	Case 3:13-cv-01346-DMS-NLS Document 1	Filed 06/10/13 Page 1 of 30				
1 2 3 4 5 6 7 8 9	John M. Restaino, Jr., D.P.M., J.D., MPH IRestaino@Restainolawfirm.com The Restaino Law Firm, P.C. 283 Columbine St., Suite 169 Denver, CO 80206 Tel: 720-924-2006 Fax: 720-221-0449 Ryan L. Thompson (<i>Pro Hac Vice</i> applicant thompson@wattsguerra.com WATTS GUERRA LLP 5250 Prue Road, Suite 525 San Antonio, Texas 78240 Office: 210.448.0500 Fax: 210.448.0501					
11	Attorneys for Plaintiff					
12 13	UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF CALIFORNIA					
14	ELECTIA JOHNSON					
15		C N. 142 CV4246 DMC NI C				
16	Plaintiff,	Cause No. <u>'13CV1346 DMS NLS</u>				
17	v.					
18	AMYLIN PHARMACEUTICALS, LLC	COMPLAINT FOR DAMAGES				
19	F/K/A AMYLIN PHARMACEUTICALS, INC., AND FILLULY AND COMPANY and	JURY TRIAL DEMANDED				
20	ELI LILLY AND COMPANY, and DOES 1-100					
21 22	Defendants.					
23						
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					

2. The true names or capacities whether individual, corporate or otherwise, of the Doe Defendants I 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 and 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, coconspirator, 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

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certain Defendant, 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 and Plaintiff were caused by the wrongful acts, omissions, and fraudulent representations of Defendants, many of which occurred within the State of California.
- At all times herein mentioned, Defendants were each engaged in 6. the business of, or were successors in interest to, entities engaged in the business of research, 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.
- 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.

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.

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- This Court has jurisdiction over the non-resident Defendants 10. 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.
- In addition, venue of this case is proper in the Southern District 11. 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.

PLAINTIFF

- Plaintiff Electia Johnson is a natural person currently residing in 13. Baton Rouge, Louisiana at the time she ingested the Drug and was diagnosed with pancreatic cancer.
- 14. Plaintiff was prescribed and used the Drug beginning on or about December 1, 2006 and continued said use through at least May 30, 2010. During or about July 2012, Plaintiff suffered severe physical, economic and emotional injuries as a result of said Drug, including but not limited to Plaintiff's being diagnosed with pancreatic cancer. Plaintiff and Plaintiff's physician were unaware that Plaintiff's injuries were caused by the Drug until shortly before the filing of this complaint.

DEFENDANTS

Amylin Pharmaceuticals, LLC f/k/a Amylin Pharmaceuticals, 15. Inc. ("Amylin, LLC") is a Delaware limited liability company, which has its principal place of business is 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.

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.

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, are 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."

 $^{^1 \}quad http://www.diabetes.org/diabetes-basics/type-2/?loc=DropDownDB-type2$

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- 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 worldwide³ 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. Two of the most recently approved classes of therapeutic agents for the treatment of type 2 diabetes, glucagon-like peptide-1 (GLP-1) receptor (GLP-1R) agonists (such as Byetta) and dipeptidyl peptidase-4 (DPP-4) inhibitors (such as Januvia), exert their actions through potentiation of incretin receptor signaling. Incretins are gut-derived hormones, principally GLP-1 and glucose-dependent insulinotropic peptide (GIP), that 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.
- 25. Byetta is a member of the new class of drugs known as glucagon-like peptide-1 (GLP-1) receptor agonists.
- 26. In February 2010, concerns were published regarding the GLP-1 drugs, including Byetta, and the DPP-4 inhibitors, including Januvia, and their potential linkage with pancreatic cancer.
- 27. Writing in DIABETES CARE, Butler *et al.* published *GLP-1–Based* Therapy for Diabetes: What You Do Not Know Can Hurt You'⁴ wherein they

 $^{^2}$ ID

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

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

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

- 28. In addition, these researchers wrote, "However, in the context of a new class of medical therapy, the proverb 'What you do not know cannot hurt you' clearly does not apply. We feel that enough preliminary evidence has accumulated to suggest that there is a plausible risk that long-term recipients of GLP-1–based therapy may develop asymptomatic chronic pancreatitis (Fig. 1), and worse, subsequently a minority of individuals treated by this class of drugs may develop pancreatic cancer."
- 29. In February 2011, the journal Gastroenterology published online the work of Elashoff *et al.*⁵ titled, *Pancreatitis, pancreatic, and thyroid cancer with glucagon-like peptide-1-based therapies*.
- 30. 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 drugs were 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. Metformin

⁵ 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.

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

- 31. These researchers reported that pancreatitis, inflammation of the pancreas, was >10-fold more frequently reported as an adverse event for patients administered Byetta and >6-fold more frequently reported in patients prescribed Januvia. Both these associations were statistically significant.
- 32. Because pancreatitis is a known risk factor for pancreatic cancer,⁶ Elashoff *et al.* evaluated the reported rates of pancreatic cancer with with Byetta and Januvia compared to control events relative to Avandia (rosiglitazone).
- 33. The reported event rate for pancreatic cancer was 2.9-fold greater in patients treated with Byetta compared to other therapies. Januvia use also showed a marked increase in the rate of pancreatic cancer.
- 34. Because pancreatitis acts as a risk factor for subsequent pancreatic cancer through the mechanisms of chronic inflammation and increased cell turnover,⁷ it is not unforeseen that there is a progressive increased risk of pancreatic cancer with prolonged exposure to the Drug.
- 35. 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.
- 36. On May 13, 2011, the Arzneimittelkommission der deutschen Ärzteschaft (Drug Commission of the German Medical Association AkdÄ)

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

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

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

- 37. In the German adverse event database, reporting of pancreatic cancer was also unusually high in association with Byetta (11 cases in 4 years, with yearly 15,000-25,000 treated patients).⁹
- 38. The period between the start of treatment with Byetta and a diagnosis of pancreatic cancer was on average 12.2 months (within a range of 2-33 months).
- 39. The manufacturers of Byetta have suggested that the most likely reason for the apparent association between the use of these drugs and acute pancreatitis is the increased risk of pancreatitis in patients with type 2 diabetes.¹⁰
- 40. However, recent animal studies showing pancreatitis as a consequence of GLP-1 mimetic therapy challenge that assumption and lead to the conclusion that asymptomatic chronic pancreatitis is an adverse effect of GLP-1-based treatment.^{11,12}
- 41. GLP-1 receptors are abundantly expressed in the pancreas, and therapy with drugs like Januvia has been shown to lead to increased pancreatic ductal replication, acinar to ductal metaplasia or cellular change,

⁸http://www.akdae.de/Arzneimittelsicherheit/Bekanntgaben/Archiv/2011/20110513.html

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

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

¹¹ Matveyenko AV, Dry S, Cox HI, et al. Beneficial endocrine but adverse exocrine effects of sitagliptin in the HIP rat model of type 2 diabetes, 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.

and, less commonly, acute pancreatitis in a rat model of type 2 diabetes.¹³ Byetta is a diabetes drug that acts like Januvia.

- 42. Increased ductal turnover and acinar to ductal metaplasia are both well-established characteristics of chronic pancreatitis in humans.¹⁴
- 43. It has also been suggested that immunomodulatory effects of DPP-4 inhibition might increase risk for all cancers. 15,16
- 44. Butler *et al.*¹⁷ also reported that human and rodent pancreases contain numerous GLP-1 receptors in areas in which cancer is thought to originate, and mice that are genetically predisposed to pancreatic cancer develop the disease more quickly than usual in response to Byetta.
- 45. In April 2012, Public Citizen, a non-profit consumer-advocacy organization based in Washington DC, sent a petition to the FDA to withdraw another drug in the GLP-1 class, Victoza (liraglutide) from the market.
- 46. Dr. Sidney Wolfe, director of the health and research group at Public Citizen, said at that time, "We don't just go after Drug 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."

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

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

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

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

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

- 47. Dr. Wolfe said at the time that his concern extends to other diabetes drugs that alter the GLP-1 pathway, which would include Byetta.
- 48. As a result of the defective nature of Byetta persons who were prescribed and ingested Byetta for even a brief period of time, including Plaintiff herein, were at increased risk for developing life-threatening pancreatic cancer. Once that cancer spreads, a patient stands just a 1.8% chance of surviving for longer than five years.
- 49. Due to the flawed formulation of Byetta, it increases the risk of pancreatic cancer in those diabetic patients to whom it is prescribed.
- 50. Defendants concealed their knowledge that Byetta can cause life threatening pancreatic cancer from Plaintiff, other consumers, the general public, and the medical community. Indeed, the manufacturers of Byetta do not even mention 'pancreatic cancer' in the Drug's product insert.
- 51. Specifically, the Defendants did not adequately inform consumers and the prescribing medical community about the risks of pancreatic 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 pancreas.
- 52. The current warnings for the Drug are simply inadequate. The Defendants have failed and continue to fail in their duties to warn and protect the consuming public, including the Plaintiff herein.
- 53. 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.
- 54. Defendants willfully, wantonly, and with malice withheld the knowledge of increased risk of pancreatic cancer in users of Byetta to

- 55. As the manufacturers and distributors of Byetta, Defendants knew or should have known that the Drug's usage was associated with pancreatic cancer.
- 56. With the knowledge of the true relationship between use of Byetta and pancreatic cancer, rather than taking steps to pull the Drug off the market or provide strong warnings, Defendants promoted and continue to promote Byetta as a safe and effective treatment for adults with type 2 diabetes.
 - 57. Byetta is one of the top selling drugs in the country.
- 58. 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. 18
- 59. While Defendants have enjoyed great financial success from their blockbuster Drug, they continue to place American citizens at risk of developing deadly pancreatic cancer.
- 60. Consumers, including Plaintiff, who have used Byetta for 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.
- 61. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with Byetta use.
 - 62. As a result of Defendants' actions, Plaintiff and Plaintiff's

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

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- 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
- At all times relevant hereto, the Defendants have directly marketed and distributed the Drug to the medical community.
- At all times relevant hereto, the Defendants have directly marketed the Drug to the consuming public throughout the United States,
- 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.
- Defendants both over-promoted the Drug and under-warned
 - 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.
- Defendants did not perform adequate safety testing on the Drug 67. as required by good pharmaceutical science practice.
- 68. Defendants failed to provide proper and full information as to the safety of the Drug.
 - 69. Defendants failed to ensure that full and correct safety labeling

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

- 70. Defendants have never sought to enlarge their warnings to include a warning about pancreatic cancer risks associated with the use of the Drug.
- 71. Instead, Defendants marketed (and continue to market) the Drug as having a low risk of side effects and continue to minimize the Drug's deadly side effects.
- 72. 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.
- 73. 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.
- 74. 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.
- 75. Plaintiff and Plaintiff's prescribing health care providers were unaware of the true degree and incidence of pancreatic 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.
- 76. Plaintiff suffered from severe and personal injuries, which were permanent and lasting in nature, including risk of death, physical pain, and

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

- 77. 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 pancreatic cancer, which resulted in damages to Plaintiff in a sum in excess of the jurisdictional limits of the Court.
- 78. 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, hospices, 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.
- 79. 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.
- By reasons of the premises, Plaintiff and Plaintiff have been 80. caused great pain and suffering.

STATEMENT OF PLAINTIFF'S INJURIES

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

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- 82. As a direct result of the ingestion of Byetta, the Plaintiff was diagnosed with pancreatic cancer during or about July 2012. Had Plaintiff and/or Plaintiff's physician been properly warned by Defendants regarding the risk of pancreatic cancer from usage of this prescription medication, Plaintiff's physician would have not prescribed the Drug and Plaintiff would never had ingested this prescription medication.
- As a direct result of being prescribed Byetta for this period of 83. time, Plaintiff was permanently and severely injured, having suffered serious consequences from Plaintiff's usage of Byetta, including but not limited to, the development of pancreatic cancer.
- Plaintiff, as a direct and proximate result of her Byetta use, suffered severe mental and physical pain and suffering, along with economic loss.
- 85. As a proximate result of Defendants' acts and omissions, Plaintiff suffered the injuries described hereinabove due to her ingestion of Byetta. Plaintiff accordingly seeks damages associated with these injuries.
- Plaintiff would not have used Byetta had Defendants properly 86. disclosed the risks associated with its use.

CAUSES OF ACTION

COUNT I

STRICT LIABILITY-FAILURE TO WARN

- 87. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.
- Defendants are liable under the theory of strict products 88. 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.

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- Byetta manufactured by Defendants reached Plaintiff without substantial changes and were ingested as directed. The Drug was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff.
- 89. The Plaintiff was administered the Drug for its intended purposes.
- 90. The Plaintiff could not have discovered any defect in the Drug through the exercise of care.
- 91. Defendants, as manufacturers of pharmaceutical drugs, 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, if not intentionally void of critical information about Byetta's deadly side effects.
- 92. 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.
- 93. 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.
- 94. 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, Defendants misled the medical community about the risk and benefit balance of the Drug, which resulted in injury to Plaintiff.

- 95. 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.
- 96. Defendants knew or should have known that consumers, Plaintiff specifically, would foreseeably and needlessly suffer injury or death as a result of Defendants' failures.
- 97. 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, their tendency to increase the risk of, and/or cause, the development of pancreatic 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, pancreatic 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 pancreatic cancer from

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ingestion of the Drug.

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- 98. 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.
- 99. 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.
- Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of the Plaintiff and the public.
- Defendants' actions described above violated the federal and 101. state Food, Drug and Cosmetic Acts and rendered the Drug misbranded.
- 102. 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

- 103. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.
- Defendants are the manufacturers, designers, distributers, sellers and suppliers of the Drug, who sold the Drug in the course of business.
- 105. 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.

- 106. 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;
 - 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' Drug had.
- 107. The Drug administered to Plaintiff was defective at the time it was distributed by the Defendants or left their control.
- 108. 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.
 - 109. The defective and unreasonably dangerous design and

- 110. 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.
- 111. 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

- 112. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.
- 113. 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 ensure that the products did not cause users to suffer from unreasonable, dangerous side effects.
- 114. 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 pancreatic cancer.
- 115. Defendants were negligent in the design, manufacture, testing, advertising, warning, marketing and sale of the Drug.

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- Despite the fact that Defendants knew or should have known 116. that the Drug caused unreasonable, dangerous side effects, Defendants continued to market the Drug to consumers including Plaintiff.
- 117. 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.
- 118. 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.
- As a proximate and legal result of Defendants' negligence, Plaintiff and Plaintiff were caused to suffer the herein described injuries and damages.

COUNT IV

BREACH OF IMPLIED WARRANTY

- 120. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.
- At all times mentioned in this Complaint, Defendants 121. compounded, packaged, manufactured, 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.
- 122. Plaintiff and Plaintiff's physicians and healthcare providers relied on the skill and judgment of the Defendants in using and prescribing the Drug.
- 123. The products were unsafe for their intended use, and they were not of merchantable quality, as warranted by Defendants, in that the Drug had very dangerous propensities when put to their intended use and would

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27 28 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.

- 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.
- 125. After Plaintiff was made aware or otherwise cam 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

- Plaintiff hereby incorporates by reference all preceding 126. paragraphs as if fully set forth herein.
- 127. The aforementioned manufacturing, compounding, packaging, testing, constructing, designing, distributing, 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.
- At the time of the making of the express warranties, Defendants 128. 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 were either known or knowable at the time of distribution.
- 129. 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

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

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

COUNT VI

NEGLIGENT MISREPRESENTATION

- 131. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.
- 132. 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.
- 133. 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.
- 134. 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.
- 135. 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.

136. 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.

- 137. 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.
- 138. 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.
- 139. 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.
- 140. 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.

- 141. 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 ultimately 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 these defendants, and reasonably but unjustifiably believing the information to be true, prescribed for the Plaintiff the Drug.
- 142. As a result of the foregoing negligent misrepresentations by Defendants, and each of them, the Plaintiff was caused to suffer the herein described injuries and damages.

COUNT VII

FRAUDULENT CONCEALMENT

- 143. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.
- 144. 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 were dangerous and defective, and likely to cause serious health consequences to users, including the injuries as described in this Complaint.
- 145. 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 connection between use of the Drug and the development of pancreatic cancer;
 - b. Did not inform prescribers and users of studies related to use of the Drug and the development of pancreatic cancer, and

- c. Concealed from prescribers and users that numerous adverse events have been reported linking use of the Drug to pancreatic cancer.
- 146. 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.
- 147. 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 pancreatic cancer and death.
- 148. 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.
- 149. 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, that the Drug would not have been prescribed as part of Plaintiff's treatment and Plaintiff would not have been injured as a result.
- 150. 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.
 - 151. 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.

- 152. 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.
- 153. 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 VIII

PUNITIVE DAMAGES

- 154. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.
- 155. Although Defendants knew or recklessly disregarded the fact that the Drug causes 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.
- 156. Defendants knew of the Drug's defective nature, as set forth herein, but continued to design, manufacture, market, and sell them 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.
- 157. 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.

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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.

158. 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 relief as follows:

- 1. Actual damages as alleged, jointly and/or severally against Defendants, in excess of \$75,000.00;
- 2. Past and future medical expenses and other economic damages in an amount to be determined at trial of this action;
- 3. Past and future loss of earnings and/or earning capacity, according to proof to be determined at trial of this action;
- 4. Past and future pain and suffering;
- 5. Punitive damages alleged against Defendants, including Plaintiff's attorney fees, in excess of \$75,000.00;
- 6. Interest on the judgment at the highest legal rate from the date of judgment until collected;
- 7. Attorneys' fees, expenses, and costs of this action; and
- 8. 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.

	Case 3:13-cv-01346-DMS-NLS Document 1 Filed 06/10/13 Page 30 of 30							
1	Dated: June 10, 2013	Respectfully submitted,						
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3		THE RESTAINO LAW FIRM, P.C.						
4		<u>/s/ John M. Restaino, Jr.</u> John M. Restaino, Jr., D.P.M., J.D., MPH (#138268)						
5		The Restaino Law Firm, P.C. 283 Columbine St., Suite 169						
6 7		Denver, CO 80206 Tel: 720-924-2006						
8		Fax: 720-221-0449						
9		And						
10		Ryan L. Thompson (<i>Pro Hac Vice</i> anticipated)						
11		WATTS GUERRA LLP						
12 13		5250 Prue Road, Suite 525 San Antonio, Texas 78240						
14		Office: 210.448.0500 Fax: 210.448.0501						
15		Attorneys for Plaintiff						
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	CIVIL COMPLAINT FOR DAMAGES							

Case 3:13-cv-01346-DMSTVIE COVER SHEET led 06/10/13 Page 1 of 1 '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

	This form, approved by the Judici ocket sheet. (SEE INSTRUCTIONS OF			9/4, is required for the use of	the Clerk of Court for the			
I. (a) PLAINTIFFS			DEFENDANTS					
Electia Johnson			Amylin Pharmaceuticals, LLC f/k/a Amylin Pharmaceuticals, Inc., and Eli Lilly and Company					
(b) County of Residence of	First Listed Plaintiff Fact Bat	on Rouge	County of Residence of	of First Listed Defendant	Jnion County			
` '	XCEPT IN U.S. PLAINTIFF CASES)	on riouge	_	(IN U.S. PLAINTIFF CASES O				
				NDEMNATION CASES, USE THOSE LAND INVOLVED.	HE LOCATION OF			
(c) Attorneys (Firm Name, 2	Address, and Telephone Number)		Attorneys (If Known)					
	e Restaino Law Firm, P.C., 28	83 Columbine St	•					
Suite 169, Denver, CO 80		,						
II. BASIS OF JURISDI	CTION (Place an "X" in One Box On	nly)	CITIZENSHIP OF PF (For Diversity Cases Only)	RINCIPAL PARTIES	Place an "X" in One Box for Plaintify and One Box for Defendant)			
□ 1 U.S. Government	☐ 3 Federal Question		PT		PTF DEF			
Plaintiff	(U.S. Government Not a Par	rty) Ci	itizen of This State	1				
☐ 2 U.S. Government Defendant	■ 4 Diversity (Indicate Citizenship of Parts		itizen of Another State	2				
			itizen or Subject of a Foreign Country	3	□ 6 □ 6			
IV. NATURE OF SUIT	(Place an "X" in One Box Only)							
CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES			
☐ 110 Insurance ☐ 120 Marine		RSONAL INJURY Personal Injury -	625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158 ☐ 423 Withdrawal	☐ 375 False Claims Act ☐ 400 State Reapportionment			
☐ 130 Miller Act	•		690 Other	28 USC 157	☐ 410 Antitrust			
☐ 140 Negotiable Instrument		Health Care/ Pharmaceutical		DDODEDTY DICHTS	☐ 430 Banks and Banking ☐ 450 Commerce			
 150 Recovery of Overpayment & Enforcement of Judgment 	*	Personal Injury		PROPERTY RIGHTS ☐ 820 Copyrights	☐ 460 Deportation			
☐ 151 Medicare Act		Product Liability		□ 830 Patent	☐ 470 Racketeer Influenced and			
☐ 152 Recovery of Defaulted Student Loans	,	Asbestos Personal Injury Product		☐ 840 Trademark	Corrupt Organizations 480 Consumer Credit			
(Excludes Veterans)	☐ 345 Marine Product	Liability	LABOR	SOCIAL SECURITY	☐ 490 Cable/Sat TV			
☐ 153 Recovery of Overpayment of Veteran's Benefits		ONAL PROPERTY Other Fraud	710 Fair Labor Standards Act	☐ 861 HIA (1395ff) ☐ 862 Black Lung (923)	□ 850 Securities/Commodities/ Exchange			
☐ 160 Stockholders' Suits			720 Labor/Management	□ 863 DIWC/DIWW (405(g))	■ 890 Other Statutory Actions			
190 Other Contract195 Contract Product Liability		Other Personal Property Damage		☐ 864 SSID Title XVI ☐ 865 RSI (405(g))	☐ 891 Agricultural Acts ☐ 893 Environmental Matters			
☐ 196 Franchise	Injury 🗖 385 I	Property Damage	751 Family and Medical	((6))	☐ 895 Freedom of Information			
	☐ 362 Personal Injury - Female Medical Malpractice	Product Liability	Leave Act 790 Other Labor Litigation		Act ☐ 896 Arbitration			
REAL PROPERTY	CIVIL RIGHTS PRISO	ONER PETITIONS	791 Employee Retirement	FEDERAL TAX SUITS	☐ 899 Administrative Procedure			
□ 210 Land Condemnation□ 220 Foreclosure	e e	eas Corpus: Alien Detainee	Income Security Act	☐ 870 Taxes (U.S. Plaintiff or Defendant)	Act/Review or Appeal of Agency Decision			
☐ 230 Rent Lease & Ejectment	☐ 442 Employment ☐ 510 N	Motions to Vacate		☐ 871 IRS—Third Party	☐ 950 Constitutionality of			
240 Torts to Land245 Tort Product Liability	Accommodations 530 C	Sentence General		26 USC 7609	State Statutes			
290 All Other Real Property		Death Penalty	IMMIGRATION					
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VI. CAUSE OF ACTION	Brief description of cause:	liobility						
VII. REQUESTED IN	Personal injury; product		DEMAND \$	CHECK YES only	if demanded in complaint:			
COMPLAINT:	UNDER RULE 23, F.R.C		DEWIND U	JURY DEMAND:	Yes No			
VIII. RELATED CASI	E(S)							
IF ANY		E Anthony Battaglia		DOCKET NUMBER 3:12	2-cv-02549-AJB-MDD			
DATE SIGNATURE OF ATTORNEY OF RECORD								
June 10, 2013	/s/ Jo	<u>ohn M. Restaino</u>	, Jr.					
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