even made to try and get this stuff.

MR. BOISE: Well, that's -- I don't think that's quite fair. I don't think that's quite fair. I mean --

DISCOVERY MASTER: All right. I'm good on this one.

MR. SUGGS: Your Honor, our final --

DISCOVERY MASTER: Just a sec. Just a sec. I'm sorry.

MR. SUGGS: Sure.

MR. BOISE: Beyond that, I guess what was being -- I just have one more point, which was Mr. Jamieson's point, is that we have a list of

Alaska prescribers from the Medicaid database of Medicaid prescribers, and is that a place to begin if we're doing research on individual prescribers, and that would be one -- one way, perhaps, to go at it.

MR. SUGGS: You know your -- the prescribers better than we do.

MR. BOISE: Well, if they're reporting to the database, you would know them I think with equal force.

MR. SUGGS: Well, I can't imagine that your sales reps would not know who the physicians were in the area in the state that they called on. I mean, that's just -- that's inconceivable.

MR. BOISE: I'm not denying --

MR. SUGGS: And in fact --

MR. BOISE: I'm not denying that we know who the prescribers are.

MR. SUGGS: In fact, if we got all of the call notes, as we're requesting, one would assume that we would have -- assuming that the sales reps were conscientious in preparing those call notes, we would then have a list of all the doctors in Alaska upon whom the sales reps called.

DISCOVERY MASTER: All right. Next chunk. Last chunk, I think.

MR. SUGGS: It's sort of a grab bag, Your Honor. It's relating to Interrogatory Nos. 5, 15, 16, 17 and 18, and Requests for Production Nos. 8, 15, 17 and 18, and the -- these were all particular requests where Lilly has either agreed to produce documents or directed us to documents it has previously produced in the MDL litigation. However, Lilly's production of documents in the MDL, as I pointed out, was not by subject matter but rather was in response to particular -- they gave us production documents from particular custodial files of individuals. Thus, there is the very real possibility that some of our requests which are not related to specific Lilly witnesses or custodial files require responsive documents which have not been previously produced.

Moreover, in many of their responses, they've said, "Well, it's in the MDL. Go look there." The MDL production they claim is now 15 million pages of documents. We don't think it's an appropriate interrogatory response or production request response to say, "Well, go look in the MDL. It's somewhere in that 15 million pages of documents."

If in fact there is our documents that were

previously produced in the MDL and they're directing us to that, they need to give us some specificity as to where that can be found by Bates number. I mean, we can't just go pawing through 15 million pages of documents every time they say go look in the MDL.

DISCOVERY MASTER: Mr. Boise.

MR. BOISE: Yeah. I was involved in the initial production in the MDL, and Mr. Suggs' colleagues on the plaintiff's steering committee were also involved, and I think just a tiny bit of history as to how this production was made is very much responsive to the comments made by Mr. Suggs.

In litigation involving the array of issues that were present in the MDL and which are present in these document requests, at some point a reasonable search needs to be defined. And what the steering committee for the plaintiffs and Lilly did, with the assistance of the Special Master, was help define what a reasonable search would include by making sure that not only custodial files or files from folks in marketing and medical and regulatory and all the different categories where you would expect information to live that's pertinent to Zyprexa and issues concerning diabetes and its promotion generally, in addition there was databases that were

produced. I mentioned some of those earlier.

There was intense negotiations, discussions and ultimately a ruling on how documents would be produced, and what Lilly was burdened with in the outset was producing documents and providing to the plaintiffs not only the documents in the electronic form, that they are electronic documents, but also producing with it a database of objective coding which would provide author and recipient and other objective information that was fully searchable.

So what the plaintiffs got were documents themselves that were searchable in part but not in whole and also a database which contained objective coding which allowed additional identification of information, and then attached to our papers here was a declaration by the head of the plaintiffs' steering committee on the tremendous efforts that the plaintiffs had made as part of this MDL repository to further OCR documents, scan them, have them searchable, have them categorized to allow Mr. Suggs, primarily Mr. Suggs, to take the deposition of dozens of Lilly's witnesses.

These 15 million documents have been pawed through, categorized for years, and they've been pawed through and categorized for years because they

are produced in a form that made them amenable to that.

The bargain there was not to have to identify each document by Bates range in response to ongoing discovery requests because they were produced in a form that made it equally accessible to either party to go forward and put things in little packages that they felt were more useful.

So the argument here is that the information is produced in a form that is equally burdensome on either side to put information into the packages that they now seek to place the information. And that's what we objected to doing now after investing and being forced to invest and engage in a production which includes all of this type of objective coding, as well as electronic documents, now packaged for them in a different form.

I'll add that productions that we're making in Alaska, we are, I guess without negotiation, agreeing to use the same format. I mean, it seems to have worked through three years and nearly 15 million pages of documents, so we're continuing to produce, to the extent that we can, electronic documents and documents with objective coding so they're searchable in multiple ways.

The burden of now trying to go back and say, "Well, does this document respond to this request?" is of equal burden to either party.

MR. SUGGS: Your Honor, I think it's -- it's my fault. I lumped these together. We need to talk about the specifics of this to show what's really involved here. For example, Interrogatory No. 15 here. All of these -- a lot of these requests deal with very specific information. We've tried to use the database that Mr. Boise refers to to find the information. We've been unable to do so. That's why we're addressing it here in these interrogatories.

For example, Interrogatory No. 15 states, "With respect to the document produced by Lilly in the Zyprexa MDL with beginning Bates No. ZY," and it's got the specific number there, "which notes in the second question and answer that the FDA told Lilly it believed there was a causal relationship between the use of Zyprexa and the development of diabetes, please, A, identify the representative of the FDA who informed Lilly that the agency believed there was a causal relationship; B, identify the employees or representatives of Lilly to whom that statement was made; C, state the date on which the statement was made; and D, identify all documents

which relate to or refer to or embody the communication from the FDA that it believed there was a causal relationship between the use of Zyprexa and the development of diabetes."

They give their laundry list of objections, and then at the end they say, "Subject to and without waiving these objections, Lilly will respond to this interrogatory by making available documents contained in Lilly's MDL collection concerning interactions with the FDA upon entry of an appropriate protective order."

Well, we haven't seen anything, Your Honor. We're asking very specific questions about very specific documents which make very specific statements.

DISCOVERY MASTER: Is your answer, Mr. Boise, we can't find that any easier than you can; or we'll make it -- we know where it is. We know where these documents are, and we'll make them -- or know how to answer these questions, and we'll do that subject to the MDL protective order?

MR. BOISE: Yeah, I mean, I think it's the former articulation. I mean, for us to go through and look at documents and locate -- there is documents around that material and around that

particular document that Mr. Suggs references. They can look at the context of those documents like we can look at the context of those documents.

MR. SUGGS: They could go to the author of that document who wrote that the FDA had told Lilly that they thought they believed there was a causal relationship, and they could ask that person these questions. You know, who in the FDA said that? When did they say it? Who did they tell this to? I mean, that's what we're asking for in these answers to interrogatories. Or pardon me. That's what we're asking for in these interrogatories. They're very specific questions. They have got control of these people. We don't.

Interrogatory No. 16 is the similar kind of thing, "With respect to the document produced by Lilly in the Zyprexa MDL with beginning Bates No.," and has a very specific number there, "which refers to an endocrine advisory board, A, identify the members of the endocrine advisory board referred to in the document. State whether there was a meeting of the endocrine board which preceded the creation of the document and formed the basis for its creation. And if so, state the date of the meeting, identify the members who attended the meeting, identify the

employees or representatives of Lilly who attended the meeting, and identify all documents relating or referring to the endocrine advisory board."

And their answer is, they give us all these objections and say, "Subject to and without waiving these objections, Lilly will respond to this interrogatory by making available documents contained in Lilly's MDL collection related to the endocrine advisory board."

Well, where are they?

MR. BOISE: And the endocrine advisory board that he references has been the subject of discovery and production and depositions in the MDL for which Mr. Suggs took. I mean, I --

MR. SUGGS: Well, then why have you not answered this interrogatory?

DISCOVERY MASTER: Hold on. Hold on. Hold on. Are you telling me that it's just as easy for Mr. Suggs to find that information as it is for you?

MR. BOISE: Yes.

MR. SUGGS: That's not a correct statement.

MR. BOISE: I mean -- well --

DISCOVERY MASTER: I'll let you respond, Mr. Suggs.

MR. BOISE: That's fair, and I would certainly if -- what I hadn't heard before, frankly, was that there was an effort to look, that it wasn't -- that information wasn't available to you, that you couldn't have, and I'm certainly prepared to have an ongoing dialogue with you, David, about issues that you say, "You know what? We've made efforts to look at this stuff, and we're not finding it." Just as I asked Mr. Steele to help me with information that he said was already produced in the Medicaid database that we don't see.

So perhaps this is one where we can have further discussion on. I don't object to that, having further discussions and helping you get information if it's not -- if you're having trouble finding it.

MR. SUGGS: The discussion needs to be with your people and to find out from these people who -- you know, where that -- what that information is.

For example, Interrogatory No. 17. It says, "With respect to the document produced by Lilly in the Zyprexa MDL," with the Bates number, "which notes that Lilly's advisors had informed the company that it looked foolish taking the position that there is no differential risk of diabetes among atypical

antipsychotics in spite of the differences in weight gain, please identify the advisors who so informed Lilly, identify the Lilly employees or representatives who were so informed, and identify all documents relating or referring to or embodying any communication with or from Lilly's advisors that the company looked foolish taking the position there was no differential risk of diabetes."

I mean, if you look at this document, you will see that this is a document that's a memo written by somebody who made those statements that our advisors are telling us we look foolish. So we're asking, "Okay. Who were those advisors? When did they say it?" And, you know, we get this response with, you know, all your general objections, and you say -- finally you conclude by saying, "Lilly will respond to this interrogatory by making available documents contained in Lilly's MDL collection."

MR. BOISE: You know, David, I don't --

MR. SUGGS: These are -- this is very base --

DISCOVERY MASTER: Finish your argument so Mr. Boise can respond.

MR. BOISE: You know, I don't object to

going to the source for documents where there is an individual and answering this question. I don't object to going back and seeing if they can provide information. Whether they have it or not I can't speak to. But I don't object to getting that information.

MR. SUGGS: Well, see, the fact that you say that you don't know whether they have it or not tells me that you never even went to try and find that out in the first place.

DISCOVERY MASTER: All right. That's not really contributing to the argument. You're telling me you're going to go back through 15, 16, 17, 18 --

MR. BOISE: I'll go back through, and --

DISCOVERY MASTER: -- 19?

MR. BOISE: -- if there is information that can be responsive, if it's -- and see if we can obtain that information.

MR. SUGGS: And I don't know that we addressed 18, Your Honor, but that's a very critical interrogatory. There is a group within the company called the Global Product Labeling Committee, which is responsible for reviewing any label changes, which is clearly relevant to our failure-to-warn case.

And Interrogatory 18 asks them to,

"Identify any and all members of the Global Product Labeling Committee from October of 1996 to the present and for each, state the following: A, whether the member was an employee of Lilly. B, if the member was an employee of Lilly, state the dates of membership on the Global Product Labeling Committee and the employee's position or title. C, if the member was not an employee of Lilly, state the member's relationship to Lilly and the member's capacity or relationship to the committee."

Again we get the same type of, you know, general objections, and they say that upon entry of an appropriate protective order, Plaintiff may have access to the MDL collection, which includes documents containing information responsive to this category.

But as I pointed out before, the MDL production was only from particular individuals, 60 of them, and I don't know if those people were on the Global Product Labeling Committee or not, which is the whole purpose of this interrogatory, is to find out who the members of this central, very key committee were so we can find out do we have all their documents.

It may be that every one of the members of

the global product committee from 1996 to the present was included in that group of 60 people from whom they produced documents. I doubt it. But, you know, we would like to find that out.

DISCOVERY MASTER: As to 19, Mr. Boise.

MR. BOISE: There certainly has been Global Product Labeling Committee documents produced and it's been the subject of testimony. I will confirm for you - I can't represent here - that the secretary or the maintainer of the documents was among the individuals that were in the list of the MDL collection and could try to confirm that for you to alleviate some of these concerns.

DISCOVERY MASTER: All right. I misspoke. We were speaking about No. 18, not 19, just so the record here is clear.

MR. BOISE: Thank you.

DISCOVERY MASTER: All right. That's the State's first motion, correct?

MR. SUGGS: That's the first motion.

DISCOVERY MASTER: Mr. Sanders.

MR. SANDERS: We obviously disagree about a lot of things, but there is one thing we do agree on and the parties agree on, and that is we want to go to trial in March, and so in the spirit of keeping

that trial date for the parties that they both want so much, when are we going to get this stuff from Lilly?

DISCOVERY MASTER: Well, I have a list of things that you all have agreed to do, and I have some other things that I'm prepared to tell people to do, not everything that's on the table, and at the end of our proceeding today we're going to talk about deadlines.

MR. SANDERS: Okay. Great.

DISCOVERY MASTER: Let's take a break.

(Recess held.)

DISCOVERY MASTER: All right. We're back on record. You all resolved or were in the process of resolving some things over the break, so let's put those resolutions on, and then we'll move forward.

MR. BOISE: Sure. There was a pending dispute concerning the length of time for Lilly's notice of deposition for a 30(b)(6) witness and whether that would be limited to nine hours. Lilly has agreed to, in good faith, attempt to complete the deposition in nine hours, and the State has agreed not to call time in bad faith should the questioning continue and need to go beyond nine hours. So we're all going to do our best to make the deposition as

expeditious as possible, recognizing that it's possible, in good faith, it may go beyond nine hours.

DISCOVERY MASTER: Mr. Marcum, is that right?

MR. MARCUM: Fair enough.

DISCOVERY MASTER: Okay. That was all. Anything else happened over the break that we need to know about?

MR. BOISE: Just to answer your question, I think the issues concerning the agent of the -- for the database, First Health, I think that's been fairly encompassed in my prior arguments, and unless Your Honor has questions concerning that that you want to pose, I think we've -- I think the point has been made on those.

DISCOVERY MASTER: All right.

MR. BOISE: On that data source.

DISCOVERY MASTER: So we've addressed all of the issues that you wanted to address in Lilly's motion?

MR. BOISE: That's correct.

DISCOVERY MASTER: One way or the other?

MR. BOISE: I think that's right, unless Your Honor has some questions concerning that motion

or those papers.

DISCOVERY MASTER: I don't.

MR. BOISE: And the other point I would make - I didn't talk to Mr. Suggs about this - would be there is I think two things left, which is the motion on Mr. Taurel's deposition, as well as the plaintiff's Second Motion to Compel.

I think that arguing the Taurel dep may potentially limit or narrow the issues focused on the State's Second Motion to Compel, as they're not wholly unrelated, and just ask that we take them in that order.

As I guess a point of convenience in addition to that, I think the logic is right. Mr. Lehner has been involved in issues concerning the Taurel dep and may have a timing issue if we go more than another hour and a half today, and that's another reason why I would ask that we take that out of turn.

MR. SUGGS: I believe my esteemed local counsel wanted to address at least the issue of whether we should take this up or not.

MR. SANDERS: Taurel's deposition.

DISCOVERY MASTER: All right. Mr. Sanders.

MR. SANDERS: Maybe I'm missing something in the procedure here, but if I understand what happened is that yesterday --

MR. LEHNER: Can I make one point? If we're going to discuss any of the substantive matters around Mr. Taurel's deposition, that this part would be done under seal. Our motion was filed under seal, and it involves matters of some confidence.

DISCOVERY MASTER: We're not getting to them yet. When we get to them, I'll ask State's lawyers what their position is, but right now we're just talking procedure. Okay. Mr. Sanders.

MR. LEHNER: Thank you very much.

MR. SANDERS: So procedurally, yesterday at five o'clock or 5:30, I had delivered to me a motion on the Taurel deposition. Not a motion for expedited consideration, a motion with nothing in support of it. And my position is that we should follow normal procedures, and if we're going to leap-frog through all these normal procedures that we usually have, motion, opposition, reply, if you want something said on expedited, it should be done, first of all.

Second of all, this is something that was ordered by Judge Rindner, and I'm not in favor of the notion that when Judge Rindner orders something be

done, that we get to come to you and try to get you to overrule Judge Rindner. I think the procedure is Judge Rindner issues -- you issue an order, we can appeal to Judge Rindner, but I don't think we can appeal to you from Judge Rindner's rulings, and so --

It's not ripe, as far as I'm concerned, and it shouldn't be heard by the Discovery Master. No offense to you. But it's -- they're asking Judge Rindner to change his order about the Taurel deposition.

This was the result of a motion we had to file to get it set up, that we've been trying to take his deposition for six months. And so if it's going to be heard, we think it should be heard by the trial judge.

MR. BOISE: Can I respond to procedure?

DISCOVERY MASTER: Yeah, respond in order to those two arguments.

MR. BOISE: Yeah. The case manager order which referred discovery matters to you provides for a provision for expedited hearing of matters, and my reading of the order also provides that issues concerning discovery are within your jurisdiction.

We're not asking you to upset an existing order or that Mr. Taurel's deposition not be taken

that has been ordered. We're simply asking for, under Rule 26(c)(7), that it be taken in a, quote, designated way. That is, that it be deferred for 30 more days for the reasons set forth in our inner motion, and that we look for ways to eliminate any perceived prejudice that could possibly accrue to the State when balanced against that.

So we believe that you are the person who has been vested with this issue in the first instance and that the procedure for filing and getting a matter on expedited hearing has been followed under the case management order.

There has been, by way of process, extensive discussions between many people on this side of the table and certain people on that side of the table over the course of several days trying to get this worked out. Given all of our presence here, given the deposition is noticed -- scheduled and was agreed upon scheduled for next week, the circumstances warrant that we try to have this resolved here and now if it at all possibly can be so resolved.

MR. JAMIESON: I did place calls and write e-mails to both Mr. Steele, Mr. Sanders and Judge Hensley yesterday advising that -- I mean, we were

still in ongoing discussions when those e-mails occurred.

So it's not like this came out of the blue as a total shock and surprise to anyone on the other side. We told them very clearly this issue was important, it was going to be -- we were going to try to raise it today. And so that's -- I think procedurally we've met certainly the spirit if not the letter of the case management order.

MR. SANDERS: Just point of clarification. The spirit of the -- what order are we talking about?

MR. JAMIESON: The protective order. We're getting a copy now. There is procedure called out there for emergency or expedited consideration. We've given adequate notice under those rules, under that order.

And once again, the very nature of what we're asking for is time-sensitive, and it's not coming as a surprise to anybody on your side of the -- or on the State's side of the table.

MR. SANDERS: Okay. Well --

DISCOVERY MASTER: Your response.

MR. SANDERS: It's coming as no surprise. Well, I don't know when -- I don't have my file in front of me because I wasn't -- I didn't expect to

have to argue this right now. But it was maybe six months ago when we first notified Lilly we wanted to take Taurel's deposition.

MR. SUGGS: It was back in January.

MR. SANDERS: January. So in January. And then they wouldn't allow us to, so we filed a motion which they opposed. We had hearing in front of Judge Rindner. Judge Rindner ruled in our favor and said you got to produce him within 45 days. Lilly then came to us and said we need 90 days. And we said okay, we'll give them 90 days. So we set the deposition. That's been set for months and months and months.

When Brewster says this was brought to our attention ahead of time, it's now ten days before the deposition is set to go, and first I heard about this was -- Brewster, when? When was the first time you talked to me about this?

MR. JAMIESON: It was after I talked to Joe several times and after other of my co-counsel had spoken with your co-counsel over the weekend and last week. So that was yesterday.

MR. SANDERS: Okay. So I wouldn't exactly call this I've known about it for a long time, because the first thing I knew about it was when I

got a call yesterday, so --

I don't think this is appropriate, what they're asking to do, procedurally. So that's -- I'm not going to go to the substance of it, but just -- if we have to go to the substance, I'm going to let somebody else argue it, but procedurally I'm opposed to it.

DISCOVERY MASTER: Just on the procedure, forgetting expedited hearings on things, I prefer following the formal procedures for shortened time, but I understand why the defendants wanted to hear that today since we're all here and we're all in the same room, and I'm here.

And I suspect that if somebody had filed a motion on shortened time with all the accoutrements, the same thing would have happened today that's going to happen today anyway, which is I'm going to turn to the plaintiffs and say: Can you respond to it? Can you argue it fairly? If you can't, how quickly can you argue it fairly? So that's my question.

MR. SANDERS: Let me just talk about procedure. I mean, again, I'm not aware of any rule or procedure that says when you file a motion, that you just file a motion, you make a lot of factual allegations without any support for it. And so I'm

not in a position to know because there is no factual allegations here except a memorandum. There is no affidavit supporting it, no affidavit from Taurel saying this is what's going on or anybody else at Lilly.

DISCOVERY MASTER: So my question to you is: Can you article the motion to continue fairly today; or if not, how much time do you need to argue the motion to continue?

MR. SANDERS: The substance of it?

DISCOVERY MASTER: Yes.

MR. SANDERS: If I had an affidavit, I would probably be ready to argue it today, or maybe Mr. Suggs would, but right now it's not a procedurally teed-up motion. There is no memorandum -- there is no -- there is a memorandum with no affidavits supporting the allegations in the memorandum. So --

DISCOVERY MASTER: Well, it's procedurally teed-up to the point where I need to know when you can fairly respond to the substance of the motion.

MR. SANDERS: With or without an affidavit? You're saying --

DISCOVERY MASTER: What kind of affidavits? Affidavit as to why it needs to be heard earlier or

an affidavit to support the substance of the motion?

MR. SANDERS: No, substance.

DISCOVERY MASTER: Okay.

MR. SANDERS: I'm beyond the procedure now. You're saying --

DISCOVERY MASTER: All right. You kind of went back there, take one more shot at it.

MR. SANDERS: No. I'm talking procedure in terms of a -- typically a motion has a --

DISCOVERY MASTER: Your complaint is that you don't have enough information to know how to oppose it; is that correct?

Well, let me tell you this. We're getting close to substance, but we're not there yet. I didn't understand really why you wanted a continuance, based on what you gave me. So if that's what you're saying, Sanders, then -- I didn't get enough information. So my question to the plaintiffs is --

MR. SUGGS: Your Honor --

DISCOVERY MASTER: -- how quickly can we respond to --

MR. SUGGS: -- I'm prepared to argue based on -- you know, as it stands right now -- I mean, we've almost been dancing around this issue. I mean,

the fact of the matter is the basic nature of our objection is there has been no showing of good cause.

We had the judge order that his deposition take place. We granted an extension of time to September 19 as an accommodation to Lilly and as an accommodation to the witness. And then last week I get a phone call from Mr. Lehner who said that they need to reschedule the deposition. And he said, you know, "We've got these three dates in October that we can offer."

And I said, "Well, glad to hear you got those dates, but why? Why are we doing this?"

And he said, "I don't know."

MR. BOISE: Well, let's -- if we're getting into substance, let's mark this portion.

DISCOVERY MASTER: I'm not sure we're there yet.

MR. BOISE: Okay. I don't know.

DISCOVERY MASTER: I want everybody to be careful.

MR. SUGGS: Okay. So anyway, I get this phone call from Mr. Lehner, he says, "We need to change the deposition."

I said, "Well, why George?"

And he said, "I don't know."

Well, that to me is just incredible. I said, "Look, before I agree to change the deposition, I want to know why, and then I can" -- I said, "I'm going to have to get back with my colleagues and find out from them, you know, what their view on this is." And I conferred with my colleagues, and it was our view that we -- look, this deposition was ordered. I've changed my schedule to accommodate Mr. Taurel before. I've had to modify my professional and personal obligations to have this deposition date of September 19, which was already an accommodation to him. And there has been no showing of good cause as to why the deposition should be postponed.

DISCOVERY MASTER: Let's go under seal at this point, and just so that, the words "confidential" and "under seal" sometimes have different meanings, we'll define that. Which means access to this by the lawyers and the Court only. Is that agreeable, access to this portion?

MR. SUGGS: Yes.

MR. JAMIESON: Can we further say that this portion of the transcript will not be transcribed for 30 days?

DISCOVERY MASTER: I don't think we're going to need it transcribed, frankly, so -- but

access to lawyers only without dissemination to anyone else.

MR. SUGGS: That's fine.

DISCOVERY MASTER: Other than clients, I guess. Is that what you want? Is that what you mean by under seal?

MR. BOISE: Yeah, just as earlier was what we were saying would have been part of a file, and it would remain under seal, under the same circumstances, under our protective order.

* * * * *

(Excerpt RE: Taurel Deposition bound under seal and under separate cover.)

* * * * *

DISCOVERY MASTER: And let's hear argument on that plaintiff's second motion -- State's Second Motion to Compel.

MR. SUGGS: Your Honor, this all stems from the March 28, 2007 letter from FDA. I don't know if Your Honor has had a chance to study that, but there

were a couple of things I wanted to point out about that.

First I'd like to point out to Your Honor that discovery in the MDL essentially was not after 2004.

MR. SANDERS: Can I say something timing-wise? Christiaan has got to get an airplane.

(Off record.)

MR. SUGGS: First off, I'd like to point out that discovery in the MDL essentially stopped after 2004. When we got this letter in 2007, it was submitted actually by Lilly's counsel to Judge Weinstein in the MDL in conjunction with the summary judgment motion, and I don't really quite know why they submitted the letter, but in fact they did. And it was at that time that we learned that apparently in the fall of 2006, FDA -- pardon me, Lilly had made several submissions to FDA regarding a combination drug known as Cymbyax which is a combination of Zyprexa and also Prozac.

The timing of those submissions are laid out in the first paragraph of the letter that's the subject of this motion. And part of that interaction that they were having with FDA at that time was to deal with the labeling for that combination drug.

And after reviewing the information, the FDA noted that: A primary concern with this application and the primary basis for our not taking a final action is our view that we lack important safety information needed to adequately update the labeling with all relevant risk information. In particular, we are concerned that the labeling is deficient with regard to information about weight gain, hyperglycemia and hyperlipidemia that is associated with the Olanzapine, O-L-A-N-Z-A-P-I-N-E, use - that's the same as Zyprexa - whether taken alone or in combination with fluoxetine. Which is the generic name for Prozac.

And then they noted that apparently Lilly had submitted to FDA some studies which showed basically that there was a tenfold increased incidence of hyperglycemia, not only in patients who were normal but also -- normal in terms of hyperglycemia, but also those who had elevated levels.

In fact, although the ratio, the tenfold difference, held true with respect to both groups, and the folks who had normal blood levels to start, theirs went up to about three percent incidence of hyperglycemia, and whereas if somebody already had

high blood glucose, about 50 percent of those patients went over the top and into the diabetic level, so hyperglycemia.

This is a stunning development for us in this litigation. It is very rare in either an epidemiology study or in a controlled clinical study that you would find an increased incidence of ten times due to a drug effect. That is very compelling evidence of causation.

As you can imagine, we want to get discovery of this. We wanted to get discovery of the studies that were done, which we have not had produced to us. We want to know who it was that did those studies. We want to get discovery of all the documents relating or referring to that study, including analyses and so on and so forth.

And the letter also addresses several other aspects. They noted that -- well, Mr. Boise has referred to a disclosure of the MDL confidential documents in the New York Times in, I believe it was January of 2007. And this letter to Lilly in March notes that apparently there had been a letter from FDA to Lilly asking what was happening with that New York Times article and asking questions about what was disclosed there. And Lilly had apparently

responded to that on February 20, 2007, and the FDA then responded that that letter, the February 20, 2007 letter, quote, has not been particularly helpful in addressing these concerns. So again the FDA was calling for more information.

So we want to get discovery of the information regarding those letters and the correspondence back and forth between FDA regarding the New York Times article. I mean, I can track through all the specific elements or the particulars of our requests regarding this, but basically we want to know everything, soup to nuts, about those studies showing the tenfold increased incidence of hyperglycemia that are referred to in here and also all the information regarding those communications back and forth between Lilly and FDA regarding the New York Times article.

We think all this information is clearly relevant, not only to our -- the issues of whether Lilly's labeling was adequate or not -- in fact, I will note here that in the FDA's letter, they said that we do not feel that current labeling for either Cymbyax or Zyprexa provides sufficient information on these risks, referring to the risk of diabetes. Clearly this is relevant to our failure-to-warn

claim.

It is also relevant with respect to our claims of misrepresentation, unfair trade practices and so forth, and it's also highly relevant on the scientific issue of whether or not Zyprexa can cause diabetes, a fact which they deny. And this finding here of a tenfold increased incidence is very compelling evidence.

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

MR. BOISE: Okay. A couple of things. As Mr. Suggs noted, the -- Cymbyax is a distinct molecule from Zyprexa and accordingly has a distinct regulatory history. Producing everything, you know, soup to nuts, involving Cymbyax would be involving the production of supplemental new drug application, a voluminous document, an evolving document, one that goes over time involving a drug that is not at issue here. And in fact, I think in the reply briefing that I saw, maybe it was last Wednesday or Thursday, on this issue, plaintiffs -- I think the State claims they're not really interested in Cymbyax on that score.

In response to discovery requests by Lilly as to when the State knew -- had knowledge of the

fraud, the fraud being the misrepresentation about Zyprexa and whether it causes diabetes or misstatements to physicians, in interrogatory response No. 36, the State said, "Well, by the summer of 2005, we knew that -- we knew that there has been misrepresentations and that misrepresentation had caused injury," and therefore filed a complaint by 2006.

Certainly there could be no further reliance by the State on actions by Lilly when they were well aware of this claimed fraud and misrepresentation concerning the safety profile of the medication. If the State continues to, you know, permit reimbursement of the medication, it did so in full knowledge of the allegations of the fraud that they claim exists and full knowledge of those claims going back to 2005.

There was a date scope involved generally in litigation, and there is good reasons for them. I mean, with a medication that is still on the market, new documents are invariably going to be created every day, and there comes a point where you need to put a stake in the ground and say, "Here's where your discovery obligations end," so we can litigate and ask questions about the time period of relevance as

opposed to the time period that goes years past the time period in which the complaint here was filed.

In the prior litigation, that date was a full year after Lilly changed its label concerning Zyprexa and diabetes. So there was a label change of interest to the State in September of 2003. The State got to see and the MDL plaintiffs got to see for a full year after that label change the fallout and effect of that, and that's been the date scope that we have used.

That's not to say for any discrete issue there aren't issues that could potentially be relevant, but as a general matter, having to engage in ongoing discovery obligations in this setting makes conducting discovery really impossible as new facts are going to be learned every day, just given the nature of the product and what we're talking about.

There was a response to the illegal leak of information that resulted in the December New York Times articles that Mr. Suggs references, and we certainly would be prepared, as that addresses Zyprexa, to produce that information. But to have an ongoing obligation for information that has yet to be created and then pretend that we have to go back and

take up positions and the like for facts not yet ever known just makes it intolerable to litigate.

Certainly the State knew of facts sufficient to file its Complaint, knew of facts claiming fraud and unlawful conduct alleged by the company, and, you know, really to go beyond that time period puts us in really one of the dilemmas that we are here.

So I think the date scope makes sense. I think if there are specific issues that we can zero in on that make sense to provide supplemental production -- we've always engaged in discussion and dialogue surrounding those issues and could so around those claimed New York Times response documents.

MR. SUGGS: Your Honor, can I briefly respond?

DISCOVERY MASTER: Yes, you can.

MR. SUGGS: This is a very, very targeted set of discovery that we sent to them. I mean, we're asking them very specific questions, and we're not asking for all of the Cymbyax regulatory materials. We're asking specifically for the studies that are specifically referenced in the second paragraph of that letter.

If you track through the order, the

proposed order that we have, I think you can tell that, you know, we're not on a fishing expedition here, and we're not saying, "Open up the doors. We want everything having anything to do with Cymbyax or Zyprexa since 2004." Everything that we've asked for is a very specific targeting relating to this letter, this particular letter, which they themselves, by the fact that they've been trying to delay Mr. Taurel's deposition because of the negotiations and the discussions going on about this letter, I think shows just how important and how critical that information is.

MR. BOISE: Just in brief response to that last point. In unsuccessfully arguing for the postponement of Mr. Taurel's deposition, we're prepared to produce what we think is otherwise not responsive, to take that issue completely off. I think the allegation is not well-founded. We have legitimate objections and concerns here, and, you know, deposition is going to go forward. Maybe there is facts that are -- these discussions could go on through 2008, 2009. We're going to open up discovery every time a new fact comes out concerning the medication that is subject to constant oversight by the FDA. And that's why we would ask for the date

scope and the second motion to be denied.

DISCOVERY MASTER: All right. Thank you. Other issues?

MR. SUGGS: Have we covered everything?

MR. LEHNER: Your Honor, could I just make one comment in going back to the prior -- not to ignore but --

DISCOVERY MASTER: This Mr. Lehner?

MR. LEHNER: -- so I make clear? If we go forward with the deposition on the 19th of Mr. Taurel, that it will be done under seal and with the adequate protections to ensure that whatever may be disclosed there relevant to the points that we've -- we're talking about are sufficiently protected and that we could have a transcript that would not be produced for 30 days or at least until some reasonable period after the deposition that matters might be more certainly certain.

DISCOVERY MASTER: As to under seal, I understand -- and I didn't bring that with me because I didn't think we were going to get in it. I only brought one bankers box of material.

I understand that Judge Rindner ordered that deposition under seal and restricted.

MR. LEHNER: Defendants, yes.

DISCOVERY MASTER: So are you asking in terms of that process anything more than that?

MR. LEHNER: That the transcript not be produced for -- at least until October 19.

MR. SUGGS: We have no objection to that.

DISCOVERY MASTER: All right. That will be --

MR. JAMIESON: That will be Lilly's court reporter that --

MR. BOISE: We use a service that would essentially agree.

MR. LEHNER: Yes, we will designate our court reporter and that the lawyers will be --

DISCOVERY MASTER: That will be the order. I'm not going to do that in writing, but we'll have a transcript of what we just talked about here. So that will be one of the limitations on the deposition.

MR. SUGGS: Okay.

MR. LEHNER: Thank you.

MR. BOISE: Mr. Jamieson wanted to speak to me outside the room for two minutes.

DISCOVERY MASTER: Sure. If not, the only other thing I think we need to take care of is I'm going to go back through things you all promised to

do and put some deadlines on them.

MR. LEHNER: Thank you, Your Honor. I appreciate you letting me participate on by phone today.

DISCOVERY MASTER: Sure. So we'll go off record.

(Recess held.)

DISCOVERY MASTER: Back on record. Are there any additional issues you all need to raise? Mr. Boise?

MR. BOISE: No, sir.

DISCOVERY MASTER: Mr. Suggs?

MR. SUGGS: No.

DISCOVERY MASTER: All right. Let's go. On the database, the State promised to do a couple, three things. One is -- and this is going to be pretty general, but we'll refer back to -- if you want specifics, we'll refer back to the transcript. You promised to do additional investigation, and if you found certain items in the database that are identified in the affidavit of Dr. --

MR. BOISE: Virnig.

DISCOVERY MASTER: Virnig, to produce them. And I'd like, you know, a deadline on that. I'd like also, to the extent you can't find things, to

describe what you did to try to find them in that same response.

And finally, you made the suggestion that you think there are some things in the database that's there and they can't find it. I want you to offer to help them find it, and we'll have a deadline on that as well.

MR. STEELE: I offered to help them find it, and I would be pleased with any deadline that you care to make.

DISCOVERY MASTER: All right. So on all three of those things, ten days. Can you do that?

MR. STEELE: Yes.

DISCOVERY MASTER: All right. All right. Getting near the end of the day, and I'm starting to be able to not read my notes. But, Mr. Boise, you promised to produce some additional things, and I'm not going to make a list, but you know what you promised. Can you do those in ten days as well?

MR. BOISE: Yes. The only caveat would be the interrogatories that we went through, I need to do some more investigation as to what's involved, but we'll push those in that time frame if at all possible. If I can't, I'll report back.

MR. SUGGS: Okay.

MR. STEELE: One thing on our ten days, if I have questions or need to seek clarity, may I do that with Mr. Boise? That would be my preference.

DISCOVERY MASTER: I would hope so.

MR. BOISE: I would hope so, too.

MR. STEELE: Okay.

MR. JAMIESON: We're getting a transcript by Friday. Okay.

MR. BOISE: Yeah. That will help.

MR. STEELE: Okay.

DISCOVERY MASTER: I had bigger plans, but I'm fading, so I'm not going to make any additional orders.

You were going to check with your client, Mr. Boise, on one issue?

MR. BOISE: Yes. That was the Interrogatory 19 involving government investigations, and I will have a response back to the Court and opposing counsel by the end of this week if at all possible.

MR. SUGGS: Okay.

MR. BOISE: Tomorrow is a travel day, Thursday is a religious holiday for me. So it may be the following Monday.

MR. SUGGS: Okay.

DISCOVERY MASTER: Yeah. For me, if you agree to produce it, tell me, so I don't deal with it. If you don't, just tell me briefly that you want a ruling on it.

MR. BOISE: I will do that as soon as I possibly can.

MR. STEELE: Is day one of my ten days, is that tomorrow and then so on?

MR. JAMIESON: Let's just pick a date certain.

DISCOVERY MASTER: Yeah. Pick a date. Pick a date.

MR. JAMIESON: Either the 21st or the 22nd.

DISCOVERY MASTER: We'll go with the 22nd.

MS. GIROLAMO-WELP: The 22nd is a Saturday.

MR. JAMIESON: It will be the 21st? That would be a Friday.

MS. GIROLAMO-WELP: 21st is Friday.

MR. JAMIESON: She's a savant. She can tell you the day of the week on any day you want.

MR. STEELE: Okay. Well, sometimes I'm an idiot, so that makes us a heck of a combo.

MR. BOISE: I'm personally unavailable that day. It's --

MR. STEELE: I'll talk to you in the meantime.

MR. BOISE: Right.

MR. STEELE: I'm just saying when we ought to be done. It's the 21st, I guess.

MR. JAMIESON: The 21st is definitely a Friday.

MR. BOISE: Right. If I ask for an accommodation if I have to be involved for that Monday, I'll just ask for it.

MR. STEELE: Yeah, sure.

MR. BOISE: It's a day I actually don't work.

MR. STEELE: Right. I just want to be able to talk to you because I don't know that you're continuing to have a problem unless you tell me, "I'm continuing to have a problem." So I'm just trying to get it done.

MR. BOISE: Right.

DISCOVERY MASTER: On State's Interrogatories 15, 16, 17 and 18, I'm going to order Lilly to answer those. Or if you cannot, explain what efforts you made to answer them and were unable to answer them. I'll explain the reasons when I put out a final order, but I want to give you a head

start on working on those, and we'll get 15 days for those. So that takes you up to the 27th. I'll just give you a date certain, 27th. That's not 15 days, is it? 27th is fine.

Anything else? All right. We're done.

(Proceedings concluded at 3:50 p.m.)

* * * * *

CERTIFICATE

I, DIANE M. BONDESON, Registered Professional Reporter and Notary Public in and for the State of Alaska, do hereby certify that the foregoing proceedings were taken before me at the time and place herein set forth;

That the proceedings were reported stenographically by me and later transcribed by computer transcription;

That the foregoing is a true record of the proceedings taken at that time; and

That I am not a party to nor have I any interest in the outcome of the action herein contained.

IN WITNESS WHEREOF, I have hereunto set my hand this FOURTEENTH day of SEPTEMBER, 2007.

Diane M. Bondeson, RPR
My Commission Expires 9/6/10

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October 10, 2007
Via Messenger

The Honorable Mark Rindner
Superior Court Judge
Alaska Court System
825 West Fourth Avenue, Room 638
Anchorage, Alaska 99501-2004

Re: *State of Alaska v. Eli Lilly and Company*
Case No. 3AN-06-05630 Civil

Dear Judge Rindner:

I agree with Brewster Jamieson's statement in his October 9, 2007 letter to you that Judge Weinstein's Order does not have any impact on the above-captioned case.

Very truly yours,

FELDMAN ORLANSKY & SANDERS

Eric T. Sanders

ETS/psc
cc – Brewster Jamieson

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 EXTENSION TO FILE OPPOSITION TO LILLY'S APPEAL FROM DISCOVERY MASTER'S ORDER

IT IS ORDERED that the plaintiff's Unopposed Motion for Extension of Time to File Opposition to Lilly's Appeal From Discovery Master's Order is GRANTED. Plaintiff shall have a one-day extension until Wednesday, October 10, 2007, to file its opposition to the Eli Lilly's Appeal from Discovery Master's Order.

ENTERED this 11th day of October, 2007.

BY THE COURT

Mark Rindner
Superior Court Judge

OCT 0 9 2007

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TEL: 907.272.3538
FAX: 907.274.0819

I certify that on 10/11/07 a copy of the above was mailed to each of the following at their addresses of record: Sanders j Jamieson

Administrative Assistant

Administrative Assistant

001801

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.	)	
	)	

UNOPPOSED MOTION FOR EXTENSION OF TIME TO FILE OPPOSITION TO LILLY'S APPEAL FROM DISCOVERY MASTER'S ORDER

Plaintiff, State of Alaska, by and through its counsel, Feldman Orlansky & Sanders, requests that this Court grant it a one-day extension to October 10, 2007, to file its opposition to Eli Lilly's Appeal from Discovery Master's Order.

DATED this 9th day of October, 2007.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
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AK Bar No. 7510085

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RICHARDSON, PATRICK, WESTBROOK
& BRICKMAN, LLC
H. Blair Hahn
Counsel for Plaintiff

Certificate of Service
I hereby certify that true and correct copies of Plaintiff's **Unopposed Motion for Extension of Time to File Opposition to Lilly's Appeal from Discovery Master's Order and [proposed] Order** were served by messenger on:

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

By MSummers

Date 10/09/07

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