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12 UNITED STATES DISTRICT COURT
13 SOUTHERN DISTRICT OF CALIFORNIA

14 ELECTIA JOHNSON

15 Plaintiff,

Cause No. '13CV1346 DMS NLS

17 v.

18 AMYLIN PHARMACEUTICALS, LLC
19 F/K/A AMYLIN
20 PHARMACEUTICALS, INC., AND
21 ELI LILLY AND COMPANY, and
22 DOES 1-100

COMPLAINT FOR DAMAGES

JURY TRIAL DEMANDED

22 Defendants.

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

26 GENERAL ALLEGATIONS

27 1. Plaintiff, Electia Johnson ("Plaintiff"), by and through her
28 attorneys, The Restaino Law Firm, P.C. and Watts Guerra LLP, brings this

1 action for personal injuries suffered as a proximate result of being prescribed
2 and ingesting the defective and unreasonably dangerous prescription drug
3 Byetta (exenatide synthetic) (“Drug”), prescription medication used to help
4 lower blood sugar levels in adults with diabetes mellitus type 2, which at all
5 times relevant hereto, was manufactured, designed, tested, packaged,
6 labeled, marketed, advertised, distributed, and sold by Defendants Amylin
7 Pharmaceuticals, LLC f/k/a Amylin Pharmaceuticals, Inc., and Eli Lilly and
8 Company (collectively, the “Amylin Lilly Defendants” for Byetta), and Does
9 1 through 100 (collectively, the “Doe Defendants”) (Amylin Lilly Defendants
10 and the Doe Defendants collectively are the “Defendants”).

11 2. The true names or capacities whether individual, corporate or
12 otherwise, of the Doe Defendants 1 through 100, inclusive, are unknown to
13 Plaintiff who therefore, sues said Defendants by such fictitious names.
14 Plaintiff believes and alleges that each of the Defendants designated herein
15 by fictitious names is in some manner legally responsible for the events and
16 happenings herein referred to and caused damages proximately and
17 foreseeably to Plaintiff and Plaintiff as alleged herein.

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

25 4. There exists, and at all times herein mentioned, there existed, a
26 unity of interest in ownership between certain Defendants and other certain
27 Defendants such that any individuality and separateness between the certain
28 Defendants has ceased and these Defendants are the alter ego of the other

1 certain Defendant, and exerted control over those Defendants. Adherence to
2 the fiction of the separate existence of these certain Defendants as any entity
3 distinct from other certain Defendants will permit an abuse of the corporate
4 privilege and would sanction fraud and would promote injustice.

5 5. The injuries and damages to Plaintiff and Plaintiff were caused
6 by the wrongful acts, omissions, and fraudulent representations of
7 Defendants, many of which occurred within the State of California.

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

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

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

24 JURISDICTION AND VENUE

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

1 Angeles, CA 90017.

2 16. Eli Lilly and Company (“Eli Lilly”) is an Indiana corporation
3 with its principal place of business located at Lilly Corporate Center,
4 Indianapolis, Indiana 46285. Eli Lilly may be served by and through its
5 registered agent: National Registered Agents, Inc., 2875 Michelle Dr., Ste.
6 100, Irvine, CA 92606.

7 FACTUAL ALLEGATIONS

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

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

18 19. According to the American Diabetes Association, “Type 2
19 diabetes is the most common form of diabetes. Millions of Americans have
20 been diagnosed with type 2 diabetes. [...] In type 2 diabetes, either the body
21 does not produce enough insulin or the cells ignore the insulin. Insulin is
22 necessary for the body to be able to use glucose for energy. When you eat
23 food, the body breaks down all of the sugars and starches into glucose,
24 which is the basic fuel for the cells in the body. Insulin takes the sugar from
25 the blood into the cells. When glucose builds up in the blood instead of
26 going into cells, it can lead to diabetes complications.”¹

27 ¹ [http://www.diabetes.org/diabetes-basics/type-2/?loc=DropDownDB-](http://www.diabetes.org/diabetes-basics/type-2/?loc=DropDownDB-type2)
28 [type2](http://www.diabetes.org/diabetes-basics/type-2/?loc=DropDownDB-type2)

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

4 21. Diabetes remains the most frequent cause of blindness,
5 amputations and dialysis worldwide.² With the current estimate of more
6 than 350 million patients worldwide³ it is considered to be one of the major
7 health challenges of the 21st century.

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

9 23. Two of the most recently approved classes of therapeutic agents
10 for the treatment of type 2 diabetes, glucagon-like peptide-1 (GLP-1)
11 receptor (GLP-1R) agonists (such as Byetta) and dipeptidyl peptidase-4
12 (DPP-4) inhibitors (such as Januvia), exert their actions through potentiation
13 of incretin receptor signaling. Incretins are gut-derived hormones,
14 principally GLP-1 and glucose-dependent insulintropic peptide (GIP), that
15 are secreted at low basal levels in the fasting state.

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

18 25. Byetta is a member of the new class of drugs known as
19 glucagon-like peptide-1 (GLP-1) receptor agonists.

20 26. In February 2010, concerns were published regarding the GLP-1
21 drugs, including Byetta, and the DPP-4 inhibitors, including Januvia, and
22 their potential linkage with pancreatic cancer.

23 27. Writing in *DIABETES CARE*, Butler *et al.* published *GLP-1–Based*
24 *Therapy for Diabetes: What You Do Not Know Can Hurt You*⁴ wherein they

25 _____
26 ² ID

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

27 ⁴ Butler PC, Dry D, Elashoff D. *GLP-1–Based Therapy for Diabetes: What*
28 *You Do Not Know Can Hurt You* *Diabetes Care* February 2010 33:453-455.

1 wrote, "History has taught us that enthusiasm for new classes of Drug,
2 heavily promoted by the pharmaceutical companies that market them, can
3 obscure the caution that should be exercised when the long-term
4 consequences are unknown. Of perhaps greatest concern in the case of the
5 GLP-1-based drugs, including GLP-1 agonists and dipeptidyl peptidase-4
6 (DPP-4) inhibitors, is preliminary evidence to suggest the potential risks of
7 asymptomatic chronic pancreatitis and, with time, pancreatic cancer."

8 28. In addition, these researchers wrote, "However, in the context of
9 a new class of medical therapy, the proverb 'What you do not know cannot
10 hurt you' clearly does not apply. We feel that enough preliminary evidence
11 has accumulated to suggest that there is a plausible risk that long-term
12 recipients of GLP-1-based therapy may develop asymptomatic chronic
13 pancreatitis (Fig. 1), and worse, subsequently a minority of individuals
14 treated by this class of drugs may develop pancreatic cancer."

15 29. In February 2011, the journal *Gastroenterology* published on-
16 line the work of Elashoff *et al.*⁵ titled, *Pancreatitis, pancreatic, and thyroid cancer*
17 *with glucagon-like peptide-1-based therapies.*

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

26 _____
27 ⁵ Elashoff M, Matveyenko AV, Gier B, Elashoff R & Butler PC Pancreatitis,
28 pancreatic, and thyroid cancer with glucagon-like peptide-1-based
therapies. *Gastroenterology* (2011) 141:150-156.

1 was not used as a control drug because it has been reported to decrease the
2 risk of pancreatic cancer.

3 31. These researchers reported that pancreatitis, inflammation of the
4 pancreas, was >10-fold more frequently reported as an adverse event for
5 patients administered Byetta and >6-fold more frequently reported in
6 patients prescribed Januvia. Both these associations were statistically
7 significant.

8 32. Because pancreatitis is a known risk factor for pancreatic
9 cancer,⁶ Elashoff *et al.* evaluated the reported rates of pancreatic cancer with
10 with Byetta and Januvia compared to control events relative to Avandia
11 (rosiglitazone).

12 33. The reported event rate for pancreatic cancer was 2.9-fold
13 greater in patients treated with Byetta compared to other therapies. Januvia
14 use also showed a marked increase in the rate of pancreatic cancer.

15 34. Because pancreatitis acts as a risk factor for subsequent
16 pancreatic cancer through the mechanisms of chronic inflammation and
17 increased cell turnover,⁷ it is not unforeseen that there is a progressive
18 increased risk of pancreatic cancer with prolonged exposure to the Drug.

19 35. These researchers noted that the potential to increase the risk of
20 cancer might be expected to occur by “permitting declaration of tumors
21 previously held in check by an intact immune system” as has been published
22 by others within the world’s medical literature.

23 36. On May 13, 2011, the Arzneimittelkommission der deutschen
24 Ärzteschaft (Drug Commission of the German Medical Association - AkdÄ)

25 _____
26 ⁶ Rebour V, Boutron-Ruault MC, Schnee M, et al. The natural history of
hereditary pancreatitis: a national series. *Gut* 2009;58: 97–103.

27 ⁷ Bhanot UK, Moller P. Mechanisms of parenchymal injury and signaling
28 pathways in ectatic ducts of chronic pancreatitis: implications for pancreatic
carcinogenesis. *Lab Invest* 2009;89:489– 497.

1 published *Pancreatic cancers associated with exenatide (Byetta®)* on its website.⁸

2 37. In the German adverse event database, reporting of pancreatic
3 cancer was also unusually high in association with Byetta (11 cases in 4
4 years, with yearly 15,000-25,000 treated patients).⁹

5 38. The period between the start of treatment with Byetta and a
6 diagnosis of pancreatic cancer was on average 12.2 months (within a range
7 of 2-33 months).

8 39. The manufacturers of Byetta have suggested that the most likely
9 reason for the apparent association between the use of these drugs and acute
10 pancreatitis is the increased risk of pancreatitis in patients with type 2
11 diabetes.¹⁰

12 40. However, recent animal studies showing pancreatitis as a
13 consequence of GLP-1 mimetic therapy challenge that assumption and lead
14 to the conclusion that asymptomatic chronic pancreatitis is an adverse effect
15 of GLP-1-based treatment.^{11,12}

16 41. GLP-1 receptors are abundantly expressed in the pancreas, and
17 therapy with drugs like Januvia has been shown to lead to increased
18 pancreatic ductal replication, acinar to ductal metaplasia or cellular change,

19 _____
20 ⁸<http://www.akdae.de/Arzneimittelsicherheit/Bekanntgaben/Archiv/2011/20110513.html>

21 ⁹ Arzneimittelkommission der deutschen Ärzteschaft. Aus der UAW-
22 Datenbank“: Pankreaskarzinome im Zusammenhang mit Exenatid
(Byetta®). Dtsch Arztebl, (2011) 108: A-1080; (as cited by Vangoitsenhoven
23 R, Mathieu C, Van Der Schueren B. GLP1 and cancer: friend or foe?
Endocrine Related Cancer. 2012 Jun 12. [Epub ahead of print])

24 ¹⁰ Monami M, Lamanna C, Marchionni N, Mannucci E. Rosiglitazone and
25 risk of cancer: a meta-analysis of randomized clinical trials. Diabetes Care
2008;31:1455–1460.

26 ¹¹ Matveyenko AV, Dry S, Cox HI, et al. Beneficial endocrine but adverse
27 exocrine effects of sitagliptin in the HIP rat model of type 2 diabetes,
28 interactions with metformin. Diabetes 2009;58: 1604–1615.

¹² Nachnani JS, Bulchandani DG, Nookala A, et al. Biochemical and
histological effects of exendin-4 (exenatide) on the rat pancreas.
Diabetologia 2009;58:1604–1615.

1 and, less commonly, acute pancreatitis in a rat model of type 2 diabetes.¹³

2 Byetta is a diabetes drug that acts like Januvia.

3 42. Increased ductal turnover and acinar to ductal metaplasia are
4 both well-established characteristics of chronic pancreatitis in humans.¹⁴

5 43. It has also been suggested that immunomodulatory effects of
6 DPP-4 inhibition might increase risk for all cancers.^{15,16}

7 44. Butler *et al.*¹⁷ also reported that human and rodent pancreases
8 contain numerous GLP-1 receptors in areas in which cancer is thought to
9 originate, and mice that are genetically predisposed to pancreatic cancer
10 develop the disease more quickly than usual in response to Byetta.

11 45. In April 2012, Public Citizen, a non-profit consumer-advocacy
12 organization based in Washington DC, sent a petition to the FDA to
13 withdraw another drug in the GLP-1 class, Victoza (liraglutide) from the
14 market.

15 46. Dr. Sidney Wolfe, director of the health and research group at
16 Public Citizen, said at that time, “We don’t just go after Drug
17 casually...(W)e only go after drugs when there is clear evidence of unique
18 dangers or risks, and when there is no evidence of a unique clinical
19 advantage.”

20 ¹³ Matveyenko AV, Dry S, Cox HI, et al. Beneficial endocrine but adverse
21 exocrine effects of sitagliptin in the HIP rat model of type 2 diabetes,
interactions with metformin. *Diabetes* 2009;58: 1604–1615.

22 ¹⁴ Bhanot UK, Moller P. Mechanisms of parenchymal injury and signaling
23 pathways in ectatic ducts of chronic pancreatitis: implications for pancreatic
carcinogenesis. *Lab Invest* 2009;89:489– 497.

24 ¹⁵ Havre PA, Abe M, Urasaki Y, et al. The role of CD26/dipeptidyl
peptidase IV in cancer. *Front Biosci* 2008;13:1634–1645.

25 ¹⁶ Matteucci E, Giampietro O. Dipeptidyl peptidase-4 (CD26): knowing the
function before inhibiting the enzyme. *Curr Med Chem* 2009;16:2943–2951.

26 ¹⁷ Gier B, Matveyenko AV, Kirakossian D, et al. Chronic GLP-1 Receptor
27 Activation by Exendin-4 Induces Expansion of Pancreatic Duct Glands in
Rats and Accelerates Formation of Dysplastic Lesions and Chronic
28 Pancreatitis in the KrasG12D Mouse Model. *Diabetes* May 2012 vol. 61 no. 5
1250-1262

1 47. Dr. Wolfe said at the time that his concern extends to other
2 diabetes drugs that alter the GLP-1 pathway, which would include Byetta.

3 48. As a result of the defective nature of Byetta persons who were
4 prescribed and ingested Byetta for even a brief period of time, including
5 Plaintiff herein, were at increased risk for developing life-threatening
6 pancreatic cancer. Once that cancer spreads, a patient stands just a 1.8%
7 chance of surviving for longer than five years.

8 49. Due to the flawed formulation of Byetta, it increases the risk of
9 pancreatic cancer in those diabetic patients to whom it is prescribed.

10 50. Defendants concealed their knowledge that Byetta can cause life
11 threatening pancreatic cancer from Plaintiff, other consumers, the general
12 public, and the medical community. Indeed, the manufacturers of Byetta do
13 not even mention 'pancreatic cancer' in the Drug's product insert.

14 51. Specifically, the Defendants did not adequately inform
15 consumers and the prescribing medical community about the risks of
16 pancreatic cancer associated with Byetta usage, nor did Defendants warn or
17 otherwise advise physicians to institute monitoring procedures looking for
18 the first signs of changes within the pancreas.

19 52. The current warnings for the Drug are simply inadequate. The
20 Defendants have failed and continue to fail in their duties to warn and
21 protect the consuming public, including the Plaintiff herein.

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

27 54. Defendants willfully, wantonly, and with malice withheld the
28 knowledge of increased risk of pancreatic cancer in users of Byetta to

1 prevent any chances of their product's registration being delayed or rejected
2 by FDA.

3 55. As the manufacturers and distributors of Byetta, Defendants
4 knew or should have known that the Drug's usage was associated with
5 pancreatic cancer.

6 56. With the knowledge of the true relationship between use of
7 Byetta and pancreatic cancer, rather than taking steps to pull the Drug off
8 the market or provide strong warnings, Defendants promoted and continue
9 to promote Byetta as a safe and effective treatment for adults with type 2
10 diabetes.

11 57. Byetta is one of the top selling drugs in the country.

12 58. In 2010, the worldwide sales of Byetta reached \$0.710 billion and
13 Visiongain predicts sales to reach \$1.00 billion by 2015 and \$1.28 billion by
14 2021.¹⁸

15 59. While Defendants have enjoyed great financial success from
16 their blockbuster Drug, they continue to place American citizens at risk of
17 developing deadly pancreatic cancer.

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

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

26 62. As a result of Defendants' actions, Plaintiff and Plaintiff's

27 _____
28 ¹⁸ www.pipelinereview.com/store/toc/sample_pages_vg0151.pdf

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

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

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

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

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

17 a. in print advertising;

18 b. on their websites and blogs;

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

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

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

26 68. Defendants failed to provide proper and full information as to
27 the safety of the Drug.

28 69. Defendants failed to ensure that full and correct safety labeling

1 and warnings were used in pharmacy sheets that accompanied the Drug to
2 the purchaser.

3 70. Defendants have never sought to enlarge their warnings to
4 include a warning about pancreatic cancer risks associated with the use of
5 the Drug.

6 71. Instead, Defendants marketed (and continue to market) the
7 Drug as having a low risk of side effects and continue to minimize the
8 Drug's deadly side effects.

9 72. Manufacturers such as the Defendants, herein, are required to
10 have systems in place to collect and analyze any complaints they receive
11 from doctors and hospitals about their products.

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

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

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

27 76. Plaintiff suffered from severe and personal injuries, which were
28 permanent and lasting in nature, including risk of death, physical pain, and

1 mental anguish, including diminished enjoyment of life, as well as the need
2 for medical treatment, monitoring and/or medication both in the past and in
3 the future.

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

9 78. As a direct and proximate result of the aforesaid conduct of the
10 Defendants, and each of them, Plaintiff was compelled to incur obligations
11 for physicians, surgeons, nurses, hospital care, medicine, hospices, x-rays,
12 medical supplies, and other medical treatment, the true and exact amount
13 thereof being unknown to Plaintiff at this time, and Plaintiff prays leave to
14 amend this complaint accordingly when the true and exact cost thereof is
15 ascertained.

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

22 80. By reasons of the premises, Plaintiff and Plaintiff have been
23 caused great pain and suffering.

24 STATEMENT OF PLAINTIFF'S INJURIES

25 81. On or about December 1, 2006, Plaintiff was prescribed and
26 began taking Byetta upon the direction of Plaintiff's physician for long-term
27 maintenance of Type II diabetes, and Plaintiff continued to take Byetta until
28 at least May 30, 2010.

1 The Byetta manufactured by Defendants reached Plaintiff without
2 substantial changes and were ingested as directed. The Drug was defective
3 and unreasonably dangerous when it entered into the stream of commerce
4 and when used by Plaintiff.

5 89. The Plaintiff was administered the Drug for its intended
6 purposes.

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

9 91. Defendants, as manufacturers of pharmaceutical drugs, are held
10 to the level of knowledge of an expert in the field, and further, Defendants
11 knew or should have known that warnings and other clinically relevant
12 information and data which they distributed regarding the risks of injuries
13 and death associated with the use of Byetta were incomplete and inadequate,
14 if not intentionally void of critical information about Byetta's deadly side
15 effects.

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

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

26 94. Defendants marketed, promoted, distributed and sold the
27 unreasonably dangerous and defective prescription drug, Byetta, to health
28 care providers empowered to prescribe and dispense the Drug to consumers,

1 including Plaintiff, without adequate warnings and other clinically relevant
2 information and data. Through both omission and affirmative
3 misstatements, Defendants misled the medical community about the risk
4 and benefit balance of the Drug, which resulted in injury to Plaintiff.

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

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

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

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

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

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

1 ingestion of the Drug.

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

7 99. By failing to provide Plaintiff and Plaintiff's physicians with
8 adequate clinically relevant information and data and warnings regarding
9 the adverse health risks associated with exposure to the Drug, and/or that
10 there existed safer and more or equally effective alternative drug products,
11 Defendants breached their duty of reasonable care and safety.

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

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

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

20 COUNT II

21 STRICT PRODUCTS LIABILITY - DESIGN DEFECT

22 103. Plaintiff hereby incorporates by reference all preceding
23 paragraphs as if fully set forth herein.

24 104. Defendants are the manufacturers, designers, distributors,
25 sellers and suppliers of the Drug, who sold the Drug in the course of
26 business.

27 105. The Drug manufactured, designed, sold, marketed, distributed,
28 supplied and/or placed in the stream of commerce by Defendants was

1 expected to and did reach the consumer without any alterations or changes.

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

- 4 a. When it left the hands of the Defendants, this drug was
5 unreasonably dangerous to the extent beyond that which
6 could reasonably be contemplated by Plaintiff or Plaintiff's
7 physicians;
- 8 b. Any benefit of this Drug was outweighed by the serious and
9 undisclosed risks of its use when prescribed and used as the
10 Defendants intended;
- 11 c. The dosages and/or formulation of the Drug sold by the
12 Defendants was unreasonably dangerous;
- 13 d. There are no patients for whom the benefits of the Drug
14 outweighed the risks;
- 15 e. The subject product was not made in accordance with the
16 Defendants' specifications or performance standards;
- 17 f. There are no patients for whom the Drug is a safer and more
18 efficacious drug than other drug products in its class; and/or
19 g. There were safer alternatives that did not carry the same risks
20 and dangers that Defendants' Drug had.

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

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

28 109. The defective and unreasonably dangerous design and

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

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

9 111. Defendants' actions and omissions as identified in this
10 Complaint show that Defendants acted maliciously and/or intentionally
11 disregarded Plaintiff's rights so as to warrant the imposition of punitive
12 damages.

13 COUNT III

14 NEGLIGENCE

15 112. Plaintiff hereby incorporates by reference all preceding
16 paragraphs as if fully set forth herein.

17 113. Defendants had a duty to exercise reasonable care in the
18 manufacture, sale and/or distribution of the Drug into the stream of
19 commerce, including a duty to ensure that the products did not cause users
20 to suffer from unreasonable, dangerous side effects.

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

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

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

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

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

10 119. As a proximate and legal result of Defendants' negligence,
11 Plaintiff and Plaintiff were caused to suffer the herein described injuries and
12 damages.

13 COUNT IV

14 BREACH OF IMPLIED WARRANTY

15 120. Plaintiff hereby incorporates by reference all preceding
16 paragraphs as if fully set forth herein.

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

23 122. Plaintiff and Plaintiff's physicians and healthcare providers
24 relied on the skill and judgment of the Defendants in using and prescribing
25 the Drug.

26 123. The products were unsafe for their intended use, and they were
27 not of merchantable quality, as warranted by Defendants, in that the Drug
28 had very dangerous propensities when put to their intended use and would

1 cause severe injury (or death) to the user. The Drug was unaccompanied by
2 adequate warnings of its dangerous propensities that were either known or
3 reasonably scientifically knowable at the time of distribution.

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

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

11 COUNT V

12 BREACH OF EXPRESS WARRANTY

13 126. Plaintiff hereby incorporates by reference all preceding
14 paragraphs as if fully set forth herein.

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

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

26 129. Plaintiff and Plaintiff's physicians reasonably relied upon the
27 skill and judgment of Defendants, and upon said express warranty, in using
28 the Drug. The warranty and representations were untrue in that the

1 products were unsafe and, therefore, unsuited for the use for which they was
2 intended. The Drug could and did thereby cause Plaintiff to suffer the
3 herein described injuries and damages.

4 130. As soon as the true nature of the products and the fact that the
5 warranty and representations were false were ascertained, Defendants were
6 notified of the breach of said warranty.

7
8 **COUNT VI**

9 **NEGLIGENT MISREPRESENTATION**

10 131. Plaintiff hereby incorporates by reference all preceding
11 paragraphs as if fully set forth herein.

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

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

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

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

1 the drug is to be dispensed.

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

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

15 138. Defendants disseminated the false information, as referenced
16 above, to physicians, the medical community and their patients with the
17 intention to deceive physicians and their patients and to induce the
18 physicians to prescribe the Drug.

19 139. Alternatively or in addition, Defendants failed to exercise
20 reasonable care to ensure that the information disseminated to physicians
21 concerning the properties and effects of the Drug were accurate and not
22 misleading, Defendants failed to exercise reasonable care to insure that
23 accurate and not misleading information was disseminated to physicians
24 concerning the properties and effects of the Drug by failing to publish or
25 disseminate current and accurate information.

26 140. Defendants expected or should have expected that patients
27 taking the Drug, pursuant to prescriptions written or issued in reliance on
28 false information, would be placed in unnecessary, avoidable, and

1 unreasonable danger due to unwarranted exposure to the Drug.

2 141. As a proximate and foreseeable result of this dissemination to
3 physicians, by Defendants consciously or negligently disseminating false
4 information, the Plaintiff suffered grievous bodily injury, and ultimately
5 death, and consequent economic and other loss, as described above, when
6 Plaintiff's physicians, in reasonable reliance upon the negligently inaccurate,
7 misleading and otherwise false information disseminated by these
8 defendants, and reasonably but unjustifiably believing the information to be
9 true, prescribed for the Plaintiff the Drug.

10 142. As a result of the foregoing negligent misrepresentations by
11 Defendants, and each of them, the Plaintiff was caused to suffer the herein
12 described injuries and damages.

13 **COUNT VII**

14 **FRAUDULENT CONCEALMENT**

15 143. Plaintiff hereby incorporates by reference all preceding
16 paragraphs as if fully set forth herein.

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

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

- 25 a. Failed to disclose any connection between use of the Drug
26 and the development of pancreatic cancer;
27 b. Did not inform prescribers and users of studies related to use
28 of the Drug and the development of pancreatic cancer, and

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

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

8 147. At all times mentioned in this Complaint, Defendants had the
9 duty and obligation to disclose to Plaintiff and to Plaintiff's physicians and
10 healthcare providers the true facts concerning the Drug, which facts include,
11 but are not limited to, the fact that the Drug was dangerous and likely to
12 cause serious health consequences to users, including pancreatic cancer and
13 death.

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

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

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

28 151. As a proximate result of the concealment or suppression of the

1 facts set forth above, Plaintiff and Plaintiff's physicians and healthcare
2 providers reasonably relied on Defendants' deception and, Plaintiff was
3 prescribed the Drug and subsequently sustained injuries and damages as set
4 forth in this Complaint. Defendants' concealment was a substantial factor in
5 causing the injuries described herein.

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

9 153. As a result of the foregoing fraudulent and deceitful conduct by
10 Defendants, and each of them, Plaintiff was caused to suffer the herein
11 described injuries and damages.

12 **COUNT VIII**

13 **PUNITIVE DAMAGES**

14 154. Plaintiff hereby incorporates by reference all preceding
15 paragraphs as if fully set forth herein.

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

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

26 157. Defendants intentionally concealed or recklessly failed to
27 disclose to the public, including Plaintiff, the potentially life-threatening side
28 effects of the Drug to ensure their continued and increased sales.

1 Defendants failed to provide warnings that would have dissuaded
2 physicians from prescribing the Drug and consumers from purchasing and
3 consuming the Drug, thus depriving physicians and consumers from
4 weighing the true risks against the benefits of prescribing and/or
5 purchasing and consuming the Drug.

6 158. The aforementioned conduct of Defendants was willful and
7 wanton and was committed with knowing, conscious, and deliberate
8 disregard for the rights and safety of consumers such as Plaintiff, thereby
9 entitling Plaintiff to punitive damages in an amount appropriate to punish
10 Defendants and deter them from similar conduct in the future.

11 PRAYER FOR RELIEF

12 **WHEREFORE**, Plaintiff prays for relief as follows:

- 13 1. Actual damages as alleged, jointly and/or severally against
14 Defendants, in excess of \$75,000.00;
- 15 2. Past and future medical expenses and other economic
16 damages in an amount to be determined at trial of this action;
- 17 3. Past and future loss of earnings and/or earning capacity,
18 according to proof to be determined at trial of this action;
- 19 4. Past and future pain and suffering;
- 20 5. Punitive damages alleged against Defendants, including
21 Plaintiff's attorney fees, in excess of \$75,000.00;
- 22 6. Interest on the judgment at the highest legal rate from the
23 date of judgment until collected;
- 24 7. Attorneys' fees, expenses, and costs of this action; and
- 25 8. Such further relief as this Court deems necessary, just and
26 proper.

27 JURY DEMAND

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

1 Dated: June 10, 2013

Respectfully submitted,

2 **THE RESTAINO LAW FIRM, P.C.**

3 /s/ John M. Restaino, Jr.

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10 And

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CIVIL COVER SHEET

'13CV1346 DMS NLS

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

Electia Johnson

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

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

John M. Restaino, Jr., The Restaino Law Firm, P.C., 283 Columbine St., Suite 169, Denver, CO 80206

DEFENDANTS

Amylin Pharmaceuticals, LLC f/k/a Amylin Pharmaceuticals, Inc., and Eli Lilly and Company

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, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 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)

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation

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

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Insurance, Personal Injury, Real Estate, etc.

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, 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. 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 SIGNATURE OF ATTORNEY OF RECORD

June 10, 2013 /s/ John M. Restaino, Jr.

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE