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ENDORSED
FILED
ALAMEDA COUNTY

MAR 05 2010
CLERK OF THE SUPERIOR COURT
By Esther Coleman, Deputy

5 Attorneys for Plaintiffs
LISA ZAPATA, individually, and
6 VERONICA ZAPATA and ZACHARY ZAPATA,
by and through their Guardian ad Litem, GABRIEL
7 REYNOSO

8 SUPERIOR COURT OF CALIFORNIA
9 COUNTY OF ALAMEDA

11 LISA ZAPATA, individually, and VERONICA)
ZAPATA and ZACHARY ZAPATA, by and)
12 through their GUARDIAN AD LITEM,)
GABRIEL REYNOSO)
13 Plaintiffs,)
14 v.)
15 LISHA WILSON, M.D., an individual;)
16 JOSEPH MARZOUK, M.D., an individual;)
SMITHKLINE BEECHAM CORPORATION,)
17 dba GLAXOSMITHKLINE, a corporation;)
DOE COMPANY, an unknown business entity;)
18 and DOES 1 through 50, inclusive,)
19 Defendants.)
20

CASE NO. RG10494568
**FIRST AMENDED COMPLAINT FOR
WRONGFUL DEATH**
1. Professional Negligence
2. Strict Liability
3. Negligence
4. Negligence Per Se
5. Breach of Implied Warranty
6. Fraud
7. Negligent Misrepresentation
8. Violations of B&PC 17200
9. Violations of B&PC 17500

21 Plaintiff Lisa Zapata, individually, and Veronica Zapata and Zachary Zapata, two minors,
22 by and through their Guardian Ad Litem, Gabriel Reynoso, ("Plaintiffs") allege against
23 Defendants, and each of them, as follows:

24 **GENERAL ALLEGATIONS**

25 1. This is an action for wrongful death by Plaintiffs, the surviving widow and two
26 minor children, after their husband/father Robert Zapata ("Robert") died on October 26, 2008
27 after ingesting the prescription drug Combivir and other drugs, as tested, studied, researched,
28 evaluated, endorsed, designed, formulated, compounded, manufactured, produced, assembled,

1 inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed or
2 ~~otherwise placed in the stream of commerce and sold by various pharmaceutical companies,~~
3 physicians, and Defendants Does 1 through 50, inclusive.

4 2. The true names, identities or capacities, whether individual, associate, corporate
5 or otherwise, of Defendants Does 1 - 50, inclusive, are unknown to Plaintiffs, who therefore sue
6 such Defendants by fictitious names. Plaintiffs are informed and believe and thereon allege that
7 each of the Defendants designated herein as a Doe is responsible in some manner for the events
8 referred to, which caused proximately caused foreseeable damages to Plaintiffs as alleged herein.

9 3. At all times herein mentioned, "Defendants" include all named herein as well as
10 Defendants Does 1- 50.

11 4. At all times herein mentioned, each of the Defendants was the agent, servant,
12 partner, aider and abettor, and/or joint venturer of each of the other Defendants herein and were
13 at all times operating and acting within the purpose and scope of said agency, service,
14 employment, partnership, conspiracy, and/or joint venture and rendered substantial assistance
15 and encouragement to the other Defendants, knowing that their conduct constituted a breach of
16 duty owed to Robert

17 5. There exists and, at all times herein mentioned, there existed, a unity of interest in
18 ownership, between certain Defendants and other certain Defendants such that any individuality
19 and separateness between the certain Defendants has ceased and these Defendants are the alter
20 ego of the other certain Defendants and exerted control and influence over those Defendants.
21 Adherence to the fiction of the separate existence of these certain defendants as an entity distinct
22 from other certain Defendants will permit an abuse of the corporate privilege and would sanction
23 a fraud and/or would promote injustice.

24 6. The injuries to Plaintiffs were caused by the wrongful acts, omissions, and
25 malicious representations of Defendants, all of which occurred within the State of California.

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1 **THE PARTIES**

2 **The Plaintiffs**

3 7. Lisa Zapata, a resident of Alameda County in California resident, is the surviving
4 widow of Decedent Robert Zapata. Lisa married Robert on October 9, 1999. They had two
5 natural minor children, Veronica, born on June 10, 2001 and Zachary, born on January 6, 2004.

6 **The Defendants**

7 8. Doctors Wilson and Marzouk (collectively, the "Physician Defendants") are
8 physicians who formed a doctor-patient relationship with Robert, and who advised, and
9 administered HIV antibody tests and prescribed Combivir ("AZT") and other drugs to treat
10 Robert, which caused or contributed to his death on October 26, 2008.

11 9. Upon information and belief, the Physician Defendants all reside and work in
12 California.

13 10. SMITHKLINE BEECHAM CORPORATION dba GLAXOSMITHKLINE
14 ("Glaxo") is a business entity based in Great Britain. Plaintiffs allege on information and belief
15 that Glaxo does business in California and this county, and, at all times relevant hereto, it
16 manufactured the drug, Combivir, also known as Zidovudine, commonly known as "AZT,"
17 which was prescribed to and used by Robert since 2000.

18 11. DOE COMPANY ("DC") is a pharmaceutical and medical diagnostic company
19 that, among other things, manufacturers, markets and sells an HIV antibody test. Plaintiffs allege
20 on information and belief that DC does business in California and this county and at all times
21 relevant hereto it manufactured the test kit, which was administered to Robert through the
22 Physician Defendants.

23 **FACTS COMMON TO ALL COUNTS**

24 12. About 2000, Dr. Wilson of the Physician Defendants at Highland Hospital
25 administered at least one Human Immunodeficiency Virus ("HIV") antibody test to Robert, one
26 of which reacted "positive," although a prior result reacted "negative." As a result of these tests,
27 Dr. Wilson advised that Robert that he had contracted HIV, and prescribed him AZT and other
28 drugs.

1 13. At no time did Dr. Wilson advise Robert, who was a married, low-risk subject,
2 about the “positive predictive value” of the HIV antibody test, nor of the risk of potential false
3 positives from the tests, including those described in the scientific literature, such as Challakere
4 et al., *False Positive human immunodeficiency virus type 1 ELISA results in low risk subjects*,
5 West. J. Med 159(2):214-215 (1993) and numerous others.

6 14. At no time did DC warn or advise Dr. Wilson or the Physician Defendants of the
7 risk of false positives to its test, the risk of a patient being wrongly diagnosed as “HIV positive,”
8 without confirmation of the actual presence of HIV, and subsequent risks of taking harmful
9 drugs, such as AZT, based on an improper diagnosis of HIV.

10 15. Despite the conflicting test results from the HIV antibody test, and despite the
11 published literature which described several cases of “false positive” results from the subject
12 HIV antibody tests, Dr. Wilson prescribed AZT to Robert.

13 16. AZT is a nucleoside analogue, DNA chain-terminator, designed and used for
14 cancer chemotherapy.

15 17. At no time did Dr. Wilson warn or advise Robert or Plaintiff that AZT was
16 designed and used for cancer chemotherapy. At no time did any of the Physician Defendants
17 warn or advise Robert or Plaintiff of all the potential toxic and negative health effects of AZT,
18 despite the well-known published literature which identifies such toxic and negative health
19 effects as leukopenia, anemia, nausea, dizziness, dementia, and muscle atrophy.

20 18. At no time did Dr. Wilson warn or advise Robert or Plaintiff that one of the
21 potential negative health effects of the AZT was cancer of the lymphatic system, called Non-
22 Hodgkin’s Lymphoma. At no time did Glaxo warn or advise the Physician Defendants that one
23 of the potential negative health effects of the AZT was Non-Hodgkin’s Lymphoma.

24 19. Both before and after prescribing AZT to Robert, there were numerous scientific
25 articles in the literature demonstrating that AZT caused an increased risk in both animals and
26 humans from contracting cancer, including Non-Hodgkin’s Lymphoma. Excerpts from the these
27 scientific papers, include, but are not limited to, the following:
28

1 a. "AZT is genotoxic in fetal mice and monkeys and is a moderately strong
2 transplacental carcinogen in mice examined at 1 year of age.:" (Olivero et al, Journal of National
3 Cancer Institute, 89:1602 (1997).)

4 b. "...AZT has been shown to be carcinogenic in adult mice after life-time
5 oral administration." (Olivero et al, Journal of National Cancer Institute, 89:1602 (1997).)

6 c. "Available literature does not allow an accurate estimation of human risk
7 implied by these data. However, our results suggest that the current practice of treating
8 HIV-1-positive women and their infants with high doses of AZT could increase cancer risk in
9 the drug-exposed children when they reach young adulthood or middle age." (Olivero et al,
10 Journal of National Cancer Institute, 89:1607 (1997).)

11 d. The anti-HIV drug [AZT] is used successfully for reduction of perinatal
12 viral transmission. However toxic side effects including carcinogenesis are possible.(Diwan,
13 Toxicology and Applied Pharmacology, 161: 82 (1999).)

14 e. "The effects at 2 years were similar to those seen after transplacental
15 exposure, with significant increases in lung, liver and mammary tumors in females. The
16 results confirm that AZT is a moderately effective perinatal carcinogen in mice, targeting several
17 tissue types." (Olivero et al, Journal of National Cancer Institute, 89:1602 (1997).)

18 f. "These data indicate that the primary mechanism of AZT mutagenicity in
19 human TK6 cells is through the production of large deletions which occur as a result of AZT
20 incorporation into DNA and subsequent chain termination. The data imply that perinatal
21 chemoprophylaxis with AZT may put children of HIV-infected women at potential risk for
22 genetic damage." (Sussman, Mutation Research/Fundamental and Molecular Mechanisms of
23 Mutagenesis, 429: 249 (1999).)

24 g. "However, AZT also has been demonstrated to have genotoxic and
25 carcinogenic effects *in vivo* and *in vitro*." (Bialkowska, Carcinogenesis, 21: 1060 (2000).)

26 h. "...there was clear evidence of carcinogenic activity based upon
27 significant dose-related trends and increases in the incidences of hemangiosarcoma in male
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1 mice and mononuclear cell **leukemia** in female rats. (Walker, Environmental and Molecular
2 Mutagenesis, 48:283. (2007.)

3 i. "Collectively, the results obtained provide convincing biological
4 plausibility of the postulate that perinatal exposure to nucleoside analogs (AZT) **puts children at**
5 **elevated risk of developing cancers later in life.**" (Wogan, *Does Perinatal antiretroviral*
6 *therapy create an iatrogenic cancer risk?*, Environmental and Molecular Mutagenesis, 48: 210
7 (2007).)

8 j. "Because mutagenesis is strongly associated with **tumor induction** in
9 experimental models, children exposed transplacentally to combinations of NRTIs (AZT) **may**
10 **be at risk for cancer** development later in life. (Meng, PNAS, 97(23): 12667 (2000).)

11 20. In one observational study of 55 patients taking AZT, a total of 8 patients (17%)
12 developed lymphoma, which compelled the researchers to estimate that "[a]fter 36 months of
13 therapy, the estimated probability of developing lymphoma increases to 46.4%." (Pluda et al.,
14 *Annals of Internal Medicine*, 113:277 (1990).

15 21. Between 2000 and 2005, Robert took AZT as prescribed the Physician
16 Defendants.

17 22. After Robert took AZT, he became ill from the various side effects and sought a
18 second opinion from an AIDS specialist, Dr. Joseph Marzouk, who formed a Doctor-Patient
19 relationship with Robert.

20 23. In 2005, Robert was diagnosed with Non-Hodgkin's Lymphoma, after a biopsy
21 was taken. At no time did Dr. Marzouk warn or advise Robert to stop taking AZT or that the
22 initial HIV antibody test was potentially a false positive.

23 24. Between 2005 and 2008, Robert's health greatly deteriorated from the AZT and
24 the cancer which developed therefrom. He was treated with conventional chemotherapy by an
25 oncologist, which caused weight-loss, nausea, osteonecrosis and a host of other maladies.

26 25. On October 26, 2008, Robert died at age 44, from the combined adverse effects of
27 underlying drug AZT, the subsequent cancer, and cancer chemotherapy given to treat the cancer.
28 At the time of his marriage to Lisa in 1999, Robert was in excellent physical health.

1 *Cohort of Patients with Severe Human Immunodeficiency Virus (HIV) Infection on Long-Term*
2 *Anti-Viral Therapy*, Annals of Internal Medicine, 113:277 (1990).

3 34. As a result of this conduct, the Physician Defendants breached the standard of
4 care in treating patients by not fully advising Robert of the risk of false positives from the HIV
5 antibody test, all harmful side effects of AZT, and despite these omissions, prescribing it to
6 Robert, when it was not medically reasonable or necessary to do so.

7 35. As a result of this conduct, Plaintiffs suffered injuries and damages, including the
8 loss of her husband/their father, loss of consortium, solace, society and support, as alleged herein.

9 **SECOND CAUSE OF ACTION**

10 **STRICT LIABILITY**

11 **(Plaintiff Lisa Zapata and Veronica and Zachary, by and through their Guardian Ad**
12 **Litem, against Glaxo and DC and DOES 1-50.)**

13 36. Plaintiffs incorporate by reference herein paragraphs 28- 35 as though set forth in
14 full in this action.

15 37. Plaintiffs are informed and believe, and thereon allege that AZT was first
16 manufactured under the brand name "Retrovir" and then under the brand name "Combivir," by
17 Glaxo or its predecessors-in-interest or subsidiaries, at the time it was prescribed to Robert by the
18 Physician Defendants

19 38. AZT was defective at the time of its manufacture, development, production,
20 testing, inspection, endorsement, prescription, sale and distribution, in that, and not by way of
21 limitation, said product and its warnings, instructions and directions, failed to warn of the
22 dangerous propensities of AZT, which risks were known or reasonably scientifically knowable to
23 Glaxo. Glaxo knew, or should have known of the properties of AZT, including the medical risks
24 associated with such products, as previously set forth herein. Specifically, Glaxo failed to warn
25 consumers that AZT contained numerous side effects, including loss of white blood cells, loss of
26 red blood cells, severe weight loss, muscle atrophy, Non-Hodgkin's Lymphoma, and death.

27 39. The Physician Defendants, Does 1-50, Robert and Plaintiffs, relied on these
28 defective warnings to prescribe and/or ingest AZT, when such drug was not the appropriate
treatment for Robert.

1 carried a substantial risk of cancer in those who ingested it. In the fact, one of the first peer-
2 reviewed, published papers on AZT, noting its harmful side effects, including its carcinogenic
3 properties, was Pluda et al., *Development of Non-Hodgkin's Lymphoma in a Cohort of Patients*
4 *with Severe Human Immunodeficiency Virus (HIV) Infection on Long-Term Anti-Viral Therapy*,
5 *Annals of Internal Medicine*, 113:277 (1990).

6 65. Subsequent published papers in the scientific literature after the Pluda paper in
7 1990, have raised grave concerns about the use and efficacy of AZT, as a potential carcinogen in
8 AIDS patients.

9 66. As a result of the foregoing fraudulent and deceitful conduct by the Glaxo, Robert,
10 who purchased the AZT, individually, suffered damages for buying a product, he otherwise
11 would not, had the truth be known. Plaintiffs suffered injuries and damages as alleged herein by
12 Robert's purchase and consumption of AZT, and subsequent death caused therefrom.

13 **SEVENTH CAUSE OF ACTION**
14 **NEGLIGENT MISREPRESENTATION**
15 **(Plaintiff Lisa Zapata, individually, and Veronica and Zachary by and through their**
16 **Guardian Ad Litem against DC and Glaxo and Does 1-50)**

17 67. Plaintiffs incorporate by reference herein paragraphs 59 - 66 as though set forth in
18 full in this cause of action.

19 68. From the time that AZT was first tested, studied, researched, evaluated, endorsed,
20 manufactured, marketed and distributed, and up to the present, Glaxo made false
21 misrepresentations, as previously set forth herein, to Robert, the Physician Defendants and the
22 general public, including but not limited to the misrepresentation that AZT was safe, fit and
23 effective for human consumption. At all times herein mentioned, Glaxo conducted a sales and
24 marketing campaign to promote the sale of the aforementioned drug product and willfully
25 deceived Robert, the Physician Defendants and the general public as to the health risks and
26 consequences of the use of the aforementioned product.

27 69. Glaxo made the foregoing representations without any reasonable ground for
28 believing them to be true. These representations were made directly by Glaxo, by sales
representatives and other authorized agents of Glaxo, and in publications and other written

1 materials directed to physicians, medical patients and the public, with the intention of inducing
2 reliance and the prescription, purchase and use of the subject product.

3 70. The foregoing representations by Glaxo were in fact false, in that the
4 aforementioned product was not safe, fit and effective for human consumption, the use of said
5 product is hazardous to health, and said injuries suffered by Plaintiffs as delineated herein.

6 71. The foregoing representations by Glaxo were made with the intention of inducing
7 reliance and the prescription, purchase and use of AZT.

8 72. In reliance on the misrepresentations by Glaxo, Robert was induced to purchase
9 and use the aforementioned product. If Robert had known of the true facts and facts concealed by
10 the Glaxo, Robert would not have used the subject product. The reliance of Robert upon Glaxo's
11 misrepresentations was justified because such misrepresentations were made and conducted by
12 individuals and entities who were in a position to know the true facts.

13 73. As a result of the foregoing negligent misrepresentations by the Glaxo, Plaintiffs
14 claim injuries and damages as alleged herein.

15 **EIGHTH CAUSE OF ACTION**
16 **VIOLATION OF BUSINESS & PROFESSION**
17 **CODE SECTION 17200**

18 **(Plaintiff Lisa Zapata, individually, and Veronica and Zachary, by and through their**
19 **Guardian Ad Litem against Glaxo and Does 1-50)**

20 74. Plaintiffs incorporates by reference herein paragraphs 67 - 73 as though set forth
21 in full in this cause of action.

22 75. Plaintiffs are informed and believe and thereon allege that Glaxo, by the acts and
23 misconduct alleged herein, violated Business & Professions Code sections 17200.

24 76. On behalf of the general public, Plaintiffs hereby seek injunctive, restitutionary
25 and other equitable relief, as appropriate against Glaxo for its violations of section 17200.

26 77. California Business & Professions Code section 17200 provides that unfair
27 competition shall mean and include "all unlawful, unfair or fraudulent business practices and
28 unfair, deceptive, untrue or misleading advertising.

78. The acts and practices described in Paragraphs 1 through 77 above, were and are
likely to mislead the general public and therefore constitute unfair business practices within the

1 meaning of Business & Professions Code §17200. The acts of untrue and misleading advertising
2 set forth in presiding paragraphs are incorporated by reference and are, by definition, violations
3 of Business & Professions Code §17200. This conduct includes, but is not limited to:

- 4 (a) Representing to Robert, the Physician Defendants and the general public
5 that AZT was safe, fit and effective for human consumption, knowing that
6 said representations were false, and concealing from Robert, the Physician
7 Defendants and the general public that said product, as a dangerous drug, ,
8 had a serious propensity to cancer in users;
- 9 (b) Engaging in advertising programs designed to create the image, impression
10 and belief by consumers, physicians and others that the use of AZT, was
11 safe for human use, had fewer side effects and adverse reactions than other
12 methods of helping patients, suffering from immune disorders, even
13 though Glaxo knew these to be false, and even though the Glaxo had no
14 reasonable grounds to believe them to be true;
- 15 (c) Purposely downplaying and understating the health hazards and risks
16 associated with AZT; and
- 17 (d) Issuing promotional literature deceiving potential users of AZT by relaying
18 positive information and manipulating statistics to suggest widespread
19 acceptability, while downplaying the known adverse and serious health
20 effects and concealing material relevant information regarding the safety
21 of said product.

22 79. These practices constitute unlawful, unfair and fraudulent business acts or
23 practices, within the meaning of California Business & Professions Code §17200, as well as
24 unfair, deceptive, untrue and misleading advertising as prohibited by California Business &
25 Professions Code §17500.

26 80. The unlawful, unfair and fraudulent business practices of Glaxo described above
27 present a continuing threat to members of the public in that Glaxo continues to engage in the
28 conduct described therein.

1 following acts and practices with intent to induce members of the public to purchase and use
2 AZT:

- 3 (a) Representing to Robert, the Physician Defendants and the general public
4 that AZT was safe, fit and effective for human consumption, knowing that
5 said representations were false, and concealing from Robert, the Physician
6 Defendants and the general public that said product had a serious
7 propensity to cause cancer to users;
- 8 (b) Engaging in advertising programs designed to create the image, impression
9 and belief by consumers and physicians that the use of AZT, was safe for
10 human use, had fewer side effects and adverse reactions than other
11 methods of providing relief to patients suffering from immune disorders,
12 even though the Glaxo knew these to be false, and even though the Glaxo
13 had no reasonable grounds to believe them to be true;
- 14 (c) Purposely downplaying and understating the health hazards and risks
15 associated with AZT; and
- 16 (d) Issuing promotional literature deceiving potential users of AZT by
17 relaying positive information and manipulating statistics to suggest
18 widespread acceptability, while downplaying the known adverse and
19 serious health effects and concealing material relevant information
20 regarding the safety of said product.

21 89. The foregoing practices constitute false and misleading advertising within the
22 meaning of California Business & Professions Code §17500.

23 90. The acts of untrue and misleading statements by Glaxo described herein above
24 present a continuing threat to members of the public in that the acts alleged herein are continuous
25 and ongoing, and the public will continue to suffer the harm alleged herein.

26 91. Pursuant to California Business & Professions Code §17535, Plaintiff seeks an
27 order of this Court compelling the Glaxo to provide restitution as a result of their unfair business
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1 practices, and injunctive relief calling for Glaxo, and each of them, to cease such unfair business
2 practices in the future.

3 **PRAYER FOR RELIEF**

4 WHEREFORE, Plaintiffs pray for judgment against all Defendants and each of them, as
5 follows, as appropriate to each cause of action alleged as follows:

- 6 1. General damages in an amount which will conform to proof at time of trial;
- 7 2. Special damages in an amount within the jurisdiction of the Superior Court and
8 according to proof at the time of trial;
- 9 3. Loss of earnings and impaired earning capacity according to proof at the time of
10 trial;
- 11 4. Medical expenses, past and future, according to proof at the time of trial;
- 12 5. Damages for loss of care, comfort, society and companionship in an amount
13 within the jurisdiction of the Superior Court and according to proof;
- 14 6. Punitive damages, to the extent allowable by law;
- 15 7. For past and future mental and emotional distress, according to proof;
- 16 8. Injunctive, restitutionary and other equitable relief;
- 17 9. For costs of suit incurred herein;
- 18 10. For pre-judgment interest as provided by law; and
- 19 11. For such other and further relief as the Court may deem just and proper.

20 DATED: March 3, 2010

YARON & ASSOCIATES

21
22
23 By: 

24 **GEORGE D. YARON**
25 **D. DAVID STEELE**
26 Attorney for Plaintiff Lisa Zapata,
27 individually, and Veronica and Zachary, by
28 and through their as Guardian Ad Litem.