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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

ELIZABETH CHILDRESS

Plaintiff,

v.

AMYLIN PHARMACEUTICALS, LLC, F/K/A AMYLIN PHARMACEUTICALS, INC., ELI LILLY AND COMPANY, and DOES 1-100

Defendants.

Case No. '13CV1114 W DHB

CIVIL COMPLAINT FOR DAMAGES

JURY TRIAL DEMANDED

COMES NOW Plaintiff and complains and alleges against Defendants, Does 1 through 100, and each of them as follows:

GENERAL ALLEGATIONS

1. Plaintiff, Elizabeth Childress ("Plaintiff"), by and through

Plaintiff's attorneys, The Restaino Law Firm, P.C. and Watts Guerra LLP, brings this action for personal injuries Plaintiff suffered as a proximate result of being prescribed and ingesting the defective and unreasonably dangerous prescription drug Byetta (exenatide synthetic) (the "Drug"), a prescription medication used to help lower blood sugar levels in adults with diabetes mellitus type 2, which at all times relevant hereto, was manufactured, designed, tested, packaged, labeled, marketed, advertised, distributed, and sold by Defendants Amylin Pharmaceuticals, LLC f/k/a Amylin Pharmaceuticals, Inc., Eli Lilly and Company (collectively, the "Amylin Lilly Defendants"), and Does 1 through 100 (collectively, the "Doe Defendants") (the Amylin Lilly Defendants and the Doe Defendants collectively are the "Defendants").

2. The true names or capacities whether individual, corporate or otherwise, of the Doe Defendants l through 100, inclusive, are unknown to Plaintiff who therefore, sues said Defendants by such fictitious names. Plaintiff believes and alleges that each of the Defendants designated herein by fictitious names is in some manner legally responsible for the events and happenings herein referred to and caused damages proximately and foreseeably to Plaintiff as alleged herein.

3. At all times herein mentioned, each of the Defendants, inclusive of the Doe Defendants, was the agent, servant, partner, aider and abettor, co-conspirator, and joint venturer of each of the remaining Defendants herein and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy, and joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their conduct constituted a breach of duty.

4. There exists, and at all times herein mentioned, there existed, a unity of interest in ownership between certain Defendants and other certain

Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants, and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as any entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction fraud and would promote injustice.

5. The injuries and damages to Plaintiff were caused by the wrongful acts, omissions, and fraudulent representations of Defendants, many of which occurred within the State of California, as Defendant Amylin Pharmaceuticals, LLC is headquartered in San Diego, California.

6. At all times herein mentioned, Defendants were each engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the Drug.

7. At all times herein mentioned Defendants were each authorized to do or otherwise engaged in business within the State of California and did in fact supply the aforementioned products within the State of California and elsewhere.

8. At all times herein mentioned, the officers and directors of Defendants authorized and directed the production and promotion of the Drug when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of the Drug, and thereby actively participated in the tortious conduct which resulted in the physical injuries described herein.

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JURISDICTION AND VENUE

9. Jurisdiction is proper in this court pursuant to 28 USC §1332 for the reason that there is complete diversity of citizenship between Plaintiffs and Defendants and the matter in controversy greatly exceeds the sum of seventy-five thousand dollars ($75,000.00), exclusive of interest and costs.

10. This Court has jurisdiction over the non-resident Defendants because they have done business in the State of California, have committed a tort in whole or in part in the State of California, and have continuing contacts with the State of California.

11. In addition, venue of this case is proper in the Southern District of California pursuant to 28 U.S.C. § 1391(b)(1) because all Defendants are residents of this state.

12. Venue is further proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred, in part, in the Southern District of California, as Defendant Amylin Pharmaceuticals, LLC is headquartered in San Diego, California, and further, Defendant Amylin Pharmaceuticals, LLC engaged in a joint venture with Eli Lilly and Company related to the Drug that, on information and belief, occurred in whole or part in San Diego, California.

PLAINTIFF

13. Plaintiff Elizabeth Childress is a natural person currently residing in Bristol, Virginia. Plaintiff was born on January 19, 1988.

14. Plaintiff was prescribed and used the Drug beginning on or about January 5, 2007 and continued said use through at least August 10, 2007. On or about May 9, 2011, at the age of 23, Plaintiff suffered severe physical, economic, and emotional injuries as a result of said Drug including, but not limited to, Plaintiff's being diagnosed with thyroid cancer. Plaintiff was unaware that Plaintiff's injuries were caused by the

Drug until shortly before the filing of this complaint.

DEFENDANTS

15. Amylin Pharmaceuticals, LLC f/k/a Amylin Pharmaceuticals, Inc. ("Amylin") is a Delaware limited liability company, which has its principal place of business at 9360 Towne Centre Drive, Suite 100, San Diego, CA 92121-3030. Amylin, LLC may be served at it's physical address: 9360 Towne Centre Drive, Suite 100, San Diego, CA 92121-3030, or by and through its registered agent: CT Corporation System, 818 W. Seventh St., Los Angeles, CA 90017. Amylin has conducted business and derived substantial revenue from within the State of California.

16. Eli Lilly and Company ("Eli Lilly") is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly may be served by and through its registered agent: National Registered Agents, Inc., 2875 Michelle Dr., Ste. 100, Irvine, CA 92606. Eli Lilly has conducted business and derived substantial revenue from within California.

FACTUAL ALLEGATIONS

17. This is an action for injuries and damages suffered by Plaintiff as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the Drug.

18. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold the Drug as a prescription that, along with diet and exercise, is designed to help lower blood sugar levels in adults with type 2 diabetes.

19. According to the American Diabetes Association, "Type 2

diabetes is the most common form of diabetes. Millions of Americans have been diagnosed with type 2 diabetes. […] In type 2 diabetes, either the body does not produce enough insulin or the cells ignore the insulin. Insulin is necessary for the body to be able to use glucose for energy. When you eat food, the body breaks down all of the sugars and starches into glucose, which is the basic fuel for the cells in the body. Insulin takes the sugar from the blood into the cells. When glucose builds up in the blood instead of going into cells, it can lead to diabetes complications."[1]

20. Type 2 diabetes mellitus is a chronic disease, characterized by insulin resistance and deficient insulin secretion leading to high blood sugar levels or 'hyperglycemia', which is the hallmark of the condition.

21. Diabetes remains the most frequent cause of blindness, amputations and dialysis worldwide.[2] With the current estimate of more than 350 million patients worldwide[3] it is considered to be one of the major health challenges of the 21st century.

22. Byetta is supposed to help prevent these diabetic complications.

23. Byetta is a member of a recently approved class of therapeutic agents for the treatment of type 2 diabetes, glucagon-like peptide-1 (GLP-1) receptor (GLP-1R) agonists, which exert their actions through potentiation of incretin receptor signaling. Incretins are gut-derived hormones, which inhabit thyroid tissue, principally GLP-1 and glucose-dependent insulinotropic peptide (GIP), and are secreted at low basal levels in the fasting state.

24. Byetta was approved by the FDA in April of 2005 and was marketed to the medical community and general public shortly thereafter.

1 http://www.diabetes.org/diabetes-basics/type-2/?loc=DropDownDB-type2

2 ID

3 IDF Diabetes atlas, http://www.idf.org/diabetesatlas/5e/diabetes.

In January 2010, the FDA approved Victoza, another member of the new GLP-1 class of drugs. As members of the same drug class, Byetta and Victoza act similarly in the human body.

25. Victoza was approved with several post-marketing requirements under the Food and Drug Administration Amendments Act (FDAAA) to ensure that the company would conduct studies to provide additional information on the safety of their product. The FDA acknowledged the need for these post-marketing requirements based on concerns about animal studies demonstrating an association between Victoza and a type of thyroid cancer known as mendullary thyroid cancer.[4]

26. Victoza's approval by the FDA came with a "black box" warning, specifically explaining that Victoza "causes thyroid C-cell tumors at clinically relevant exposures in rodents. It is unknown whether Victoza causes thyroid C-cell tumors, including mendullary thyroid carcinoma (MTC), in humans, as human relevance could not be determined by clinical or nonclinical studies…" Victoza's GLP-1 counterpart, Byetta, wholly fails to mention thyroid cancer in the warning section of its label, despite the Byetta label's admission that, "Benign thyroid C-cell adenomas were observed in female rats at all exenatide doses."[5]

27. Victoza was approved with a Risk Evaluation and Mitigation Strategy consisting of a Medication Guide and a Communication Plan. This communication plan included warning of thyroid tumors and thyroid cancer in Victoza's medication guide, a "Dear Healthcare Provider" letter sent to all healthcare professionals likely to prescribe Victoza, and specific

[4]http://www.fda.gov/downloads/AdvisoryCommittees/Committees%20MeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM151129.pdf

[5]http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021773s029s030lbl.pdf at 20.

highlighted information to be distributed by the manufacturer's representative. Further, the FDA required the manufacturer of Victoza to conduct additional animal studies in mice to evaluate the potential risk of thyroid cancer in humans. The Defendants wholly failed to take any of the above actions with respect to Byetta and its connection to thyroid cancer.

28. In February 2011, the journal Gastroenterology published on-line the work of Elashoff et al[6] titled, "*Pancreatitis, pancreatic, and thyroid cancer with glucagon-like peptide-1-based therapies.*"

29. These researchers used the FDA Adverse Event Reporting System (AERS) with the primary goal of their analysis being to assess the association between treatment with Byetta (and similar drugs) and an adverse event report of pancreatitis, where the Drug was listed as the primary suspect associated with a pancreatitis report in the database. A secondary goal was to examine the FDA AERS database for reported pancreatic or thyroid cancer associated with use of Byetta (and similar drugs), with various other anti-diabetic drugs used as controls.

30. Because thyroid tumors were reported to be increased in rodents treated with Victoza in a filing to the FDA, Elashoff et al evaluated the reported rates of thyroid cancer with Byetta and Januvia, another anti-diabetic drug, compared to control events relative to Avandia (rosiglitazone).

31. The reported event rate for thyroid cancer was 4.73-fold greater in patients treated with Byetta compared to other therapies. While Byetta's association with thyroid cancer was statistically significant, thyroid cancer diagnosis in Januvia users was not statistically significant.

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6 Elashoff M, Matveyenko AV, Gier B, Elashoff R & Butler PC Pancreatitis, pancreatic, and thyroid cancer with glucagon-like peptide-1-based therapies. Gastroenterology (2011) 141:150-156.

32. These researchers noted that the potential to increase the risk of cancer might be expected to occur by "permitting declaration of tumors previously held in check by an intact immune system" as has been published by others within the world's medical literature.

33. In January 2012, Defendant Amylin Pharmaceuticals also gained FDA approval for Bydureon. Through its website, Amylin touts that Byetta and Bydureon are the same, and Bydureon is merely a longer-lasting version of Byetta, "BYDUREON is a long-acting form of the medication in BYETTA®[…]"[7]

34. Amylin was required by the FDA to conduct a clinical trial to assess whether Bydureon increases the risk of heart attacks and other cardiovascular problems. As part of this trial, Amylin must also look at whether the drug increases the risk for thyroid cancer and other health problems.

35. Moreover, the label for Bydureon contains a "black box" warning for thyroid tumors. Indeed, the Bydureon label warns in bold letters, "**Exenatide extended-release causes thyroid C-cell tumors at clinically relevant exposures in rats. It is unknown whether BYDUREON causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as human relevance could not be determined by clinical or nonclinical studies.**"[8] While admitting Bydureon and Byetta are the same, Defendants have been indifferent to the health and safety of Byetta users, having wholly failed to provide any warning whatsoever on the Byetta label related to its link to thyroid cancer.

36. In April 2012, Public Citizen sent a petition to the FDA to

[7] http://www.bydureon.com/

[8] http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022200Orig1s000lbledt.pdf

withdraw another Byetta-like drug in the GLP-1 class, Victoza (liraglutide), from the market. In a statement announcing the Victoza recall petition, Public Citizen pointed out that when the agency approved Victoza in January 2010, it did so against the advice of two reviewing FDA pharmacologists and an FDA clinical safety reviewer. The group also pointed out that Victoza is the only known medication approved by the FDA that causes thyroid C-cell tumors in both sexes of rats and mice, and does so at exposures similar to those seen in people taking the recommended dose. In pre-approval studies, papillary thyroid cancer was increased 3-fold and thyroid C-cell hyperplasia (increased proliferation of such cells) was increased 2.4-fold, compared to patients taking other drugs for diabetes, Public Citizen said.

37. Sidney Wolfe, director of the health and research group at Public Citizen, a non-profit consumer-advocacy organization based in Washington DC, said at that time, "We don't just go after drugs casually…(W)e only go after drugs when there is clear evidence of unique dangers or risks, and when there is no evidence of a unique clinical advantage." Dr. Wolfe said at the time that his concern extends to other diabetes drugs that alter the GLP-1 pathway, which includes the deadly Byetta.

38. Due to the flawed formulation of Byetta, it increases the risk of thyroid cancer in those diabetic patients to whom it is prescribed.

39. Despite undeniable knowledge of the risk, and with full appreciation of the deadly side-effects posed by ingesting Byetta, Defendants concealed their knowledge that Byetta can cause life-threatening thyroid cancer from Plaintiff, other consumers, the general public, and the medical community. Indeed, the Defendants who manufacture and market Byetta never even mentioned 'thyroid cancer' in

their product's inserts.

40. Specifically, the Defendants did not adequately inform consumers and the prescribing medical community about the risks of thyroid cancer associated with Byetta usage, nor did Defendants warn or otherwise advise physicians to institute monitoring procedures looking for the first signs of changes within the thyroid.

41. The current warnings for the Drug are simply inadequate, especially in light of the warnings made by competing drugs within Byetta's own drug family. The Defendants have failed and continue to fail in their duties to warn and protect the consuming public, including the Plaintiff herein.

42. Even if the warnings were sufficient, which Plaintiff strongly denies, Byetta still lacks any benefit sufficient to tolerate the extreme risk posed by the ingestion of the Drug. Other drugs to treat diabetes are available. Byetta is quite simply too dangerous and defective as formulated. The Defendants should withdraw Byetta from the market.

43. Defendants willfully, wantonly, and with malice withheld the knowledge of increased risk of thyroid cancer in users of Byetta to prevent any chances of their product's registration being delayed or rejected by FDA.

44. As the manufacturers and distributors of Byetta, Defendants knew or should have known that the Drug's usage was associated with thyroid cancer.

45. With full knowledge of the true relationship between use of Byetta and thyroid cancer, rather than taking steps to pull the Drug off the market or provide strong warnings, Defendants promoted and continue to promote Byetta as safe and effective treatments for adults with type 2 diabetes.

46. The Defendants deadly silence has been profitable. Byetta is one of the top selling drugs in the country. In 2010, the worldwide sales of Byetta reached $0.710 billion and visiongain predicts sales to reach $1.00 billion by 2015 and $1.28 billion by 2021.[9]

47. While Defendants have enjoyed great financial success from their blockbuster Drug, they continue to place American citizens at risk of developing thyroid cancer.

48. Consumers, including Plaintiff, who have used Byetta for the treatment of their type 2 diabetes had several alternative safer products available to treat their condition and have not been adequately warned about the significant risks and lack of benefits associated with Byetta therapy.

49. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with Byetta use.

50. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff would be exposed to the risks identified in this Complaint. The increased risks and subsequent medical damages associated with Plaintiff's Byetta use were the direct and proximate result of Defendants' conduct.

51. At all times relevant hereto, the Defendants have directly marketed and distributed the Drug to the medical community.

52. At all times relevant hereto, the Defendants have directly marketed the Drug to the consuming public throughout the United States, including the Plaintiff, herein.

9 www.pipelinereview.com/store/toc/sample_pages_vg0151.pdf

53. Defendants departed from and failed to meet requirements of laws, regulations and class and product specific requirements including failing to undertake adequate post approval marketing studies on safety of the Drug as dictated by good pharmaceutical science standards.

54. Defendants both over-promoted the Drug and under-warned about its risks, including:

a. in print advertising;

b. on their websites and blogs;

c. advertised to users that use of the Drug was "safe" whereas it was not and Defendants knew or should have know it was not; and

d. promoted the Drug to doctors, clinics and users as safer than (or as safe as) other diabetes drugs.

55. Defendants did not perform adequate safety testing on the Drug as required by good pharmaceutical science practice.

56. Defendants failed to provide proper and full information as to the safety of the Drug.

57. Defendants failed to ensure that full and correct safety labeling and warnings were used in pharmacy sheets that accompanied the Drug to the purchaser.

58. Defendants have never sought to enlarge their warnings to include a warning about thyroid cancer risks associated with the use of the Drug, despite full knowledge of the risk.

59. Instead, Defendants marketed (and continue to market) the Drug as having a low risk of side effects and continue to minimize (or conceal) the Drug's severe side effects.

60. Manufacturers such as the Defendants, herein, are required to have systems in place to collect and analyze any complaints they receive

from doctors and hospitals about their products.

61. Defendants did not timely apprise the F.D.A., the public, nor treating physicians of the defect(s) in Defendants' Drug, despite Defendants' knowledge that injuries had occurred and had been reported to Defendants due to the above-described defects.

62. At all times mentioned herein, Defendants knew, or in the exercise of reasonable care should have known, that the Drug was of such a nature that it was not properly designed, manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared, and/or provided with proper warnings, was not suitable for the purpose it was intended and was unreasonably likely to injure the product's users.

63. Plaintiff and Plaintiff's prescribing health care providers were unaware of the true degree and incidence of thyroid cancer associated with the use of the Drug and would have used and prescribed other methods for diabetes control if they had been so informed.

64. Plaintiff suffered from severe and personal injuries, which were permanent and lasting in nature, including risk of death, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for medical treatment, monitoring and/or medications both in the past and in the future.

65. As a direct and proximate result of the aforesaid conduct of Defendants and each of them as set forth hereinafter, Plaintiff suffered injuries, including but not limited to thyroid cancer, which resulted in damages in a sum in excess of the jurisdictional limits of the Court.

66. As a direct and proximate result of the aforesaid conduct of the Defendants, and each of them, Plaintiff was compelled to incur obligations for physicians, surgeons, nurses, hospital care, medicine, x-rays, medical

supplies, and other medical treatment, the true and exact amount thereof being unknown to Plaintiff at this time, and Plaintiff prays leave to amend this complaint accordingly when the true and exact cost thereof is ascertained.

67. As a further direct and proximate result of the said conduct of the Defendants, and each of them, Plaintiff suffered a loss of income, wages, profits and commissions, a diminishment of earning potential, and other pecuniary losses, the full nature and extent of which are not yet known to Plaintiff; and leave is requested to amend this complaint to conform to proof at the time of trial.

68. By reasons of the premises, Plaintiff has been caused great pain and suffering.

STATEMENT OF PLAINTIFF'S INJURIES

69. On or about January 5, 2007, Plaintiff was prescribed and began taking Byetta upon the direction of Plaintiff's physician for long-term maintenance of Type II diabetes, and she continued to take Byetta through at least August 2007.

70. Subsequently, and as a direct result of the ingestion of Byetta, the Plaintiff was diagnosed with thyroid cancer on or about May 9, 2011. Had Plaintiff and/or Plaintiff's physician been properly warned by Defendants regarding the risk of thyroid cancer from usage of these prescription medications, Plaintiff's physician would have not prescribed Byetta and Plaintiff would never have ingested this prescription medication.

71. As a direct result of being prescribed Byetta for this period of time, Plaintiff was permanently and severely injured, having suffered serious consequences from Plaintiff's Byetta usage, including but not limited to, the development of thyroid cancer.

72. Plaintiff, as a direct and proximate result of Plaintiff's Byetta use, suffered severe mental and physical pain and suffering, along with economic loss.

73. As a proximate result of Defendants' acts and omissions, Plaintiff suffered the injuries described hereinabove due to Plaintiff's ingestion of Byetta. Plaintiff accordingly seeks damages associated with these injuries.

74. Plaintiff would not have used Byetta had Defendants properly disclosed the risks associated with their use.

CAUSES OF ACTION

COUNT I

STRICT LIABILITY-FAILURE TO WARN

75. Plaintiff hereby incorporates by reference all paragraphs of this Complaint as if fully set forth herein.

76. Defendants are liable under the theory of strict products liability. Defendants were at all times relevant to this suit, and are now, engaged in the business of designing, manufacturing, testing, marketing, and placing into the stream of commerce pharmaceuticals for sale to, and use by, members of the public, including the Byetta at issue in this lawsuit. The Byetta manufactured by Defendants reached Plaintiff without substantial changes and was ingested as directed. The Drug was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff.

77. The Plaintiff was administered the Drug for its intended purposes.

78. The Plaintiff could not have discovered any defect in the Drug through the exercise of care.

79. Defendants, as manufacturers of pharmaceutical products,

including the Drug, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks of injuries and death associated with the use of Byetta were incomplete and inadequate.

80. Plaintiff did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians. The warnings that were given by the Defendants were not accurate, clear, and/or were ambiguous or incomplete.

81. Defendants had a continuing duty to provide consumers, including Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with the Drug, as it became or could have become available to Defendants.

82. Defendants marketed, promoted, distributed and sold the unreasonably dangerous and defective prescription drug, Byetta, to health care providers empowered to prescribe and dispense the Drug to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, if not intentional concealment, Defendants misled the medical community about the risk and benefit balance of the Drug, which resulted in injury to Plaintiff.

83. Despite the fact that Defendants knew or should have known that the Drug caused unreasonable and dangerous side effects, they continued to promote and market the Drug without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

84. Defendants knew or should have known that consumers, Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Defendants' failures.

85. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff and to Plaintiff's intermediary physicians, in at least the following ways:

a. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of the Drug including, among other things, its tendency to increase the risk of, and/or cause, the development of thyroid cancer;

b. Defendants failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, thyroid cancer; and

c. Defendants continued to aggressively promote and sell the Drug even after they knew or should have known of the unreasonable risks of developing thyroid cancer from ingestion of the Drug.

86. Defendants had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to the Drug, and/or that there existed safer and more or equally effective alternative drug products.

87. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to the Drug, and/or that

there existed safer and more or equally effective alternative drug products, Defendants breached their duty of reasonable care and safety.

88. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of the Plaintiff and the public.

89. Defendants' actions described above violated the federal and state Food, Drug and Cosmetic Acts and rendered the Drug misbranded.

90. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Plaintiff was exposed to the Drug and suffered the injuries and damages set forth hereinabove.

COUNT II

STRICT PRODUCTS LIABILITY - DESIGN DEFECT

91. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

92. Defendants are the manufacturers, designers, distributers, sellers and suppliers of the Drug, who sold the Drug in the course of business.

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

94. The Drug administered to Plaintiff was defective in design or formulation in the following respects:

a. When it left the hands of the Defendants, this drug was unreasonably dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff or Plaintiff's physicians;

b. Any benefit of this Drug was outweighed by the serious and undisclosed risks of its use when prescribed and used as the

Defendants intended;

c. The dosages and/or formulation of the Drug sold by the Defendants was unreasonably dangerous;

d. There are no patients for whom the benefits of the Drug outweighed the risks;

e. The subject product was not made in accordance with the Defendants' specifications or performance standards;

f. There are no patients for whom the Drug is a safer and more efficacious drug than other drug products in its class; and/or

g. There were safer alternatives that did not carry the same risks and dangers that Defendants' the Drug had.

95. The Drug administered to Plaintiff was defective at the time it was distributed by the Defendants or left their control.

96. The foreseeable risks associated with the design or formulation of the Drug include, but are not limited to, the fact that the design or formulation of the Drug is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or did not have the claimed benefits.

97. The defective and unreasonably dangerous design and marketing of the Drug was a direct, proximate and producing cause of Plaintiff's injuries and damages. Under strict products liability theories set forth in Restatement (Second) of Torts, Defendants are liable to Plaintiff for all damages claimed in this case.

98. As a direct, legal, proximate, and producing result of the defective and unreasonably dangerous condition of the Drug, Plaintiff suffered personal injuries, economic and non-economic damages, including pain and suffering.

99. Defendants' actions and omissions as identified in this

Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT III

NEGLIGENCE

100. Plaintiff hereby incorporates by reference all paragraphs of this Complaint as if fully set forth herein.

101. Defendants had a duty to exercise reasonable care in the manufacture, sale and/or distribution of the Drug into the stream of commerce, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects.

102. Defendants failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of the Drug into interstate commerce in that Defendants knew or should have known that the Drug created a high risk of unreasonable, dangerous side effects, including causing and increasing the risk of developing thyroid cancer.

103. Defendants were negligent in the design, manufacture, testing, advertising, warning, marketing and sale of the Drug.

104. Despite the fact that Defendants knew or should have known that the Drug caused unreasonable, dangerous side effects, Defendants continued to market the Drug to consumers, including Plaintiff.

105. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

106. Defendants willfully and deliberately failed to avoid those consequences, and in doing so, Defendants acted with a conscious disregard of the safety of Plaintiff as alleged previously.

107. As a proximate and legal result of Defendants' negligence, Plaintiff was caused to suffer the herein described injuries and damages.

COUNT IV

BREACH OF IMPLIED WARRANTY

108. Plaintiff hereby incorporates by reference all paragraphs of this Complaint as if fully set forth herein.

109. At all times mentioned in this Complaint, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold the Drug, and prior to the time it was prescribed to Plaintiff, Defendants impliedly warranted to Plaintiff, and Plaintiff's physicians and healthcare providers, that the Drug was of merchantable quality and safe for the use for which it was intended.

110. Plaintiff and Plaintiff's physicians and healthcare providers relied on the skill and judgment of the Defendants in using and prescribing the Drug.

111. The product was unsafe for its intended use, and it was not of merchantable quality, as warranted by Defendants, in that the Drug had very dangerous propensities when put to its intended use and would cause severe injury (or death) to the user. The Drug was unaccompanied by adequate warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution.

112. As a proximate and legal result of the defective and unreasonably dangerous condition of the Drug manufactured and supplied by Defendants, Plaintiff was caused to suffer the herein described injuries and damages.

113. After Plaintiff was made aware or otherwise came to believe that the injuries discussed herein were a result of the Drug, notice was duly given to Defendants of the breach of said warranty.

/ / /

COUNT V

BREACH OF EXPRESS WARRANTY

114. Plaintiff hereby incorporates by reference all paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

115. The aforementioned manufacturing, compounding, packaging, designing, distributing, testing, constructing, fabricating, analyzing, recommending, merchandizing, advertising, promoting, supplying and selling of the Drug was expressly warranted to be safe for use by Plaintiff, and other members of the general public.

116. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which the Drug was to be used and warranted the same to be in all respects, fit, safe, and effective and proper for such purpose. The Drug was unaccompanied by adequate warnings of its dangerous propensities that was either known or knowable at the time of distribution.

117. Plaintiff and Plaintiff's physicians reasonably relied upon the skill and judgment of Defendants, and upon said express warranty, in using the Drug. The warranty and representations were untrue in that the product was unsafe and, therefore, unsuited for the use for which it was intended. The Drug could and did thereby cause Plaintiff to suffer the herein described injuries and damages.

118. As soon as the true nature of the product and the fact that the warranty and representations were false was ascertained, Defendants were notified of the breach of said warranty.

COUNT VI

NEGLIGENT MISREPRESENTATION

119. Plaintiff hereby incorporates by reference all paragraphs of this

Complaint as if fully set forth herein.

120. Defendants owed a duty in all of their several undertakings, including the communication of information concerning the Drug, to exercise reasonable care to ensure that they did not, in those undertakings, create unreasonable risks of personal injury to others.

121. Defendants disseminated information to physicians concerning the properties and effects of the Drug, with the intent and expectation that physicians would rely on that information in their decisions regarding the prescribing of drug therapy for their patients.

122. Alternatively or in addition, when Defendants disseminated information to physicians concerning the properties and effects of the Drug, they should have realized, in the exercise of due care to avoid causing personal injury to others, that physicians would reasonably rely on that information in their decisions concerning the prescription of drug therapy for their patients.

123. By uniformly honored custom and practice, the label for a prescription drug product, whether name brand or generic, as it is distributed to pharmacies for dispensing to patients, per the prescriptions of their physicians, accompanies or is placed on or in the package from which the drug is to be dispensed.

124. A drug company will generally distribute to physicians the labels for a name brand prescription drug product along with samples of the product, when it is being introduced to the market, and disseminate the content of the labels (i.e., the product labeling) to physicians through publication of the drug's monograph in the PDR, and otherwise communicate information regarding the drug through advertising, distribution of promotional materials, sales presentations by company sales representatives, group sales presentations, and sponsored publications and

seminar speakers.

125. Defendants disseminated false information, as referenced above, to physicians and the medical community and to their patients with knowledge that the information was false or in conscious disregard of its truth or falsity.

126. Defendants disseminated the false information, as referenced above, to physicians, the medical community and their patients with the intention to deceive physicians and their patients and to induce the physicians to prescribe the Drug.

127. Alternatively, or in addition, Defendants failed to exercise reasonable care to ensure that the information disseminated to physicians concerning the properties and effects of the Drug were accurate and not misleading, Defendants failed to exercise reasonable care to insure that accurate and not misleading information was disseminated to physicians concerning the properties and effects of the Drug by failing to publish or disseminate current and accurate information.

128. Defendants expected or should have expected that patients taking the Drug, pursuant to prescriptions written or issued in reliance on false information, would be placed in unnecessary, avoidable, and unreasonable danger due to unwarranted exposure to the Drug.

129. As a proximate and foreseeable result of this dissemination to physicians, by Defendants consciously or negligently disseminating false information, the Plaintiff suffered grievous bodily injury, and the risk of death, and consequent economic and other loss, as described above, when Plaintiff's physicians, in reasonable reliance upon the negligently inaccurate, misleading and otherwise false information disseminated by the Defendants, and reasonably but unjustifiably believing the information to be true, prescribed for the Plaintiff the Drug.

130. As a result of the foregoing negligent misrepresentations by Defendants, and each of them, the Plaintiff was caused to suffer and will continue to suffer the herein described injuries and damages.

COUNT VII

FRAUDULENT CONCEALMENT

131. Plaintiff hereby incorporates by reference all paragraphs of this Complaint as if fully set forth herein.

132. At all times mentioned in this Complaint, Defendants had the duty and obligation to disclose to Plaintiff and to Plaintiff's physicians, the true facts concerning the Drug, that is, that the Drug was dangerous and defective, and likely to cause serious health consequences to users, including the injuries as described in this Complaint.

133. Defendants concealed important facts from Plaintiff and from Plaintiff's physicians and healthcare providers which facts include, but are not limited to, the fact that Defendants:

a. Failed to disclose any information related to a connection between use of the Drug and the development of thyroid cancer;

b. Did not inform prescribers and users of studies related to use of the Drug and the development of thyroid cancer, and

c. Concealed from prescribers and users that numerous adverse events have been reported linking use of the Drug to thyroid cancer.

134. At all times mentioned in this Complaint, Defendants made affirmative representations to Plaintiff and Plaintiff's prescribing physicians prior to the day the Drug was first prescribed to Plaintiff that the Drug was safe as set forth above while concealing the material facts set forth herein.

135. At all times mentioned in this Complaint, Defendants had the

duty and obligation to disclose to Plaintiff and to Plaintiff's physicians and healthcare providers the true facts concerning the Drug, which facts include, but are not limited to, the fact that the Drug was dangerous and likely to cause serious health consequences to users, including death.

136. At all times mentioned in this Complaint, Defendants intentionally, willfully, and maliciously concealed or suppressed the facts set forth above from Plaintiff's physicians, and therefore from Plaintiff, with the intent to defraud as alleged herein.

137. At all times mentioned in this Complaint, neither Plaintiff nor Plaintiff's physicians or healthcare providers were aware of the concealed facts set forth herein. Had they been aware of those facts, they would not have acted as they did, that is, the Drug would not have been prescribed as part of Plaintiff's treatment and Plaintiff would not have been injured as a result.

138. Had Plaintiff been informed of the deaths and serious injury adverse reports associated with the Drug's usage, Plaintiff would have immediately discontinued the Drug or never taken the Drug in the first instance.

139. As a proximate result of the concealment or suppression of the facts set forth above, Plaintiff and Plaintiff's physicians and healthcare providers reasonably relied on Defendants' deception and Plaintiff was prescribed the Drug and subsequently sustained injuries and damages as set forth in this Complaint. Defendants' concealment was a substantial factor in causing the injuries described herein.

140. As a result of the foregoing fraudulent and deceitful conduct by Defendants, and each of them, Plaintiff, for the sake of example and by way of punishing said defendants, seeks punitive damages according to proof.

141. As a result of the foregoing fraudulent and deceitful conduct by

Defendants, and each of them, Plaintiff was caused to suffer the herein described injuries and damages.

COUNT IX

PUNITIVE DAMAGES

142. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

143. Although Defendants knew or recklessly disregarded the fact that the Drug cause debilitating and potentially lethal side effects, Defendants continued to market the Drug to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for treating type 2 diabetes.

144. Defendants knew of the Drug's defective nature, as set forth herein, but continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the Drug.

145. Defendants intentionally concealed or recklessly failed to disclose to the public, including Plaintiff, the potentially life-threatening side effects of the Drug to ensure their continued and increased sales. Defendants failed to provide warnings that would have dissuaded physicians from prescribing the Drug and consumers from purchasing and consuming the Drug, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming the Drug.

146. The aforementioned conduct of Defendants was willful and wanton and was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish

Defendants and deter them from similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants, and each of them, as follows:

1. Actual damages as alleged, jointly and/or severally against Defendants, in excess of $75,000.00;
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Pain and suffering;
4. Punitive damages alleged against Defendants, including Plaintiff's attorney fees, in excess of $75,000.00;
5. Interest on the judgment at the highest legal rate from the date of judgment until collected;
6. Attorneys' fees, expenses, and costs of this action; and
7. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: May 9, 2013

Respectfully submitted,

THE RESTAINO LAW FIRM, P.C.

/s/ John M. Restaino
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And

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San Antonio, Texas 78240
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Attorneys for Plaintiff

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

'13CV1114 W DHB

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

ELIZABETH CHILDRESS

(b) County of Residence of First Listed Plaintiff Bristol County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Ryan L. Thompson; Watts Guerra LLP, 5250 Prue Road, Suite 525, San Antonio, TX 78240; 210-448-0500

DEFENDANTS

AMYLIN PHARMACEUTICALS, LLC, F/K/A AMYLIN PHARMACEUTICALS, INC., ELI LILLY AND COMPANY, and DOES 1-100

County of Residence of First Listed Defendant Union County
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	☒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. 1332(a)

Brief description of cause:
Personal Injury/Product Liability

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Anthony Battaglia DOCKET NUMBER 3:12-cv-02549-AJB-MDD

DATE 5/9/2013

SIGNATURE OF ATTORNEY OF RECORD s/ John M. Restaino

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE