

IN THE CIRCUIT COURT, FOURTH  
JUDICIAL CIRCUIT, IN AND FOR  
DUVAL COUNTY, FLORIDA

16- 2009-CA- 019382

XX-MA


SHADIA SALEM INDIVIDUALLY and  
SHADIA SALEM AS PERSONAL  
REPRESENTATIVE OF THE ESTATE OF  
FRED J. SALEM, DECEASED

Plaintiffs,

CASE NO.:  
DIVISION:

**DIVISION CV-C**

vs.

 ELI LILLY AND COMPANY,  
AMYLIN PHARMACEUTICALS, INC., and  
DOES 1 through 50, Inclusive,

Defendants.

FILED  
IN COMPUTER  
V. B.

COMPLAINT

Plaintiffs, SADIA SALEM, individually, and SADIA SALEM, AS PERSONAL REPRESENTATIVE OF THE ESTATE OF FRED J. SALEM, Deceased, sue Defendants, ELI LILLY AND COMPANY, and AMYLIN PHARMACEUTICALS, INC. and DOES 1 through 50, Inclusive, and allege as follows:

JURISDICTION AND VENUE

1. This is an action for damages arising out of Florida's Wrongful Death statute, negligence and breach of warranty in excess of Fifteen Thousand Dollars (\$15,000.00). Venue is proper in this County as the acts and conduct of the Defendant occurred in Duval County, Florida and the decedent died in Duval County, Florida.

PARTIES

2. At all relevant times, Plaintiff SADIA SALEM, was a resident of Duval County, Florida. At the time of Fred J. Salem's death, SADIA SALEM, had been married to Fred J. Salem

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for over 29 years. SADIA SALEM is (or will be) the duly appointed Personal Representative of the Estate of Fred J. Salem.

3. The decedent, Fred J. Salem, was at times relevant a resident of Duval County Florida. Fred J Salem died of cancer and complications of cancer, including pancreatitis on January 5, 2008.

4. The true names and or capacities, whether individual, corporate, associate, or otherwise of defendants, DOES 1 through 50, inclusive, are unknown to Plaintiffs, who therefore sue said defendant by such (a) fictitious names. Plaintiffs are informed and believe and thereon allege that each of the defendants fictitiously named herein as DOE is legally responsible in some manner for the events and happenings hereinafter referred to and proximately thereby caused the injuries and damages to Plaintiffs as hereinafter alleged. Plaintiffs will seek leave of Court to amend the Complaint to assert the true name and/or capacities of said fictitiously named defendants when the same shall be ascertained.

5. Defendant, AMYLIN PHARMACEUTICALS, INC. (hereinafter referred to as "AMYLIN") was and is a corporation which owns or operates a pharmaceutical company doing business in the state of Florida and is licensed to do business and is doing business in Duval County, Florida. At all times relevant, Defendant, AMYLIN conducted regular and sustained business in Florida by selling and distributing its products in Florida and engaged in substantial commerce and business activity in Duval County, Florida.

6. Defendant, ELI LILLY AND COMPANY (hereinafter referred to as "ELI LILLY") was and is a corporation whose principal place of business is in the State of Indiana, and who is licensed to do business and is doing business in the Duval County, Florida. At all times relevant,

Defendant, ELI LILLY, conducted regular and sustained business in Florida by selling and distributing its products in Florida and engaged in substantial commerce and business activity in Duval County, Florida.

7. At all times herein mentioned, the defendants, and each of them, were authorized to do business within the State of Florida, and did in fact supply the drug Byetta within the State of Florida.

8. At all times herein mentioned, one or more of the individual DOE defendants was, and is, a resident of the State of Florida

9. At all times relevant, the defendants, were the agents, servants, employees, and joint venturers of each of the remaining defendants, and were at all times mentioned herein acting within the scope, course and purpose of said agency, employment and joint venture.

#### **GENERAL ALLEGATIONS**

10. Plaintiffs bring this case against Defendants for damages associated with Fred J. Salem's use of the pharmaceutical drug Byetta, an injection used to treat diabetes. Specifically, Fred J. Salem died of cancer, including liver and pancreatic cancer, and of other conditions as a direct result of his use of Byetta.

11. At all times material, the defendants, were engaged in the business of, or were successors in interest to entities engaged in the business of, researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug known as Byetta (exenatide) for use by the Plaintiff.

12. As a result of Defendants claims regarding the effectiveness and safety of Byetta, Fred

J. Salem's medical provider prescribed and Fred J. Salem began using Byetta in July 2007. Thereafter he began to manifest signs of distress, including a loss of weight, skin coloration changes, nausea and fever, that eventually required his hospitalization. Mr. Salem's medical condition was later diagnosed as liver cancer and pancreatic cancer. On January 5, 2008, just six months after his first injection of Byetta, Mr. Salem died.

13. Prior to July 2007, Defendants knew or should have known that the drug Byetta was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale, and distribution, in that, and not by way of limitation, said product and its warnings, instructions, and directions failed to warn prescribing physicians and patients of the dangerous propensities of Byetta to cause or contribute to the development of liver cancer, pancreatic cancer and other conditions, including pancreatitis and complications associated with same which risks were known or reasonably scientifically knowable to defendants.

14. At all times herein mentioned, Byetta was defective, and defendants, and each of them, knew that it was to be used by the user without inspection for defects therein.

15. Defendants, knew or should have known of the defective condition, characteristics and risks associated with Byetta.

16. Mr. Salem neither knew, nor had reason to know at the time of the use of Byetta of the existence of the aforementioned defects.

17. Had Mr. Salem and / or his health care providers known the risks and dangers associated with Byetta, he would not have used Byetta and would not have died as a result.

18. As a direct and proximate result of the defective condition of Byetta Fred J. Salem suffered injuries, damages and death.

19. The potential beneficiaries of **THE ESTATE OF FRED J. SALEM** (other than **THE ESTATE OF FRED J. SALEM** itself), their relationship to Cooper, and their dates of birth, are as follows:

<b>Name</b>	<b>Relationship</b>	<b>Date of Birth</b>
Shadia Salem	Wife	
Nadine Salem	Daughter	11/22/84
Joseph Salem	Son	5/5/86
Jason Salem	Son	7/17/88

20. As a result of Mr. Salems death, the Plaintiff seeks damages on behalf of **THE ESTATE OF FRED J. SALEM** for funeral and medical expenses incurred, and for a loss of prospective net accumulations.

21. As a result of Mr. Salems death, Plaintiff seeks damages on behalf of Shadia Salem, his wife for the following:

- a. The value of lost support and services from the date of Mr. Salem death until the date of Shadia Salem's death;
- b. Lost companionship and protection from the date of Mr. Salem 's death until the date of Shadia Salem's death;
- c. Mental pain and suffering from the date of Mr. Salem death until the date of Shadia Salem's death; and
- d. Medical and funeral expenses.

22. As a result of Mr. Salem's death, the Plaintiff seeks damages on behalf of Nadine Salem, Joseph Salem and Jason Salem for the following:

- a. The value of lost support and services;

- b. Lost parental companionship, instruction, and guidance; and
- c. Mental pain and suffering,

from the date of Mr. Salem's death until the date of Nadine Salem, Joseph Salem and Jason Salem deaths.

23. The Plaintiff has complied with all common law and statutory conditions precedent to the filing of the action.

24. The undersigned attorney for the Plaintiff hereby certifies that a reasonable investigation has been undertaken in connection with this case, and said investigation has given rise to a good faith belief that grounds exist for an action against each named defendant.

### COUNT I

#### STRICT LIABILITY - DESIGN DEFECT

25. Plaintiff SADIA SALEM, AS PERSONAL REPRESENTATIVE OF THE ESTATE OF FRED J. SALEM incorporates by reference herein paragraphs 1 through 24, as fully set forth herein.

26. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Byetta.

27. The Byetta product, the manufactured, designed, distributed, sold or supplied and / or placed in the stream of commerce by Defendants was expected to and did reach the consumer without any alterations or changes.

28. The Byetta product manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an

ordinary consumer would expect.

29. The foreseeable risks associated with the design or formulation of Byetta, include, but are not limited to, the fact that the design or formulation of Byetta is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

30. As a direct and proximate result of use of Byetta as manufactured, designed, distributed, sold or supplied and introduced into the stream of commerce by Defendants, Mr. Salem suffered personal injuries and Plaintiffs economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

**WHEREFORE**, Plaintiff, demands judgment from the Defendants for compensatory damages, costs, and such other remedies as the Court may deem just and proper.

## COUNT II

### STRICT LIABILITY - FAILURE TO WARN

31. Plaintiff SADIA SALEM, AS PERSONAL REPRESENTATIVE OF THE ESTATE OF FRED J. SALEM incorporates by reference herein paragraphs 1 through 24, as fully set forth herein.

32. As a direct and proximate result of the negligence of defendants, and each of them, Mr. Salem was injured to his body, including but not limited to his, liver, kidneys and pancreas, which caused and great physical, mental and nervous pain and suffering. Mr. Salem thereafter died of his injuries.

33. As a further, direct and proximate result of the negligence and carelessness of the defendants, and each of them, Mr. Salem was compelled to and did employ the services of

physicians, surgeons and other medical personnel, and he was compelled to, and did incur other incidental expenses relative to the care and treatment of said injuries.

34. As a further direct and proximate result of the negligence and carelessness of the defendants, and each of them, Mr. Salem died.

**WHEREFORE**, Plaintiff, demands judgment from the Defendants for compensatory damages, costs, and such other remedies as the Court may deem just and proper.

### **COUNT III**

#### **NEGLIGENCE**

35. Plaintiff SADIA SALEM, AS PERSONAL REPRESENTATIVE OF THE ESTATE OF FRED J. SALEM incorporates by reference herein, paragraphs 1 through 24, as fully set forth herein.

36. At all times herein mentioned, defendants, and each of them, had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, prepare for use, sell, prescribe, consult, and adequately warn of the risk and dangers of the aforementioned product, Byetta.

37. At all times herein mentioned, the defendants, and each of them, negligently and carelessly manufactured, designed, formulated, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, consulted, or failed to consult, prepare for use and sold the aforementioned products and failed to adequately test and warn of the risks and dangers of the aforementioned product. In particular, defendants, and each of them, knew, or in the exercise of reasonable care required of an expert in the fields of drug design and labeling, should have known, that Byetta could cause or contribute to the development of pancreatitis and complications associated

with pancreatitis in individuals who used the product for the control Type II diabetes.

38. Despite the fact that defendants knew or should have known that Byetta caused unreasonable and dangerous side effects, defendants, and each of them, failed to adequately warn prescribing physicians, including Mr. Salem's prescribing physician, of the risk of pancreatitis, including, but not limited to the risk of developing necrotizing pancreatitis and/or hemorrhagic pancreatitis, of the measures needed to properly assess the appropriateness of prescribing the drug Byetta to certain categories of patients for the control of Type II diabetes, and of the measures doctors and patients could and should take to minimize the risk of morbidity associated with Byetta-induced pancreatitis. In addition, Defendants' negligent conduct in the marketing and promotion of the drug Byetta to prescribing physicians and patients overstated the drug's benefits while downplaying the nature and extent of the risks, with the result that any warnings in the labeling for Byetta relating to the risk of pancreatitis were overshadowed and rendered ineffective.

39. Defendants knew or should have known that consumers such as Mr. Salem would reasonably suffer injury as a result of defendants' failure to exercise ordinary care as described above.

40. Defendants' negligence was a proximate cause of Mr. Salem's injuries, harm and economic loss which the Plaintiff suffered.

41. As a direct and proximate result of the negligence of defendants, and each of them, Mr. Salem was injured to his body, including but not limited to his kidneys and pancreas, which caused great physical, mental and nervous pain and suffering and death.

42. As a further, direct and proximate result of the negligence and carelessness of the defendants, and each of them, Mr. Salem was compelled to and did employ the services of physicians, surgeons and other medical personnel, and he was compelled to, and did incur other

incidental expenses relative to the care and treatment of said injuries.

43. As a further direct and proximate result of the negligence and carelessness of the defendants, and each of them, Mr. Salem sustained personal injuries and thereafter died.

**WHEREFORE**, Plaintiff, demands judgment from the Defendants for compensatory damages, costs, and such other remedies as the Court may deem just and proper.

#### **COUNT IV**

#### **BREACH OF IMPLIED WARRANTY**

44. Plaintiff SADIA SALEM, AS PERSONAL REPRESENTATIVE OF THE ESTATE OF FRED J. SALEM incorporates by reference herein paragraphs 1 through 24, as though fully set forth herein.

45. Prior to the time that the aforementioned Byetta drug was used by the Plaintiff, defendants implied warranted to the Plaintiff and the Plaintiffs' agents and physicians that said Byetta was of merchantable quality, and safe and fit for the use for which it was intended.

46. The Plaintiff was and is unskilled in the research, design and manufacture of the aforementioned pharmaceutical drug and reasonably relied entirely on the skill, judgment and implied warranty of the defendants in using the aforementioned Byetta.

47. The aforementioned pharmaceutical product was neither safe for its intended use nor merchantable quality, as warranted by defendants, in that Byetta had dangerous propensities when used as instructed and would cause severe injuries to the consumer.

48. As a result of the aforementioned breach of implied warranties by the defendants, the Plaintiff suffered injuries and damages as alleged herein.

49. As a direct and proximate result of the negligence of defendants, and each of them,

the Plaintiff was injured to his body, including but not limited to their kidneys and pancreas, which caused great physical, mental and nervous pain and suffering.

50. As a further, direct and proximate result of the negligence and carelessness of the defendants, and each of them, Plaintiffs were compelled to and did employ the services of physicians, surgeons and other medical personnel, and Plaintiffs were compelled to, and did incur other incidental expenses relative to the care and treatment of said injuries.

51. As a further direct and proximate result of the negligence and carelessness of the defendants, and each of them, Plaintiff died.

**WHEREFORE**, Plaintiff, demands judgment from the Defendants for compensatory damages, costs, and such other remedies as the Court may deem just and proper.

#### **COUNT V**

#### **BREACH OF EXPRESS WARRANTY**

52. Plaintiff SADIA SALEM, AS PERSONAL REPRESENTATIVE OF THE ESTATE OF FRED J. SALEM incorporate by reference herein paragraphs 1 through 24, as though fully set forth.

53. At all times herein mentioned, defendants expressly warranty to Plaintiff and to Plaintiff's agents and physicians, by and through statements made by defendants or its authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the pharmaceutical drug Byetta was safe, effective, fit and proper for its intended use.

54. In utilizing the aforementioned pharmaceutical product, Byetta, Plaintiffs relied on skill, judgment, representation, and the foregoing express warranties of the defendants.

55. Said warranties and representations were false in that the aforementioned pharmaceutical product, Byetta, was not safe and was, in fact, unfit for the uses for which it was intended.

56. As a result of the foregoing breach of express warranties by the defendants, and each of them, Plaintiffs suffered injuries and damages as alleged herein.

57. As a direct and proximate result of the negligence of defendants, and each of them, Plaintiffs were injured to their bodies, including but not limited to their kidneys and pancreas, which have caused and continue to cause great physical, mental and nervous pain and suffering.

58. As a further, direct and proximate result of the negligence and carelessness of the defendants, and each of them, Plaintiffs were compelled to and did employ the services of physicians, surgeons and other medical personnel, and Plaintiffs were compelled to, and did incur other incidental expenses relative to the care and treatment of said injuries. Plaintiffs are informed and believe and thereon alleges that they will be compelled to seek further treatment in the future for the care of said injuries and to incur further, reasonable medical and related expenses for the same. Plaintiffs will give proof of both past and future claimed medical expenses at the time of trial.

59. As a further direct and proximate result of the negligence and carelessness of the defendants, and each of them, Plaintiffs have sustained personal injuries, a portion of which are permanent. Such injuries have impaired Plaintiffs' ability to work, and to achieve promotions with their chosen profession and will continue to do so in the future. Plaintiffs will give proof of said damages at the time of trial herein.

**WHEREFORE**, Plaintiff, demands judgment from the Defendants for compensatory damages, costs, and such other remedies as the Court may deem just and proper.