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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

PLAINTIFF'S MEMORANDUM DESCRIBING ITS CLAIMS AND ITS PROOF

I. INTRODUCTION

The State of Alaska ("the State") filed this civil action on its own behalf against drug manufacturer Eli Lilly & Co. ("Lilly") for damages proximately caused to the State by Lilly's introduction of the defective drug Zyprexa into the State's Medicaid population. The State alleges that it has been and in the future will pay additional expenses for the medical care of Alaska's Medicaid population, because Medicaid recipients developed diabetes and diabetes-related illnesses as a direct result of ingesting Zyprexa. The State also seeks civil penalties for Lilly's deceptive Zyprexa marketing practices.

The State's complaint asserts five claims for relief: (1) violations of Alaska's Unfair Trade Practices and Consumer Protection Act (AS 45.50.471 *et seq.*); (2) strict products liability (failure to warn); (3) strict products liability (design defect); (4) negligence; and (5) fraud and negligent misrepresentation.

The court requested a brief recitation of the State's *prima facie* causes of action, and an outline of the proof that the State expects to produce to satisfy each element. Lilly has argued that, in order to prove its case, the State must present a large number of the affected Medicaid recipients and their prescribing physicians. This memorandum demonstrates that such proof is not necessary, and that the State may prove its claims using aggregate data and statistical, epidemiological, and endocrinological analyses.

The State did not file this action on behalf of a class of individuals or as an action in subrogation; it filed this lawsuit to recover its own monetary damages. Thus, the State need not rely upon evidence of injury to specific persons. Rather, the State can and will prove its own case through expert testimony based on scientifically derived statistical evidence of Zyprexa's effect upon the State's Medicaid population and the damages the State has sustained as a result of Lilly's actions.

II. BACKGROUND

In 1996, Lilly began marketing the prescription pharmaceutical drug Zyprexa as a supposedly safer alternative to older, conventional antipsychotic drugs such as

haloperidol and thorazine. Other companies developed similar drugs, and as a group these newer medications are often referred to as "atypical antipsychotics." During clinical trials it became apparent that Zyprexa (more so than the other atypical antipsychotics) caused patients to experience significant weight gain, which led to hyperglycemia and diabetes. When Lilly sought approval of Zyprexa from the FDA, Lilly failed to disclose fully the hyperglycemic and diabetic side effects it had observed. Ignorant of these dangerous side effects, the FDA approved Zyprexa for the treatment of schizophrenia, and later also approved it for the treatment of bipolar disorder. These are the only two indications for which Zyprexa ever received FDA approval.

Lilly initially marketed Zyprexa with no warnings or precautions regarding hyperglycemia or diabetes, choosing instead to bury any reference to those side effects by inaccurately characterizing them as "infrequent" events observed in clinical trials. Once on the market, however, many patients taking Zyprexa experienced significant weight gain and then developed diabetes and diabetes-related conditions, causing death in extreme cases. Though post-marketing adverse event reports of these conditions mounted, at no time did Lilly choose to warn physicians of them, or even mention them in the post-marketing events section of Zyprexa's label.

While outwardly denying any connection between Zyprexa and diabetes, Lilly's own doctors and executives internally acknowledged the link. Lilly's documents show

that, rather than warning physicians of the problem, Lilly instead focused on devising ways to broaden the market for Zyprexa and to evade any safety concerns the medical or regulatory community might have.

In 2000, Lilly launched a marketing campaign for the drug, entitled "Viva Zyprexa." "Viva Zyprexa" revolved around marketing Zyprexa to primary care physicians and family doctors who generally do not treat the serious psychiatric conditions for which Zyprexa is approved. Thus, instead of marketing Zyprexa to these physicians as a treatment for schizophrenia and bipolar disorder (the only conditions for which Zyprexa legally could be marketed), Lilly falsely touted the drug as "safe" and "efficacious" for a variety of symptoms and disorders, such as geriatric dementia and general malaise, the kind of symptoms that primary care physicians are more likely to see in their patients. As part of its marketing campaign, Lilly developed a number of fictional patient exemplars to illustrate to primary care physicians the type of nebulous and ill-defined off-label conditions it claimed Zyprexa could treat effectively. "Donna" was one such patient:

> Donna is a single mom in her mid-30s, appearing in your office in drab clothing and seeming somewhat ill at ease. Her chief complaint is, "I feel so anxious and irritable lately." Today, she says she's been sleeping more than usual and has trouble concentrating at work and at home.[1]

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[1] Taken from Lilly's promotional materials.

Regarding Zyprexa's safety profile, Lilly told physicians that weight gain on Zyprexa was a "therapeutic benefit." (The FDA later cited Lilly for misleading physicians and ordered Lilly to delete the claim that weight gain is a benefit.) Lilly also referred to weight gain on Zyprexa as "manageable" when it knew it was not. With regard to diabetes, Lilly avoided the issue altogether with physicians if possible. Lilly instructed its drug representatives that, if asked a direct question, they should provide answers that Lilly knew were false and tell physicians that there is no link between Zyprexa and diabetes, that diabetes occurs at comparable rates among all atypical antipsychotics, and that diabetes occurred at rates comparable to placebo in clinical trials.

As a result of Lilly's aggressive overpromotion of Zyprexa, prescriptions rose, along with Lilly's revenues. As the number of persons taking Zyprexa went up, so did the number of patients who suffered extreme weight gain, hyperglycemia, diabetes, and diabetes-related conditions. In September 2003, the FDA mandated that Zyprexa and all other atypical antipsychotic drugs include warnings regarding hyperglycemia and diabetes and recommendations for baseline and periodic blood glucose testing. Lilly finally communicated these warnings and recommendations to physicians in March 2004.

III. PROVING THE STATE'S DIRECT CLAIMS AGAINST LILLY: AN OVERVIEW

A significant portion of the Alaska residents who took Zyprexa for both approved and non-approved uses are recipients of the State's Medicaid program. Thus, the State

paid for thousands of prescriptions of a defective drug. Moreover, as a result of Zyprexa's defect, namely that it causes people to develop diabetes and diabetes-related conditions, the State must now provide life-long care to many Medicaid recipients who suffer these problems because they took Zyprexa. Thus, Lilly's misleading marketing proximately caused the State significant monetary damages. Under state law, the State of Alaska is authorized -- and indeed required -- to bring suit to recover its damages, and accordingly the State filed this action on its own behalf.

In order to prove its case and recover its damages, the State must prove only Lilly's liability for the State's own damages, not those of individual Medicaid recipients. The State's claim does not rest in the experience of the many individual Zyprexa users, but in the aggregate effect upon the State's Medicaid program. This effect can most easily and accurately be seen and measured through examination of the State's Medicaid data.

The State of Alaska maintains an immense database of information on the benefits it provides through its Medicaid program. This database contains basic information concerning the diagnosis and treatment of all recipients, consisting of reports made by doctors under state and federal law. Each doctor is required to indicate by code (International Classification of Diseases, Ninth Revision, or ICD-9) the reason for each

patient visit for which Medicaid is billed. The records in the database establish each recipient's diagnoses, what treatment was provided, and how much Medicaid paid.

By examining the database, the State can identify every Medicaid recipient who took Zyprexa, whether it was prescribed to treat an approved or off-label condition, and how much was paid to treat each condition. By comparing the group of Medicaid recipients who took Zyprexa against similar, properly controlled groups who did not take Zyprexa, the State can measure the increased incidence of diabetes in users of the drug, and thereby prove the number of diabetes cases within the Medicaid population that are directly attributable to Zyprexa. From its records, the State also can accurately calculate the increased costs it already has incurred to provide care for Zyprexa-related diabetes, and it can project the extra costs it will incur in the future to provide care for Medicaid recipients who developed diabetes and diabetic complications as a result of consuming Zyprexa.

Lilly may argue that the State must prove which specific cases of diabetes were caused by Zyprexa, but this is incorrect. For example, the State expects analysis of Alaska's Medicaid database to demonstrate that Zyprexa users are more than three times more likely to develop diabetes than a control group of non-users. This would be comparable to the scientifically and statistically sound data from other states that establish that Zyprexa use was directly responsible for a 370 percent increase in diabetes

cases in patients taking Zyprexa within those states' Medicaid population.[2] In this case, because individual patients are not seeking reimbursement, there is no need to prove which individuals within the Medicaid population comprise those who would not have developed diabetes without taking Zyprexa, as distinct from those who would have developed diabetes even without taking the drug. The State is responsible for all Medicaid patients who developed diabetes; it paid the extra costs for those whose diabetes is Zyprexa-related, and it can recover those costs by proving the total extra costs it incurred as a result of Lilly's marketing a defective drug.

A key point in this case, from the State's perspective, is understanding the difference between generic and specific causation. Generic causation refers to proof that an agent, for example a pharmaceutical drug, can or does cause a particular injury or condition in a population of individuals. Specific causation refers to proof that the agent proximately caused an injury or condition in a specific individual. As pointed out above, because the State seeks compensation for increased costs incurred within a population, the State's burden in this case is to establish generic causation in that population (i.e., the rate by which Alaska Medicaid recipients who took Zyprexa show an increased incidence

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[2] *See* Exhibit A, *Risk of Diabetes Mellitus Associated with Atypical Antipsychotic Use among Medicaid Patients with Bipolar Disorder: A Nested Case-Control Study,* PHARMACOTHERAPY (Vol. 27 No. 1 January 2007) at page 1, Measurements and Main Results.

of diabetes compared to the background rate of the disease in matched controls); the State does not need to prove specific causation in any particular individual in this population.

Use of statistical data to study the incidence and progression of disease within a particular population is known as epidemiology. Epidemiological data are routinely used to prove generic causation of injuries in tort litigation. In fact, there is likely no more widely used science in the courtroom than epidemiology, particular in toxic tort and products liability cases.[3] Epidemiologic evidence is often relied upon to establish or dispute whether exposure to a particular agent causes harm or disease.[4] Generally,

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[3] *See* Exhibit B, MICHAEL D. GREEN, D. MICHAEL FREEDMAN, & LEON GORDIS, REFERENCE GUIDE ON EPIDEMIOLOGY, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (2000) [hereafter "REFERENCE GUIDE"] at 335.

[4] *See, e.g., Siharath v. Sandoz Pharm. Corp.,* 131 F. Supp. 2d 1347, 1356 (N.D. Ga. 2001) ("epidemiological studies provide the primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or disease" (internal quotation omitted)); *see generally* Exhibit B, REFERENCE GUIDE at 335 n.5 (citing additional cases).

In a case involving the ingestion of aspirin in the development of Reye's Syndrome, the Court in *Tyler v. Sterling Drug, Inc.,* 19 F. Supp. 2d 1239 (N.D. Okla. ____), relied upon six factors set out in *General Electric Co. v. Joiner,* 522 U.S. 136, ___ (1997), for determining when reliance on epidemiological evidence is sufficient to prove causation: (1) the studies must be relevant and reliable; (2) the subject of the studies must be similar to the case on trial; (3) the authors of the study must be able to draw conclusions from the study; (4) the studies should suggest a link between the increase of the incidence of illness and exposure to the product at issue; (5) the studies should involve the product at issue; and (6) the studies should not show exposure to more than one potentially toxic product as a cause of the illness. Further, "the studies should not have too great an analytical gap between the data and the expert opinion proffered." Applying these

epidemiology that proves a relative risk of 2.0 or greater is acceptable evidence of generic causation and, even in some cases, specific causation.[5]

The use of epidemiology to analyze a state's Medicaid data to determine an increase in the incidence of diabetes in Zyprexa users is not novel. The methodology that the State will use in this case is comparable to that reported in a recently published study, *Risk of Diabetes Mellitus Associated with Atypical Antipsychotic Use among Medicaid Patients with Bipolar Disorder: A Nested Case-Control Study,* PHARMACOTHERAPY (Vol. 27 No. 1 January 2007).[6] The authors analyzed a data base of 45 million individuals from the Medicaid populations of seven states, compiling the ICD-9 codes of those recipients who took Zyprexa. Using the ICD-9 diagnosis codes, the authors identified patients who were prescribed atypical antipsychotics such as Zyprexa and who subsequently developed diabetes, and a control group that did not receive these drugs. The authors refined the data by controlling for confounders such as age, sex, psychiatric

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standards, the Court found that the epidemiological studies relied upon demonstrated a connection between aspirin and Reye's Syndrome. The State's evidence will satisfy these standards.

[5] *See* Exhibit B, REFERENCE GUIDE at 384 (stating that a "relative risk greater than 2.0 would permit an inference that an individual plaintiff's disease was more likely than not caused by the implicated agent" and that a "substantial number of courts" accept this reasoning); *see also id.* at nn.39-40 (citing cases).

[6] A copy of this study is provided as Exhibit A.

and medical comorbidities, and concomitant drugs that increase a patient's risk for diabetes. Based on standard statistical analyses, the authors demonstrated that there is a statistically significant increased risk of diabetes[7] in patients treated with Zyprexa. Similar studies involving other drugs have been conducted upon the Medicaid population of California.[8]

The State has retained the necessary experts to examine the Medicaid database and to conduct a similar, Alaskan study, using the same epidemiological methods to determine Zyprexa's effect on Alaska's Medicaid population. This study will show the extent to which diabetes and diabetes-related illnesses increased among Zyprexa users in Alaska's Medicaid population. It is expected that the results of this study will be similar to all previous studies -- a marked increase in diabetes among Zyprexa users.

To quantify its damages, the State will use the science of endocrinology, which studies the long-term effects of diabetes and its related diseases. The progression of diabetes is well-studied. For example, based upon numerous studies of diabetes, if a population of 1000 diabetics is tracked statistically, it is a medical fact that a certain percentage of that group will eventually suffer from blindness as a consequence of the

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[7] The authors determined a "Hazard Ratio" of 3.7, meaning a Zyprexa user is 3.7 times more likely to develop treatment emergent diabetic complications. *See* Exhibit A.

[8] *See* B.L. Lambert, C.H. Chou, K.Y. Chang, E. Tafese, & W. Carson, *Antipsychotic exposure and type 2 diabetes among patients with schizophrenia: a matched case-control study of California Medicaid claims,* PHARMACOEPIDEMIOL DRUG SAF 2005,14:417-25.

diabetes, a certain percentage will suffer a heart attack as a result of diabetes, etc. Endocrinological analysis will assist the State in quantifying these effects in the Zyprexa-diabetic population.[9]

Finally, the State will rely upon a economic model, scientifically derived, which calculates the increase in costs related to diabetes and diabetic complications for the given population. Together, the endocrinological and economic analyses will prove the State's monetary damages due to the increase in diabetes among Medicaid patients who took Zyprexa.

IV. PROVING THE STATE'S CLAIMS AGAINST LILLY: A CLAIM BY CLAIM ANALYSIS

The State's complaint alleges claims for strict products liability for design defect; strict liability for failure to warn; violations of the Alaska Unfair Trade Practices Act; negligence; and fraud. These causes of action and the State's intended proof are addressed in turn in the following sections.

A. Strict Products Liability -- Design Defect

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[9] Some examples of epidemiological studies involving endocrinology include T.L. Gary, L.R. Bone, M.N. Hill, D.M. Levine, M. McGuire, C. Saudek, & F.L. Brancati, *Randomized controlled trial of the effects of nurse case manager and community health worker interventions on risk factors for diabetes-related complications in urban African Americans,* PMID:12799126; A. Adeniyi, A.R. Folsom, F.L. Brancati, M. Desvorieux, J.S. Pankow, & H. Taylor, *Incidence and risk factors for cardiovascular disease in African Americans with diabetes: the Atherosclerosis Risk in Communities (ARIC) study,* J NATL MED ASSOC. 94(12):1025-35 (Dec. 2002). Plaintiff will use the same methods relied upon by these peer-reviewed articles.

Under Alaska law, if Lilly marketed a defectively designed drug, it may be held strictly liable for the damages suffered by the State, regardless of Lilly's intent or the source of the drug's defects.

> The focus of attention in strict liability cases is not on the conduct of the defendant, but rather on the existence of the defective product which causes injuries. Liability is attached, as a matter of policy, on the basis of the existence of a defect rather than on the basis of the defendant's negligent conduct.[10]

"A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being."[11] Thus, upon a demonstration that Zyprexa was defective in design and that the defect is the proximate cause of the State's damages, Lilly must be held strictly liable for those damages.

In its case, the State will prove that Zyprexa is defective in design, in that it causes serious injuries when used for its intended purpose. In other words, when Zyprexa is prescribed and ingested as recommended by Lilly, Zyprexa causes significant side effects that imperil the health of users and increase the State's costs for these patients' treatment. As a result of the design defect, the State has suffered damages and will continue to

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10 *Shanks v. The Upjohn Co.*, 835 P.2d 1189, 1199 (Alaska 1992).

11 *Clary v. Fifth Ave. Chrysler Center,* 454 P.2d 244, 247 (Alaska 1969).

suffer damages stemming from the extra cost of medical care required by Alaska Medicaid recipients who used Zyprexa.

The preceding section of this memorandum outlined the way the State will prove causation and damages. The following sections outline the two ways in which the State will prove that Zyprexa was defectively designed. The Alaska Supreme Court has recognized two ways to establish a design defect in a drug.[12] These prongs are independent; only one need be proved to establish design defect. The State is prepared to prove both.

1. Zyprexa failed to perform as safely as an ordinary doctor would expect when used by patients in an intended and reasonably foreseeable manner.

Under Alaska law, if a prescription drug does not perform as safely as an ordinary doctor[13] would expect it to perform when used by his patients in the intended manner, the drug is by law "defective," and the manufacturer of the drug is strictly liable for any damages proximately caused by such use of the drug.[14] The "ordinary doctor's expectation" is an objective standard. Just as courts do not expect testimony from the

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12 *See Shanks,* 835 P.2d at 1194-95.

13 The *Shanks* Court explained that when dealing with prescription drugs, it is the expectation of the prescribing physician -- and not the patient -- that must be considered in this test. *See id.* at ___.

14 *See id.* at __.

man on the street to discover the views of a "reasonable man," so the State will not offer (and the court should not allow defendants to offer) testimony from individual "ordinary physicians." Rather, the State will rely on expert testimony and documentary evidence to prove that the "ordinary doctor" would expect a drug that was marketed for the safe treatment of an illness to treat that illness safely (both for approved conditions and for off-label conditions for which the drug was promoted). In this case, the evidence will establish that ordinary doctors did not expect that Zyprexa had side effects that placed patients at risk of developing lifelong debilitating illnesses. Documentary evidence will corroborate the expert testimony by showing that, when Zyprexa's problems were revealed, fewer doctors prescribed it.

The State's evidence that Zyprexa did not perform as safely as expected when used by patients in the intended and reasonably foreseeable manner will include:

1) Scientific, epidemiological evidence that Zyprexa carries a significant risk of diabetes, several times that of the normal population, which was unexpected by the ordinary doctor;

2) Statistical evidence from Japan showing that new prescriptions went down by approximately 75%, after Lilly was forced to issue full warnings of the drug's risk;

3) Epidemiological evidence showing that once adequate warnings were given in the United States regarding Zyprexa's risks, physicians' prescribing practices changed and the number of prescriptions went down;

4) Evidence from Lilly's own documents demonstrating that when the link between Zyprexa and diabetes became known, or when adequate warnings were given, the number of prescriptions decreased;

5) Internal Lilly documents discussing the fact that, if the connection between Zyprexa and diabetes were known, physicians would generally not prescribe the drug off-label, because they would be required to subject their patients to regular blood-glucose monitoring;

6) Lilly marketing materials instructing the sales force to avoid the diabetes issue, thereby actively seeking to eliminate the risk of diabetes from the "ordinary doctor's" risk-benefit analysis;

7) Expert testimony about the reasonable expectation of the ordinary doctor with regard to safe performance of a drug that is unaccompanied by adequate warnings.

This evidence will be more than ample to establish that the medical community did not expect Zyprexa's side effects, and will more than adequately satisfy the standard of proving a defective drug as set forth by the Alaska Supreme Court in the first test in *Shanks*.

2. Zyprexa's defect, the increased risk of diabetes, proximately caused the State's damages, and on balance the benefits of Zyprexa's design do not outweigh its inherent risk of danger.

The second method of proving pharmaceutical design defect under *Shanks* is to show that the design of the drug proximately caused the plaintiff's damages, and the

defendant fails to prove that the benefits of the drug outweigh the inherent risks of its design.[15]

In *Shanks,* the Alaska Supreme Court articulated a multi-factored test for the trier of fact to consider when deciding whether a drug's benefits outweigh its risks. Those factors are:

- The seriousness of the side effect;
- The likelihood that the side effect will occur;
- The feasibility of an alternative design that would eliminate or reduce the side effect without reducing efficacy;
- The harm of an alternative design in reduced efficacy or new side effects; and
- The seriousness of the condition for which the drug is indicated.[16]

The State's evidence, much of it already developed in the Multi-District Litigation ("MDL"), will be sufficient to refute any evidence that Lilly presents on the risk/benefit balance. The evidence will include:

1) Epidemiological and endocrinological evidence addressing the seriousness of Zyprexa's side effects, including that the use of Zyprexa requires constant monitoring and carries significant risks of hyperglycemia, diabetes, and diabetic complications such as blindness, amputation, and death;

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15 *See id.* at __.

16 *See id.* at 1196-97.

2) Epidemiological evidence showing that the likelihood of the side effect -- developing diabetes as a result of taking Zyprexa -- is high, with studies indicating that Zyprexa users are three to four times more likely to develop the disease than non-users;

3) Expert testimony that alternative drugs effectively treat schizophrenia and bipolar disorder and do not carry risks similar to Zyprexa;

4) Expert testimony that alternative drugs effectively treat the off-label uses for which Zyprexa was marketed and do not carry the same serious side effects.

That the risk/benefit balance did not justify marketing Zyprexa will be particularly easy for the State to show with respect to the off-label uses for which Lilly promoted Zyprexa. For the many individuals who were prescribed Zyprexa for treatment of depression, anxiety, geriatric dementia, general malaise, and countless other maladies as a result of Lilly's "Viva Zyprexa" marketing campaign, the drug carried no benefit whatsoever. There are many other efficacious alternative drugs that have been approved for these conditions and they do not carry the serious diabetes-related side effects.

As the above sections show, under either prong of the *Shanks* test, the State's proof of Lilly's liability for damages caused by a design defect does not require the testimony of numerous patients or physicians.

B. Strict Products Liability -- Failure to Warn

The Alaska Supreme Court explained the basis for a strict liability claim for failure to warn as follows:

> Under a strict liability failure to warn theory, if the plaintiff proves the product as marketed posed a risk of injury to one who uses the product in a reasonable and foreseeable manner and the product is marketed without adequate warnings of the risk, the product is defective. If such a defect is the proximate cause of the plaintiff's injuries, the manufacturer is strictly liable unless the defendant manufacturer can prove the risk was scientifically unknowable at the time the product was distributed to the plaintiff.[17]

In evaluating the effectiveness of a warning, adequacy is generally evaluated with the following factors in mind: (1) whether the scope of risk or danger posed by the product is clearly indicated; (2) whether the extent or seriousness of harm resulting from the risk or danger is reasonably communicated; and (3) whether the warning is conveyed in a manner likely to alert a reasonably prudent physician.[18] In the context of prescription drugs, the warning should be sufficient to put an ordinary physician on notice of the nature and extent of any scientifically knowable risks or dangers inherent in the use of the drug.[19] The State will present evidence that clearly demonstrates Lilly was well aware of Zyprexa's association with hyperglycemia and diabetes and its related complications before the drug was introduced to the market, and thus Lilly should have warned about the risk of that serious hazard from day one. It should be undisputed that Lilly did not provide these warnings until forced to do so by the FDA.

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17 *Id.* at 1200.

18 *See id.*

19 *See id.* (citing *Polley v. Ciba-Geigy Corp.*, 658 F. Supp. 420 (D. Alaska 1987)).

The State's proof for this cause of action is much the same as already outlined above for other claims:

1) The State will prove the product poses a risk of severe harm by using Lilly's own documents that establish Lilly knew that, when used as recommended by Lilly, Zyprexa causes weight gain and is associated with diabetes and diabetic conditions;

2) The State will show the lack of adequate warning through expert testimony and by demonstrating the 75 percent drop in new prescriptions when proper warnings were given in Japan, as well as the drop-off in prescriptions in the United States after warnings were provided;

3) The State will prove that the defects in Zyprexa proximately caused the State's injuries using epidemiological data for Alaska's Medicaid population, which should align with other studies that establish a three- to four-fold increase in diabetes among Zyprexa users as compared to a control group;

4) The State will show that the risk of diabetes was not only scientifically knowable but was actually known by Lilly, using internal documents in which Lilly executives discussed the diabetes problem; and

5) The State will quantify its damages through endocrinological and economic models, as discussed above.

Again, the State can meet its burden of proof on all elements of a *prima facie* case without relying on testimony from individual physicians or patients.

C. Violation of Alaska's Unfair Trade Practices Act

The State must prove two primary elements to establish a *prima facie* case of unfair or deceptive acts or practices under the Act: (1) that the defendant is engaged in

If successful in proving any of these violations, the State may collect three times its actual damages.[24] As discussed in preceding sections, the State will prove its actual damages by showing that, due to Lilly's misrepresentations and other unfair acts, physicians prescribed Zyprexa in situations where they otherwise would not have prescribed the drug, and, without the misrepresentations, the incidence of diabetes in Medicaid patients would have been much less. Further, there would have been less direct cost to the State, as the drug would have been used only for the very limited indications for which it is approved. Through epidemiological and endocrinoligical studies, and statistical and aggregate data about the Medicaid population, the State can quantify its actual damages. Once again, testimony about any individual consumer of the drug is not required to meet any portion of the State's burden of proof under this cause of action.

D. Negligence

The tort of negligence consists of four distinct elements: (1) duty, (2) breach of duty, (3) causation, and (4) damages.[25] The existence and extent of a duty is a question of law.[26] "The concept of 'duty' in negligence encompasses a broad range of policy

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24 *See* AS 45.50.531(a).

25 *See, e.g., Lyons v. Midnight Sun Transp. Servs., Inc.,* 928 P.2d 1202, 1204 (Alaska 1996).

26 *See, e.g., Mulvihill v. Union Oil Co.,* 859 P.2d 1310, 1314 n.4 (Alaska 1993).

bringing about the injury."[29] As discussed above, the State will prove that Lilly's negligence was the proximate cause of its injuries through expert testimony and epidemiological evidence. For the reasons discussed above, the State only needs to prove the extent of damages caused by Zyprexa to the group of Alaska Medicaid patients as a whole, and need not identify each individual patient who developed diabetes as a result of taking Zyprexa. The State will prove its claim by showing that, as a direct result of Lilly's failure to include warnings of Zyprexa's side effects in the United States, Alaska Medicaid recipients suffered numerous injuries for which the State has been and will be financially responsible. The expert testimony and epidemiological evidence are more than sufficient to demonstrate that Lilly's conduct was a substantial contributing factor in bringing about the State's damages. The State's damages, as discussed above, are the past, present and future costs of treating Medicaid recipients with diabetes and diabetic conditions who would not have developed these conditions had they not been prescribed Zyprexa.

E. Fraud

In Alaska, "[t]he elements for a cause of action for knowing misrepresentation or deceit include: a false representation of fact, scienter, intention to induce reliance,

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29 *P.G. v. State,* 4 P.3d 326, 334 (Alaska 2000).

justifiable reliance, and damages."[30] Scienter means that the defendant know the falsity of the representation.[31] Specific intent to deceive is not required; rather, it is sufficient that the defendant have reason to expect that its false statement will influence the other's conduct.[32]

To prove its fraud claim, the State will present evidence to show that Lilly represented Zyprexa as safe and effective for a variety of conditions, knowing that it was not safe and expecting and intending that others would rely on that false representation. As outlined above, the State will show that Lilly's fraudulent misrepresentations about Zyprexa and its side effects were the proximate cause of damages to the State and its Medicaid program. Key evidence on the fraud claim will include:

1) Lilly's own internal documents and marketing materials showing that its marketing campaign to doctors -- including Alaska doctors -- contained false representations about Zyprexa's design, risks, and side effects;

2) Lilly's internal documents showing that Lilly was aware of Zyprexa's risks and side effects at the time it was issuing misleading marketing materials to physicians, and knew that the marketing materials were misleading in nature, thus satisfying the scienter requirement;

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30 *Barber v. National Bank of Alaska*, 815 P.2d 857, 862 (Alaska 1991).

31 *See City of Fairbanks v. Amoco*, 952 P.2d 1173, ____ n.4 (Alaska 1998).

32 *See Lightle v. State Real Estate Comm'n,* 146 P.3d 980, 984 (Alaska 2006).

3) Lilly's internal documents and marketing materials that instructed its sales representatives to shun discussion of Zyprexa's diabetes-related side effects and to misrepresent that connection so as to induce physicians to rely on Lilly's positive promotions and to prescribe Zyprexa to their patients, demonstrating the intent to induce reliance;

4) Expert testimony that physicians justifiably relied upon Lilly's misrepresentations as the drug manufacturer;

5) Statistical evidence, including Lilly's own internal documents, showing that when the misrepresentations were made, prescriptions went up, yet when Lilly began to issue adequate warnings, prescriptions decreased, demonstrating that physicians as a whole relied upon the misrepresentations, and altered their prescribing practices once those misrepresentations were revealed; and

6) Damages in the form of increased costs of medical care for the affected Medicaid population, as described throughout this brief.

Lilly well knew, when it instructed its drug representatives to make fraudulent misrepresentations to Alaska physicians, that the State was by far the largest purchaser of Zyprexa, as well as the purchaser of much of the medical care that would be required by patients who developed diabetes after using Zyprexa. Lilly also knew that its misrepresentations were inevitably going to damage the State's Medicaid department through the purchase of Zyprexa for Medicaid patients. These facts establish that Lilly foresaw the harm to the State and that Lilly's fraudulent m isrepresentations are the proximate cause of the State's monetary damages.

As with each other cause of action, the State does not need testimony from individual physicians or patients to prove any element of this claim. The statistical, expert, and documentary evidence that the State will present amply addresses the question of justifiable reliance on Lilly's misrepresentations within the medical community. Statistical and expert testimony will prove the State's damages.

IV. NATURE AND EXTENT OF THE STATE'S DAMAGES AND INJURIES

The preceding sections of this brief touch frequently on the nature of the State's damages, and how it intends to prove these damages; this section offers a few comments specifically focused on proving damages.

As plaintiff, the State must prove it damages by a preponderance of the evidence.[33] It must establish with "reasonable probability" the nature and extent of any future damages, which it can do by producing evidence that gives the jury "some reasonable basis upon which . . . [to] estimate with a fair degree of certainty the probable loss which plaintiff will sustain in order to enable it to make an intelligent determination of the extent of the loss."[34] That there may be some uncertainty or difficulty in measuring the damage does not bar plaintiff's damage claim. It is necessary for the State to prove the *fact* of damages. However, "[o]nce the fact of damages has been proven to a reasonable

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33 *See Pluid v. B.K.*, 948 P.2d 981, 985 (Alaska 1997).

34 *See Lyndon Inc. v. Walker*, 30 P.3d 609 (Alaska 2001).

probability, the *amount* of such damages, on the other hand, need only be proven to such a degree as to allow the finder of fact to reasonably estimate the amount to be allowed for the item of damage."[35]

After demonstrating through epidemiological studies an increase in the incidence of diabetes related to Zyprexa use, the State will rely upon endocrinology, clinical literature, and treatment guidelines (introduced through expert witnesses) to demonstrate the amount of care occasioned by the increase in diabetes. Through the use of expert endocrinolgical testimony, the State will demonstrate the medical sequelae which may be expected once a patient develops diabetes. The State will prove through clinical literature and expert testimony the percentage of diabetics who go on to develop specific complications. Diabetes is a progressive disease. Experts will describe the care that is needed as a patient progresses from diabetic complication to diabetic complication.

Thus, the State will specify the annual and recurring resources associated with good medical practice to diagnose, treat, and manage patients with type-2 diabetes mellitus, pancreatitis, and other serious acute diabetic events as well as secondary injuries such as heart attack, stroke, blindness, and amputation. While medical experts may identify the complete "standard of care" for each type of complication, Medicaid only covers a portion of the tests, procedures, and resources needed in the standard continuum

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35 *Pluid,* 948 P.2d at 985.

of care. The State will seek compensation only for its actual costs. Billing and coding experts, therefore, will testify about the codes that identify procedures covered under Alaska's Medicaid program, and they will identify the rates that Medicaid pays to health care providers for the covered medical services.

Proving past damages is relatively straightforward. To prove future damages, actuaries and statisticians will testify from the State's records about the amount of time the average Medicaid recipient with the specific complications remains on the Medicaid rolls. Thus, the State will be able to calculate with reasonable certainty the amount of damages the State will suffer in the future as a result of the introduction of Zyprexa into the State Medicaid population. Once the State proves by a preponderance of the evidence that it has suffered and will suffer damages as a result of Zyprexa's introduction into Alaska's Medicaid population, it need only prove the amount of damages to such a degree as to allow the jury to reasonably estimate the amount to award. Yet again, the proof will be through expert witnesses and aggregate data. The State can prove its damages claim without presenting testimony by individual physicians or patients.

CONCLUSION

The evidence produced in the MDL proves the defectiveness of Zyprexa. Similar and additional evidence will be developed through discovery in this case. Epidemiological evidence proves the relationship between the established defect and the

damages suffered. Endocrinological evidence provides an explanation for the causal relationship between Zyprexa and weight gain, diabetes, and diabetic-related conditions. Further, experts in endocrinology explain the course and treatment of persons who contract diabetes as a result of taking Zyprexa. Thus, Alaska has more than ample evidence to prove its case in chief, and there is no need to take testimony from numerous doctors or Medicaid Recipients.

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DATED this 1st day of March, 2007.

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Certificate of Service
I hereby certify that a true and correct copy of **Plaintiff's Memorandum Describing its Claims and its Proof** was served by mail / messenger on:

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