IN THE ~~DISTRICT~~/SUPERIOR COURT FOR THE STATE OF ALASKA
AT ANCHORAGE

STATE OF ALASKA,

Plaintiff(s),

vs.

ELI LILLY AND COMPANY,

Defendant(s).

CASE NO. 3AN-06-5630CI

SUMMONS

To Defendant: Eli Lilly and Company

You are hereby summoned and required to file with the court a written answer to the complaint which accompanies this summons. Your answer must be filed with the court at 825 W. 4th Ave., Anchorage, Alaska 99501 within 20 days* after the day you receive this summons. In addition, a copy of your answer must be sent to the plaintiff's attorney, Eric T. Sanders, whose address is: 500 L Street, Suite 400, Anchorage, AK 99501.

If you fail to file your answer within the required time, a default judgment may be entered against you for the relief demanded in the complaint.

☒ This case has been assigned to Superior Court Judge Rindner.

☐ This case has been assigned to District Court Judge _____.

CLERK OF COURT

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3-1-06
Date

By: _____
Deputy Clerk

* The State or a state officer or agency named as a defendant has 40 days to file its answer.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

COMPLAINT

Plaintiff, the State of Alaska (hereinafter "the State"), hereby alleges for their Complaint against Defendant Eli Lilly and Company (hereinafter "Defendant" or "Eli Lilly") as follows:

JURISDICTION AND PARTIES

1. Jurisdiction over the subject matter of this cause of action is based upon AS 44.23.020 and 45.50.501, which grant the State authority to file suit against Defendant.

2. Personal jurisdiction over this Defendant is proper under the Alaska Long Arm Statute as codified in AS 09.05.015.

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3. Because the State of Alaska is not a citizen for purposes of diversity jurisdiction, no federal court can exercise subject matter jurisdiction over this case by virtue of diversity of citizenship.

4. Venue is proper in the Third Judicial District at Anchorage pursuant to Rule 3 of the Alaska Rules of Civil Procedure, in that many of the unlawful acts committed by Defendant were committed in Anchorage, including the making of false statements and misrepresentations of material fact to the State of Alaska, its departments, agencies, instrumentalities, and contractors, and to the Alaska Medicaid Program.

5. Defendant Eli Lilly and Company is an Indiana corporation with its principal place of business in Indianapolis, Indiana. At all times relevant hereto, Eli Lilly and Company was engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third parties or related entities, the pharmaceutical prescription drug Zyprexa (hereinafter "Zyprexa" or "the product"). At all times relevant to this action, Eli Lilly did business within the State of Alaska by marketing and selling Zyprexa within the State to both the State and its agencies, and to the general public.

ALLEGATIONS OF FACT

6. This is a civil action for damages and penalties arising from the marketing and sale of the prescription drug Zyprexa.

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7. Prior to selling Zyprexa, Lilly knew there was a risk of Zyprexa users developing severe and harmful health conditions including, but not limited to, hyperglycemia, acute weight gain, exacerbation of diabetes mellitus, and pancreatitis. Furthermore, Defendant has been aware of studies linking Zyprexa to these conditions, yet has failed to warn the Food and Drug Administration, the State, physicians, and consumers of these risks. This failure to warn the Food and Drug Administration of these known risks is relevant to Plaintiff's complaint.

8. At all times relevant to this action, Defendant has been responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling Zyprexa.

9. In 1996, the United States Food & Drug Administration (hereinafter "FDA") approved Zyprexa for use in the treatment of schizophrenia.

10. In 2000, the FDA approved Zyprexa for use in the short-term treatment of acute mixed or manic episodes associated with bipolar disorder.

11. In 2004, the FDA approved Zyprexa for maintenance in the treatment of bipolar disorder, also known as manic-depression.

12. Notwithstanding the limited uses approved by the FDA, Defendant advertised and sold Zyprexa for a number of non-approved or "off-label" uses including, but not limited to, Alzheimer Disease, Geriatric Dementia, Tourette's Syndrome,

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Pervasive Developmental Delay, Autism, Anorexia Nervosa, and general depression. This was in spite of the fact that no testing approved by the FDA had demonstrated the effectiveness of Zyprexa for such uses. Lilly recognized that the small number of psychiatric patients would provide an undesirably small market for the product. In a continuing effort to illegitimately receive greater profits from Zyprexa, Lilly's sales force concentrated on primary care physicians, rather than psychiatrists, and focused upon marketing and selling the drug as treatment for depression and anxiety, rather than the psychotic conditions for which Zyprexa had been approved. To this end, Lilly employed its immense marketing resources to encourage and promote sales for unapproved uses. Lilly made this effort even though it knew Zyprexa was not approved for treatment for those conditions.

13. Shortly after the Defendant began selling Zyprexa, the FDA began to receive reports of Zyprexa consumers developing hyperglycemia, acute weight gain, exacerbation of diabetes mellitus, pancreatitis, and other severe diseases and conditions. These conditions occurred not only in patients with the psychiatric conditions for which Zyprexa had been approved but also in the non-approved or "off-label" uses.

14. Beginning in 1998, scientific journals began to publish studies that established a causal association between using Zyprexa and developing or exacerbating diabetes mellitus (hereinafter "diabetes") and development of dangerously high blood

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sugar levels, also known as hyperglycemia. Studies have consistently continued to find a relationship between Zyprexa and these dangerous conditions.

15. In April, 2002, the British Medicines Control Agency warned about the risk of diabetes for patients prescribed Zyprexa. The agency reported forty known incidents of diabetes, hyperglycemia, diabetic ketoacidosis, diabetic coma, and one death among users of Zyprexa. Subsequently, the British government required Defendant to warn consumers about the risk of diabetes and diabetic ketoacidosis, and further required Defendant to instruct patients who were using Zyprexa to monitor their blood sugar levels.

16. In that same month, the Japanese Health and Welfare Ministry issued emergency safety information regarding the risk of diabetes, diabetic ketoacidosis, and diabetic coma for users of Zyprexa.

17. Defendant has failed to warn consumers in this country, including the State, about the serious risks of diabetes, hyperglycemia, diabetic ketoacidosis, and other serious conditions associated with the use of Zyprexa.

18. The Defendant knew, or was reckless in not knowing, of the risks involved in consuming Zyprexa. Furthermore, the Defendant has been aware of studies and journal articles linking use of Zyprexa with these and other severe and permanent diseases since 1998.

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19. Defendant failed to warn consumers, including the State, its physicians, and Medicaid recipients, of the dangerous and permanent health consequences caused by the use of Zyprexa. In fact, Defendant instructed its representatives to minimize and misrepresent the dangers of Zyprexa, affirmatively and consciously placing company profits above the public safety. This is particularly true of the prescriptions written for off-label uses. This failure to warn was designed and intended to maximize company profits, even after Lilly's own experts were questioning the safety of Zyprexa.

20. Beginning in the 1990s, Defendant's strategy has been to aggressively market and sell Zyprexa by willfully misleading potential users about serious dangers resulting from the use of Zyprexa. Defendant undertook an advertising blitz, extolling the virtues of Zyprexa in order to induce widespread use. This marketing campaign consisted of advertisements, telephone conferences, live conferences, direct promotional presentations to doctors and other healthcare providers, and other promotional materials provided directly to Zyprexa users. Defendant has also advertised the use of Zyprexa for off-label uses, including geriatric dementia, pediatric symptoms, and for general depression.

21. The advertising program sought to create the impression and belief by consumers and physicians that Zyprexa was safe for human use, and had fewer side effects and adverse reactions than other atypical antipsychotic medications. This was

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done even though Defendant either knew these representations to be false or had no reasonable grounds to believe them to be true.

22. The advertising program purposefully disguised the risks associated with Zyprexa use, including serious illness and death. Eli Lilly relayed only positive information and relied upon manipulated statistics to suggest widespread acceptability, while at the same time concealing adverse factual material, including relevant information of serious health risks from the State, physicians, and the general public. In particular, the advertising materials produced by Defendant falsely represented the severity, frequency, and nature of adverse health effects caused by Zyprexa. Further, they falsely represented that adequate testing had been done on Zyprexa. In particular, Defendant misrepresented that testing had been performed for off-label uses when if fact, no such testing had been done and the FDA had not approved Zyprexa for such uses.

23. As a result of Defendant's advertising and marketing campaign, Zyprexa has become one of Defendant's top-selling drugs, and has been prescribed to over 12 million people worldwide. In 2003, approximately seven million prescriptions for Zyprexa were dispensed, resulting in more than $2 billion in sales. In 2003, Zyprexa was the seventh largest selling drug in the country. In 2004, Zyprexa sales exceeded $4.4 billion.

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24. Shortly after Defendant began selling its product Zyprexa, it received reports of Zyprexa users developing severe and harmful health conditions including but not limited to, hyperglycemia, acute weight gain and associated cardiovascular risks, exacerbation of diabetes mellitus, and pancreatitis. These reports further confirmed known risks of Zyprexa. This information was knowingly withheld or misrepresented to the Federal Drug Administration, the State, and the general public. This information was material and relevant to Plaintiff.

25. In making Zyprexa available to Medicaid patients, Defendant knowingly misrepresented to the State of Alaska that Zyprexa was safe and effective. The State of Alaska allowed the purchase of Zyprexa for Alaska Medicaid recipients based upon such representations by Defendant.

26. Zyprexa has been 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. The State has thus suffered and will continue to suffer additional financial loss in the care of those Medicaid recipients who consumed prescriptions which were ineffective, unsafe, and actively

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harmful. In addition, the State has paid for Zyprexa prescriptions for uses which were not approved.

27. The State, as the financially responsible party and in its *parens patriae,* has the right to bring this suit.

FIRST CLAIM FOR RELIEF
(Strict Products Liability – Failure to Warn)

28. Plaintiff incorporates paragraphs 1 through 27 as if fully set forth herein.

29. Defendant is the manufacturer and/or supplier of Zyprexa.

30. The Zyprexa manufactured and/or supplied by Defendant was and is unaccompanied by proper warnings or packaging regarding all possible side effects associated with the use of Zyprexa. The Defendant failed to warn of the comparative severity, incidence, and duration of such adverse effects. The warnings given to the State, physicians, and the general public did not accurately reflect the signs, symptoms, incidents, or severity of the side effects of Zyprexa.

31. Defendant failed to adequately test Zyprexa. Such testing would have shown that Zyprexa possessed serious potential side effects to which full and proper warnings should have been made.

32. The Zyprexa manufactured or supplied by Defendant was defective due to inadequate post-marketing warnings, packaging, or instructions. After the manufacturer knew or should have known of the risks of injury from Zyprexa, it failed to provide

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adequate warnings to physicians, the general public, or the State as the prescribers, users, and financially responsible party, respectively. Further, Defendant continued to aggressively market Zyprexa for both approved and non-approved uses.

33. Defendant actually knew of the defective nature of Zyprexa, but continued to market and sell Zyprexa without proper warning, so as to maximize sales and profits, in conscious disregard for the foreseeable harm caused by Zyprexa.

34. As a proximate cause and legal result of Defendant's failure to warn of known and reasonably knowable dangers associated with the use of Zyprexa, the State has suffered and will continue to suffer damages as outlined in paragraph 26 above.

SECOND CLAIM FOR RELIEF
(Strict Products Liability: Design Defect)

35. Plaintiff incorporates paragraphs 1 through 34 as if fully set forth herein.

36. At all times material and relevant to this action, Zyprexa was defective in design and manufacture, and was so at the time it was prescribed by doctors participating in the State's Medicaid program. Zyprexa was defective and dangerous in that it caused serious injuries when used for its intended and foreseeable purpose, i.e., when ingested as prescribed and in the manner recommended by Defendant.

37. The defects in Zyprexa were known to Defendant at the time of approval by the Federal Food and Drug Administration. Such defects were concealed and withheld from the FDA. Disclosure by Defendant was inaccurate, incomplete, misleading, and

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fraudulent. Further, Defendant misrepresented and concealed the fact that Zyprexa was being used for off-label uses for which it had not been approved and was not known to be effective.

38. Defendant knew Zyprexa would be used by the consumer without inspection for defect and that the State, physicians, and medicinal users of Zyprexa were relying upon Defendant's representations that the product was safe.

39. Adequate post-approval testing would have revealed the further extent of the dangers of ingesting Zyprexa, and would have shown that the use of Zyprexa could cause extensive medical complications and costs for injuries relating to its use.

40. As a proximate and legal result of the design defect, as well as Defendant's failure to adequately test the product so as to discover the defect, the State has suffered and will continue to suffer the damages alleged in paragraph 26.

THIRD CLAIM FOR RELIEF
(Fraud and Negligent Misrepresentation)

41. Plaintiff incorporates paragraphs 1 through 40 as if fully set forth herein.

42. Defendant's warning of side effects associated with Zyprexa contained false representations and/or failed to accurately represent the material facts of the full range and severity of side effects and adverse reactions associated with the product. Further, Lilly fraudulently misrepresented the appropriateness of the suitability of Zyprexa for unapproved and off label uses.

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43. Defendant's claims and assertions to the Food and Drug Administration, the State of Alaska, physicians, and the general public regarding Zyprexa contained false representations as to the safety of Zyprexa and its defective design. Further Defendant's claims concerning off-label use were false and fraudulent.

44. Defendant was negligent in not making accurate representations regarding the side effects and adverse medical conditions caused by the use of Zyprexa.

45. Defendant knew or reasonably should have known through adequate testing that the claims made to the State with regard to the safety and efficacy of Zyprexa were false or incomplete, and misrepresented the material facts of Zyprexa's unsafe and defective condition.

46. Defendant's misrepresentations in this regard were done with the intention of inducing the State to approve of the distribution of Zyprexa to participants in the Alaska Medicaid Program for both approved and off label uses.

47. As a proximate and legal result of Defendant's fraudulent misrepresentations, the State has suffered and will continue to suffer the damages alleged in paragraph 26.

FOURTH CLAIM FOR RELIEF
(Negligence)

48. Plaintiff incorporates paragraphs 1 through 47 as if fully set forth herein.

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49. Defendant had a duty to exercise reasonable care in the manufacture, sale, and/or distribution of Zyprexa, including a duty to ensure that users would not suffer from unreasonable, dangerous, undisclosed, or misrepresented side effects. This duty extends to the State of Alaska as the party ultimately bearing financial responsibility for Alaska Medicaid patients.

50. Defendant breached this duty, as it was negligent in the testing, marketing, manufacture, sale, and packaging of Zyprexa.

51. As a direct and proximate result of Defendant's negligence, the State has suffered and will suffer the damages alleged in paragraph 26 above.

FIFTH CLAIM FOR RELIEF
(Violations of the Unfair Trade Practices and Consumer Protection Act)

52. Plaintiff incorporates paragraphs 1 through 51 as if fully set forth herein.

53. Defendant violated the Alaska Unfair Trade Practices and Consumer Protection Act, as codified in AS 45.50.471, *et seq.*, by engaging in deceptive trade practices through the marketing and advertising of Zyprexa. These violations were made in the following particulars:

a. Defendant represented that Zyprexa had characteristics, uses, benefits, and/or qualities that it did not have, in violation to AS 45.50.471(b)(4);

b. Defendant represented 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);

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c. Defendant advertised Zyprexa with an intent not to sell it as advertised, in violation of AS 45.50.471(b)(8).

d. Defendant engaged 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).

e. Defendant used misrepresentations or omissions 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).

f. Defendant violated the labeling and advertising provisions of AS 17.20, in violation of AS 45.50.471(b)(48).

54. Defendants knowing and intentional acts or omissions constitute repeated violations of Alaska law.

55. As a direct and proximate result of one or more of these violations, the State has suffered and will continue to suffer damages as alleged in paragraph 26. In addition to those damages, Defendant is also liable for actual attorneys' fees and costs incurred by Plaintiff, and penalties as set forth in AS 45.50.551.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendant as permitted by Alaska law, as follows:

1. For an award of damages in excess of the $100,000 jurisdictional limit of the court against Defendant Eli Lilly for the Zyprexa-related damages of past, present, and future medical expenses for recipients of the Alaska Medicaid program;

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2. For restitution damages for the cost of all Zyprexa prescriptions paid by the State;

3. For civil penalties of $5,000 per violation of the Unfair Trade Practices Act;

4. For costs, interest and actual attorneys' fees; and

5. For all other relief deemed just by the court.

Respectfully SUBMITTED and DATED this 28 day of February, 2006

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