



## **Parties**

2. Plaintiff, Beatriz E. Ebel is the widow of Philip Wayne Ebel. She is a resident of Brownsville, Texas. Thus, she is a statutory beneficiary of the cause of action created by the Texas Wrongful Death Act, and an appropriate party to allege claims on behalf of the Estate of Philip Wayne Ebel under the Texas Survival statute. She brings this suit in her own capacity and her representative capacity to recover damages for herself and for all wrongful death beneficiaries, including Philip's two minor children, Eric Fernando Ebel and Gabriela Nicole Ebel.

3. Defendant Eli Lilly and Company is an Indiana corporation with headquarters in Indianapolis, Indiana. It is a pharmaceutical company which, among other things, develops and markets psychoactive drugs, including OLANZAPINE [hereinafter "Zyprexa"].

## **Jurisdiction and Venue**

4. Jurisdiction is based on diversity of citizenship. 28 U.S.C. §1332. The amount in controversy is substantially in excess of Seventy-Five Thousand Dollars (\$75,000), exclusive of interest and costs. The actions giving rise to this cause of action happened within this District. Therefore, venue is permissible in this District pursuant to 28 U.S.C. §1391.

## **Facts**

It has become necessary to file this suit as a result of the following facts.

### Zyprexa and Suicidality

5. Zyprexa is Eli Lilly's brand name for a powerful, mind altering drug, the chemical name of which is OLANZAPINE. It is in the class of drugs commonly known as "psychotropics". Lilly markets Zyprexa for the treatment of schizophrenia, bipolar disorders, and, ironically enough, in an injectable formula for the treatment of "agitation" associated with these disorders.

6. The irony lies in the fact that, in actuality, for some patients, Zyprexa **causes** extremely troubling "agitation". Specifically, its side effects include both insomnia and other sleep disturbances and a pernicious neurological condition known as "akathisia". For example, in its clinical trials of OLANZAPINE for the treatment of schizophrenia, the incidence of treatment emergent akathisia on this drug was 5%, as compared to only 1% on placebo.

7. The actual number and rate of completed suicides for patients in clinical trials on antipsychotic drugs, as submitted to the FDA, is higher on OLANZAPINE than on any of the other drugs in this class. Specifically, Lilly reported that, of 2500 patients on Zyprexa, there were 12 completed suicides, as compared to none on placebo. However, despite its recent avowed intention of making all of its adverse event clinical trial data available to the public, to date Lilly has refused to divulge information about non-fatal suicidal acts of patients on Zyprexa.

8. Both sleep disturbances and akathisia are precursors of suicide. Lilly has been well aware for many years that insomnia and drug induced akathisia can trigger suicide, because its flagship drug, Prozac, also triggers these side effects, and, thereby, triggers suicidality in some patients. Indeed, the relationship between akathisia and suicidality is so well known and generally accepted that it is even incorporated into the DSM-IV-TR, §333.99.

9. Although Lilly has adamantly denied that Prozac causes suicidality in any group of patients, on October 15, 2004, the FDA issued a statement acknowledging the causal link between Prozac and other similar antidepressant medications on the one hand and increased suicidality in the pediatric and adolescent patient population on the other. Moreover, the FDA has now mandated

**BLACK BOX WARNINGS**

regarding this increased risk, i.e. something that Lilly should have voluntarily pursued years ago.

10. On information and belief it is alleged that, notwithstanding its knowledge of the potential risk of Zyprexa induced suicidality, Lilly has failed to conduct any prospective tests to determine the frequency of this phenomenon or to develop means of identifying and protecting those patients who are at risk. It has

also failed adequately to warn prescribing physicians, pharmacists, and patients about this risk or to instruct them on the known ways to reduce or ameliorate the risk.

11. Lilly has not only promoted, but also actually over-promoted Zyprexa. It has achieved great financial success in doing so. Zyprexa is now Lilly's #1 selling drug. Indeed, it has even surpassed Prozac in annual earnings for Lilly, garnering 34% of Lilly's \$12.6 billion in sales in calendar year 2003.

12. On information and belief, Lilly has failed to implement warnings about the increased risk of suicide with Zyprexa because of its concern that warnings would hurt sales. A public acknowledgment of the link between Zyprexa and suicidality could threaten, not only Lilly's profits from Zyprexa, but, indeed, the very viability of the company. By way of illustration, Plaintiff would show the Court and Jury that, on February 7, 1990, when word of Prozac's potential to trigger suicidality was first hitting the reputable professional journals, Lilly's top scientist wrote that this link could cause Lilly itself to "go down the tubes". Lilly's top management responded to that risk by establishing, as its "#1 priority" the goal to "PROTECT PROZAC".

13. History is repeating itself. Obviously, now, Lilly's #1 goal is to "protect" its new, multi-billion dollar a year pill. To do so, it is employing the same stratagems that worked so well for it with regard to Prozac, i.e. (a) denying the

association between Zyprexa and suicide, (b) refusing to warn about this risk, (c) blaming the deaths on the “disease” and the publicity on trial lawyers, the media, and others.

14. This pattern of behavior demonstrates a reprehensible tendency to vaunt profits over patient safety. To curb such irresponsible behavior, Lilly should be held fully accountable for all damages provided by law, including exemplary damages as authorized by the Texas Constitution and statutory law.

#### The Tragic, Untimely and Unnecessary Death of Philip Ebel

15. Philip Wayne Ebel was born on November 19, 1964 in LaGrange, Texas. He met and married Beatriz E. Ciseneros. Before his death on November 11, 2002, they had been married for 14 years. He considered his wife to be his best friend. Philip and Bea had two children, Eric Fernando Ebel and Gabriela Nicole Ebel.

16. Over the years, Mr. Ebel had problems with chronic tension headaches. He sought and received extensive medical treatment for this condition. Unfortunately, the severity of it was such that he ultimately became disabled from his regular job. However, Mr. Ebel was an exceedingly smart and highly motivated man. Therefore, he and his family moved to the Valley and, in the months preceding his death, he was pursuing a significant new business opportunity.

17. Needless to say, the headaches, and the associated disability, triggered concomitant, associated depression. However, despite his physical pain and his depression, Philip was never violent or suicidal. His physicians tried a number of different medications to treat both the headaches and the depression. One of these, which was begun shortly after Philip's July 2002 appointment with his physician, was Zyprexa. In the wake of taking Zyprexa, Mr. Ebel developed akathisia. This, obviously, put him at risk of suicide.

18. That risk was subsequently exacerbated when, on November 9, 2002, he was put on Paxil<sup>1</sup>, an "SSRI" drug in the same class as Lilly's Prozac. Two days later, on the afternoon of November 11, 2002, Mr. Ebel drove to Academy, bought a shotgun, parked around the corner and then killed himself. Everyone that knew him knows that, in his right and normal mind, he could never have done this.

19. Zyprexa was a proximate cause of Philip Ebel's death. It caused it by triggering akathisia and sleep disturbances, known risk factors for suicide. On information and belief, it also caused it via the drug-drug interaction between

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<sup>1</sup> Plaintiff believes that GlaxoSmithKline, the maker of Paxil, and Lilly, are joint tortfeasors and that both drugs, i.e. Paxil and Zyprexa, are proximate causes of the death of her husband. Indeed, Plaintiff previously filed suit against GSK, in this Court, under Civil Action No. B-03-102. The parties in that case have reached a tentative settlement, subject to the approval of the Court. Plaintiff is filing a Motion for Leave to Amend in that case. If amendment is granted, then this suit will be dismissed. Lilly may, or may not, be entitled to contribution credits as a result of that settlement.

Zyprexa and Paxil. Lilly's tortious conduct was also a proximate cause of Mr. Ebel's death.

### The Perils of Polypharmacy

20. Polypharmacy, i.e. the multiple prescription of several different psychoactive drugs – sometimes known as a drug “cocktail” – is a significant problem in today's world of medicine. It is problem enough when the prescribing physician is a skilled psychiatrist who has studied psychoactive drugs and who tries to remain current in his knowledge about them. It is even more problematic when, as here, the Zyprexa is prescribed by a primary care physician.

21. Lilly knows about the potential risks of polypharmacy. By way of example, Plaintiff would show that since May 1990, the Prozac label has carried a “contraindication”, warning physicians against putting patients on Prozac and a MAOI at the same time. The reason is that this combination of drugs causes or exacerbates various “activation” types of side effects, including a constellation of symptoms branded as “neuroleptic malignant syndrome” and akathisia.

22. One would hope that Lilly would have realized the potentially synergistic effects about combining Zyprexa with an SSRI like Paxil, and would have put a similar contraindication or warning on the label. Or, at the very minimum, some instructions for the safe coadministration of multiple psychoactive drugs. However,

to the contrary, instead of **discouraging** the concomitant use of these two powerful psychoactive medications, Lilly has actually **encouraged** such practices in several ways, including (a) promoting “combination” therapy of Zyprexa with other psychoactive drugs, and, now, even (b) designing its own “combination” capsule which contains both Prozac and Zyprexa and marketing this dual-drug pill under the brand name Symbyax for the treatment of bipolar depression.

### **Legal Theories and Causes of Action**

23. Defendant Lilly is liable under one or more of three different theories of liability recognized under Texas law. FIRST: Defendant Lilly is strictly liable under the principles of Restatement (Second) of Torts, §§402A and 402B, and the new Restatement (Third) of Torts, for product defects and misrepresentations.

24. SECOND: Defendant Lilly ’ conduct is unreasonable, or negligent, and was a proximate cause of Philip Wayne Ebel’s death. The negligence includes failure to warn, failure to test, failure to implement appropriate patient screening mechanisms, and over-promotion of Zyprexa.

25. THIRD: Lilly is liable under a breach of warranty theory.

### **Damages and Remedies**

26. Plaintiff sues under the Texas Survival Statute to recover personal injury damages on behalf of Philip Ebel from the time of his initial ingestion of Zyprexa

until his death. Plaintiff also sues under the Texas Wrongful Death Act for wrongful death damages on behalf of all statutory beneficiaries of that cause of action. The amount of actual damages is alleged to be in the millions, and the *ad damnum* will be particularized on request.

27. As noted above, there is clear and convincing evidence of Lilly's "gross negligence", as that term is defined in the Texas Civil Practice & Remedies Code., as follows:

"Gross negligence" means an act or omission:

(A) which when viewed objectively from the standpoint of the actor at the time of its occurrence involves an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and

(B) of which the actor has actual, subjective awareness of the risk involved, but nevertheless proceeds with conscious indifference to the rights, safety, or welfare of others.

Consequently, Lilly should also be liable in this case for exemplary damages.

28. Moreover, because of Mr. Ebel's disability, in accordance with subsection (c) of section 41.008, Tex.Civ.Pract. & Rem. Code, the limitations of subsection (b) of that section do not apply. (Note: Lilly is not a "health care provider" and selling Zyprexa is not providing "health care" as those terms are defined by section 74.001).

29. Plaintiff is also entitled to recover prejudgment interest and costs of court.

**Jury Demand**

30. Plaintiff hereby invokes her right to trial by jury.

WHEREFORE, Plaintiff prays that the Defendant Eli Lilly & Company be cited to appear and answer herein, and that, after a trial, she receive such monetary damages and other relief as is sought herein and appropriate under the law and the facts.

Respectfully submitted,

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