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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

THIS DOCUMENT APPLIES TO ALL CLAIMS MADE BY ALL PLAINTIFFS IN MDL NO. 2452 AGAINST ANY OR ALL OF THE DEFENDANTS NAMED HEREIN Plaintiffs v. MERCK SHARP & DOHME CORP.; NOVO NORDISK INC.; AMYLIN PHARMACEUTICALS, LLC; ELI LILLY AND COMPANY; ANY OTHER NAMED DEFENDANT; and DOES 1-100 Defendants	Case No.: 13md2452 AJB(MDD) In Re: Incretin-Based Therapies Products Liability Litigation **MDL NO. 2452** **MASTER FORM COMPLAINT FOR DAMAGES** Pertains To All Related Cases Consolidated in 12cv2549-AJB (MDD) JURY TRIAL DEMANDED

COMES NOW Co-Lead Counsel Ryan L. Thompson, Hunter J. Shkolnik, and Tor A. Hoerman, by and on behalf of all Plaintiffs in MDL No. 2452 who bring

and/or adopt this Master Long Form Complaint, and complain and allege against Defendant(s), Does 1 through 100, and each of them, as follows:

GENERAL ALLEGATIONS

1. Plaintiff(s) herein, by and through Plaintiff's attorneys, brings this action for personal injuries and/or wrongful death suffered by the injured party (the "Injured Party," and collectively, the Injured Party and/or Plaintiff(s) are the "Plaintiff(s)"), as detailed more fully herein, suffered as a proximate result of the Injured Party's being prescribed and ingesting the defective and unreasonably dangerous prescription drug(s) Januvia, Janumet, Byetta, and/or Victoza (the "Drugs"), prescription medication(s) used to help lower blood sugar levels in adults with diabetes mellitus type 2, which at all times relevant hereto, were manufactured, designed, tested, packaged, labeled, marketed, advertised, distributed, and sold by the defendants identified herein (collectively, the "Defendants"). This Master Long Form Complaint sets forth questions of fact and law common to those claims subsumed within the context of this multidistrict proceeding.

2. This Master Complaint does not necessarily include all claims asserted in all of the transferred actions to this Court, nor is it intended to consolidate for any purpose the separate claims of the Plaintiffs herein. It is anticipated that individual plaintiffs may adopt this Master Complaint and the necessary causes of action herein through use of a separate short form complaint. Any separate facts and additional claims of individual plaintiffs are set forth in those actions filed by the respective plaintiffs. This Master Complaint does not constitute a waiver or dismissal of any actions or claims asserted in those individual actions, nor does any Plaintiff relinquish the right to move to amend their individual claims to seek any additional claims as discovery proceeds. As more particularly set forth herein, each Plaintiff maintains, among other things, that the Drugs are defective, dangerous to human health, marketed and sold in the United States, and lacked proper warnings of the dangers associated with use of the Drugs.

3. The true names or capacities whether individual, corporate or otherwise, of the Doe Defendants 1 through 100, inclusive, are unknown to Plaintiff(s), who therefore sue said Defendant(s) by such fictitious names. Plaintiff(s) believe and allege that each Defendant designated herein by a fictitious name is in some manner legally responsible for the events and happenings herein referred to and caused damages proximately and foreseeably to Plaintiff(s) as alleged herein.

4. At all times herein mentioned, the Defendants responsible for each of the Drugs, inclusive of the Doe Defendants, was the agent, servant, partner, aider and abettor, co-conspirator, and joint venturer of each of the remaining Defendants herein who are also related to that particular Drug, 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.

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

6. The injuries and damages to Plaintiff(s) were caused by the unreasonably dangerous condition of one or more of the Drugs and Defendants' wrongful acts and omissions.

7. At all times herein mentioned, Defendants were each engaged in the business of, or were successors in interest to, entities engaged in the business of

research, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the Drugs.

8. 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, including the Plaintiff(s)' state of residence.

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

JURISDICTION AND VENUE

10. 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.

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

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

13. Venue is further proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to each Plaintiff's claims occurred, in part, in the Southern District of California.

14. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

15. Finally, venue of this case is proper in the Southern District of California pursuant to the Court's direct filing order entered in this MDL.

PLAINTIFF/INJURED PARTY GENERALLY

16. The Injured Party was prescribed and used the Drugs as described and upon the direction of the Injured Party's physician for long-term maintenance of Type II diabetes, or as otherwise prescribed. Ultimately, the Injured Party suffered severe physical, economic, and emotional injuries as a result of said Drugs, including but not limited to the Injured Party being diagnosed with pancreatic cancer.

17. Plaintiff was unaware that the Drugs caused said injuries until recently.

18. As a direct result of the ingestion of the Drugs, the Injured Party was diagnosed with pancreatic cancer. Had the Injured Party or the Injured Party's physician been properly warned by Defendants regarding the risk of pancreatic cancer from usage of these prescription medications, the Injured Party's physician would have not prescribed the Drugs and the Injured Party would have not ingested these prescription medications.

19. As a direct result of being prescribed the Drugs for this period of time, the Injured Party was permanently and severely injured, having suffered serious consequences from the Injured Party's usage of the Drugs, including but not limited to, the development of pancreatic cancer.

20. Plaintiff, as a direct and proximate result of the Injured Party's use of the Drugs, suffered severe mental and/or physical pain and suffering, along with economic loss.

21. As a proximate result of the unreasonably dangerous condition of the Drugs and Defendants' acts and omissions, each Plaintiff suffered the injuries described herein due to the Injured Party's ingestion of the Drugs. Plaintiffs

accordingly seek damages associated with these injuries.

22. The Injured Party would not have used the Drugs had Defendants properly disclosed the risks associated with their use.

DEFENDANTS GENERALLY

23. MERCK SHARP & DOHME CORP. ("MERCK") is a New Jersey corporation, which has its principal place of business at 2000 Galloping Hill Rd., Kenilworth, NJ 07033. Merck may be served at CT Corporation System, 818 W. Seventh St., Los Angeles, CA 90017. Merck has conducted business and derived substantial revenue from within the state of California.

24. NOVO NORDISK INC. ("Novo Nordisk") is a Delaware corporation, which has its principal place of business at 800 Scudders Mill Road, Plainsboro, NJ 08536. Novo Nordisk may be served by and through its registered agent: CT Corporation System, 818 W. Seventh St., Los Angeles, CA 90017. Novo Nordisk has conducted business and derived substantial revenue from within the state of California.

25. AMYLIN PHARMACEUTICALS, LLC F/K/A AMYLIN PHARMACEUTICALS, INC. ("Amylin") is a Delaware limited liability company. The sole member of Amylin is BMS Holdco, Inc., a Delaware corporation with its principal place of business in New York. Amylin may be served by and through its registered agent: CT Corporation System, 818 W. Seventh St., Los Angeles, California 90017. Amylin has conducted business and derived substantial revenue from within the state of California.

26. ELI LILLY AND COMPANY ("LILLY") is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285. LILLY may be served by and through its registered agent: National Registered Agents, Inc., 2875 Michelle Drive, Suite 100, Irvine, California 92606. Lilly has conducted business and derived substantial revenue from within the state of California.

GENERAL FACTUAL ALLEGATIONS

27. 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 Drugs.

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

29. 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]

30. 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.

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

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

[2] *Id.*

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

32. Januvia, Janumet, Byetta, and Victoza are supposed to help prevent these diabetic complications.

33. The two most recently approved classes of therapeutic agents for the treatment of type 2 diabetes, glucagon-like peptide-1 (GLP-1) receptor agonists (such as Byetta and Victoza) and dipeptidyl peptidase-4 (DPP-4) inhibitors (such as Janumet and 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.

34. Januvia was approved by the Food and Drug Administration ("FDA") on October 16, 2006 "as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus as monotherapy and in combination with metformin or a PPARγ agonist (e.g., thiazolidinediones) when diet and exercise plus the single agent do not provide adequate glycemic control."[4]

35. Following FDA approval, Defendants launched Januvia in North America in 2006.

36. Janumet was approved by the FDA on March 30, 2007 "as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus who are not adequately controlled on metformin or sitagliptin alone or in patients already being treated with the combination of sitagliptin and metformin."[5]

37. Following FDA approval, Defendants launched Janumet in North America in 2007. Janumet is the successor of Januvia, which was the first in a new class of drugs that inhibit the proteolytic activity of DPP-4, thereby potentiating the action of endogenous glucoregulatory peptides, known as incretins.[6]

[4] http://www.accessdata.fda.gov/Drugatfda_docs/appletter/2006/021995s000ltr.pdf
[5] http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2007/022044s000ltr
[6] Drucker D, Easley Continuing, Kirkpatrick P. Sitagliptin. Nature Reviews Drug Discovery. Feb. 2007. 6:109-10.

38. Byetta was approved by the FDA in April of 2005 and was marketed to the medical community and general public shortly thereafter. Byetta is a member of the new class of drugs known as GLP-1 receptor agonists.

39. Victoza is manufactured by Novo Nordisk of Bagsvaerd, Denmark and was approved by the FDA on January 25, 2010. Novo Nordisk, Inc. is responsible in all respects for Victoza in the United States. Victoza is also a member of the new class of drug known as GLP-1 receptor agonists.

40. Victoza was approved with several post-marketing requirements under the Food and Drug Administration Amendments Act (FDAAA) to ensure that the company will conduct studies to provide additional information on the safety of this product.

41. Victoza was approved with a Risk Evaluation and Mitigation Strategy consisting of a Medication Guide and a Communication Plan. The FDA acknowledged the need for these post-marketing requirements after five clinical trials involving more than 3,900 people found that pancreatitis occurred more often in patients who took Victoza than in patients taking other diabetes medicines. Pancreatitis also emerged as a side effect of therapy with another GLP-1 receptor agonist, initially reported as case reports and subsequently confirmed by numerous reports made through the FDA adverse reporting mechanism.

42. In February 2010, concerns were published regarding the GLP-1 drugs, including Victoza and Byetta, and the DDP-4 inhibitors, including Januvia and Janumet, and their potential link with pancreatic cancer.

43. Writing in DIABETES CARE, Butler *et al*. published *GLP-1–Based Therapy for Diabetes: What You Do Not Know Can Hurt You*'[7] wherein they wrote, "History has taught us that enthusiasm for new classes of drugs, heavily promoted by the pharmaceutical companies that market them, can obscure the caution that

[7] 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.

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."

44. 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…, and worse, subsequently a minority of individuals treated by this class of drug may develop pancreatic cancer."

45. In February 2011, the journal Gastroenterology published on-line the work of Elashoff *et al.*[8] titled, *Pancreatitis, pancreatic, and thyroid cancer with glucagon-like peptide-1-based therapies*.

46. These researchers used the FDA Adverse Event Reporting System (AERS) to assess the association between treatment with Victoza and Januvia 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 Victoza and Januvia, with various other anti-diabetic drugs used as controls. Metformin was not used as a control drug because it has been reported to decrease the risk of pancreatic cancer.

47. These researchers reported that pancreatitis, inflammation of the pancreas, was >10-fold more frequently reported as an adverse event for patients

[8] 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.

administered GLP-1 class of drugs (which includes Victoza and Byetta) and >6-fold more frequently reported in patients prescribed Januvia (and other DPP-4 inhibitors, which includes Janumet). Both these associations were statistically significant.

48. Because pancreatitis is a known risk factor for pancreatic cancer,[9] Elashoff *et al.* evaluated the reported rates of pancreatic cancer with Januvia (and similar drugs) compared to control events relative to Avandia (rosiglitazone).

49. The reported event rate for pancreatic cancer was 2.9-fold greater in patients treated with Byetta (and similar drugs in the GLP-1 class, like Victoza) compared to other therapies. The reported event rate for pancreatic cancer was 2.7-fold greater with Januvia (and similar DPP-4 drugs, like Janumet) than other therapies.

50. Because pancreatitis acts as a risk factor for subsequent pancreatic cancer through the mechanisms of chronic inflammation and increased cell turnover,[10] it is forseeable that there is a progressive increased risk of pancreatic cancer with prolonged exposure to the Drugs.

51. 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.

52. On May 13, 2011, the Arzneimittelkommission der deutschen Ärzteschaft (Drug Commission of the German Medical Association - AkdÄ) published *Pancreatic cancers associated with exenatide (Byetta ®)* on its website.[11]

53. 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

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

[10] 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.

[11] http://www.akdae.de/Arzneimittelsicherheit/Bekanntgaben/Archiv/2011/20110513.html

15,000-25,000 treated patients).[12]

54. 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).

55. Some of the manufacturers of the Drugs 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.[13]

56. However, animal studies showing pancreatitis as a consequence of GLP-1 mimetic therapy (and other incretin-based therapies) challenge that assumption and lead to the conclusion that asymptomatic chronic pancreatitis is an adverse effect of GLP-1-based treatment, which is further confirmed by specific studies as applied to sitagliptin (active ingredient in Janumet and Januvia)[14] and Exenatide (Byetta).[15]

57. GLP-1 receptors are abundantly expressed in the pancreas, and sitagliptin therapy has been shown to lead to increased pancreatic ductal replication, acinar to ductal metaplasia or cellular change, and also, acute pancreatitis in a rat model of type 2 diabetes.[16]

58. Increased ductal turnover and acinar to ductal metaplasia are both well-established characteristics of chronic pancreatitis in humans.[17]

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[12] 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])

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

[14] 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.

[15] 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.

[16] 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.

[17] 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–

Footnote continued on next page

59. It has also been suggested that the immunomodulatory effects of DPP-4 inhibition might increase risk for all cancers.[18,19]

60. Butler *et al*.[20] 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.

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

62. Dr. Sidney Wolfe, director of the health and research group at Public Citizen, said at that time, "We don't just go after drugs casually…(W)e only go after drugs when there is clear evidence of unique dangers or risks, and when there is no evidence of a unique clinical advantage."

63. Dr. Wolfe said at the time that his concern extends to other diabetes drugs that alter the GLP-1 pathway, which would include Januvia, Janumet and Victoza. The petition to withdraw Victoza was based on information pulled from the FDA's adverse-event reporting database. Public Citizen counted 28 cases of pancreatic cancer reported between February 2010 and September 2011 among patients on Victoza, compared with just one case in a patient taking a diabetes drug that does not manipulate the GLP-1 pathway.

64. In February 2013, the results of the first case-controlled

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

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

[20] Gier B, Matveyenko AV, 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

epidemiological study looking at the Drugs and their effects upon the pancreas were published by Singh et. al. out of the Johns Hopkins School of Medicine and School of Public Health.[21]

65. Singh et al used administrative claims data from the BlueCross Blue Shield Association plans of Tennessee, Hawaii, Michigan, and North Carolina; Highmark, Inc. and Independence Blue Cross of Pennsylvania; and Wellmark, Inc. of Iowa and South Dakota. They evaluated 1,269 hospitalized cases with acute pancreatitis using a validated algorithm and 1,269 control subjects matched for age category, sex, enrollment pattern, and diabetes complications. The strengths of this study include the large size of the sample, the ability to adjust for confounders, and the independence of the authors from the companies marketing the Drugs.

66. After adjusting for available confounders and metformin hydrochloride use, current use of GLP-1–based therapies within 30 days demonstrated the existence of a statistically significant adjusted Odds Ratio (OR) of 2.24 in relation to the development of acute pancreatitis. For those patients who had used the GLP-1-based therapies in the recent past 30 days, and less than 2 years, the statistically significant OR was 2.01 for the development of acute pancreatitis as compared to the odds of 'nonusers' of these drugs. 'Any use' was also associated with statistically significantly higher odds of acute pancreatitis with a statistically significant adjusted OR of 2.07. Significantly, the Confidence Intervals for each of these findings were “tight” attesting to the robust nature of their findings.

67. The results from the case-controlled epidemiological study "...support findings from the previously mechanistic studies and spontaneous reports submitted to the US Food and Drug Association that such an association may be causal."[22] The import of this language - "*...such an association may be causal”* - by these

[21] Singh S et al. Glucagonlike Peptide 1–Based Therapies and Risk of Hospitalization for Acute Pancreatitis in Type 2 Diabetes Mellitus. JAMA Intern Med. 2013 Feb 25:1-6. [Epub ahead of print].

[22] *Id.*

epidemiologists and physicians as peer-reviewed and published in the *Journal of the American Medical Association - Internal Medicine*, one of the finest medical journals in the world, cannot be understated.

68. It is easy to appreciate the increased risk of pancreatitis associated with the Drugs is of critical importance. Antecedent pancreatitis is the most common risk factor for subsequent pancreatic cancer. Analysis of the FDA adverse event reporting system, discussed *supra,* already showed a signal for pancreatic cancer with exenatide and sitagliptin by 2009, and likely, much earlier.

69. Pancreatic cancer develops after progressive accumulation of somatic mutations leads to the formation of pancreatic intraepithelial neoplasia (PanIN) of increasing grade that, in a subset of individuals, transforms to malignant neoplasms.[23]

70. The PanIN lesions are relatively common in middle-aged adults and express the GLP-1 receptor. Glucagon-like peptide 1 induces growth of lesions similar to intraductal papillary mucinous neoplasia in rats and accelerates dysplasia of PanIN lesions and pancreatitis in mice prone to pancreatic cancer.[24]

71. Therefore, in those individuals with preexisting PanIN lesions or intraductal papillary mucinous neoplasia, GLP-1–based therapy promotes growth of these lesions, causing partial ductal obstruction and pancreatitis in some individuals. Of even greater concern, GLP-1–based therapy can accelerate the progression and transformation of premalignant PanIN lesions, much like the effect of estrogen therapy in women with estrogen receptor–expressing breast neoplasia. In other words, the incretin-based therapies are to pancreatic premalignant cells as

[23] Gier B, Butler PC. Glucagonlike Peptide 1-Based Drugs and Pancreatitis: Clarity at Last, but What About Pancreatic Cancer?: Comment on "Glucagonlike Peptide 1-Based Therapies and Risk of Hospitalization for Acute Pancreatitis in Type 2 Diabetes Mellitus". JAMA Intern Med. 2013 Mar 5:1-3. doi: 10.1001/jamainternmed.2013.3374. [Epub ahead of print]

[24] Gier B, Matveyenko AV, Kirakossian D, Dawson D, Dry SM, Butler PC. 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*. 2012;61(5): 1250-1262.

wheat is to the prairie fire.

72. On March 22 2013, in an on-line publication within the journal *Diabetes,* Butler et al published the results of their examinations of the pancreata obtained from age-matched brain dead organ donors with and without diabetes treated by incretin-based therapies (> 1 yr) or other therapy and non diabetic controls.[25]

73. These researchers observed that pancreatic mass was increased approximately 40 percent in diabetes patients treated with incretin-based therapies compared to that in individuals with diabetes not treated with such agents, and that the increase was statistically significant. They also observed that the pancreatic fractional insulin area, that area occupied by each cell type, was approximately 60 percent reduced in diabetics patients not treated with incretin-based therapies compared to non-diabetic controls, again, a statistically significant result. In contrast, they observed that the pancreatic fractional insulin area was approximately 5-fold increased in diabetic patients treated with incretin-based therapies when compared to individuals not treated with incretin-based therapies, also statistically significant.

74. Furthermore, actual beta (ß) cell mass was increased 6-fold in incretin-based therapies treated diabetics and the ß cell mass was 3-fold greater in individuals with diabetes treated with incretin-based therapies in comparison to non diabetic controls, both observations also being statistically significant. These researchers noted that the increased pancreatic mass in diabetics induced by incretin-based therapies was accompanied by increased whole pancreas cell and an increase in the presence of pancreatic intraepithelial neoplasia (PanINs), both observations being statistically significant.

[25] Butler AE, Campbell-Thompson M, Gurlo T, Dawson DW, Atkinson M, Butler PC. Marked Expansion of Exocrine and Endocrine Pancreas with Incretin Therapy in Humans with increased Exocrine Pancreas Dysplasia and the potential for Glucagon-producing Neuroendocrine Tumors. Diabetes. 2013 Mar 22. [Epub ahead of print]

75. The observation by Butler et al that the pancreatic mass of the individuals with diabetes treated with incretin-based therapies was increased by 40 percent in comparison to diabetics not treated with incretin-based therapies is consistent with the prior rodent studies that revealed proliferative actions of GLP-1 on the exocrine pancreas – extending the animal studies to human studies.[26, 27]

76. Of further concern is the marked alpha (α) cell hyperplasia, glucagon expressing microadenomas and glucagon expressing neuroendocrine tumors noted by Butler et al in individuals with diabetes treated with incretin-based therapies. These findings reproduce the α cell hyperplasia, abnormal α cell distribution, and predisposition to glucagon expressing neuroendocrine tumors previously reported in the literature.[28, 29, 30]

77. As a result of the defective nature of the Drugs, persons who were prescribed and ingested the Drugs, for even a brief period of time, including Plaintiffs, 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.

78. "At present, the GLP-1 class of drugs is heavily promoted (and

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[26] Matveyenko AV, Dry S, Cox HI, Moshtaghian A, Gurlo T, Galasso R, Butler AE, Butler PC: Beneficial endocrine but adverse exocrine effects of sitagliptin in the human islet amyloid polypeptide transgenic rat model of type 2 diabetes: interactions with metformin. Diabetes 2009;58:1604-1615

[27] Gier B, Matveyenko AV, Kirakossian D, Dawson D, Dry SM, Butler PC: 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 Kras(G12D) mouse model. Diabetes 2012;61:1250-1262

[28] Gelling RW, Du XQ, Dichmann DS, Romer J, Huang H, Cui L, Obici S, Tang B, Holst JJ, Fledelius C, Johansen PB, Rossetti L, Jelicks LA, Serup P, Nishimura E, Charron MJ: Lower blood glucose, hyperglucagonemia, and pancreatic alpha cell hyperplasia in glucagon receptor knockout mice. Proc Natl Acad Sci U S A 2003;100:1438-1443

[29] Yu R, Dhall D, Nissen NN, Zhou C, Ren SG: Pancreatic neuroendocrine tumors in glucagon receptor-deficient mice. PLoS One 2011;6:e23397

[30] Zhou C, Dhall D, Nissen NN, Chen CR, Yu R: Homozygous P86S mutation of the human glucagon receptor is associated with hyperglucagonemia, alpha cell hyperplasia, and islet cell tumor. Pancreas 2009;38:941-946

prescribed) as having purported advantages that outweigh its risks."[31] Singh et al, *supra,* show that, "…despite large numbers of underpowered studies claiming the contrary from marketing companies, little is yet known about long-term adverse effects of the GLP-1 class of drugs on the exocrine pancreas."[32] A striking finding in the studies by Butler et al[33] is the marked expansion of the exocrine and endocrine compartments of the pancreas with incretin-based therapies. The findings of an increased pancreatic mass, increased PanIN lesions, and endocrine proliferations by Butler et al in response to GLP-1 mimetic therapy adds significantly to concerns already shown regarding the adverse actions of GLP-1 mimetic therapy to induce pancreatitis and accelerate pancreatic dysplasia.[34] Prior reports concerning pancreas changes with incretin-based therapy were generally confined to studies of rodent pancreas, but have since been unquestionably extended by Butler et al to humans with the added concern of developing neuroendocrine tumors. These findings demonstrate the effects of long term GLP-1 related therapy with respect to both unintended proliferative actions on the exocrine pancreas and an increased risk of neuroendocrine tumors.

79. Due to the flawed formulation of the Drugs, the Drugs increase the risk of pancreatic cancer in those diabetic patients to whom they are prescribed.

80. Defendants concealed their knowledge that the Drugs can cause, promote, or otherwise accelerate life threatening pancreatic cancer from Plaintiff, other consumers, the general public, and the medical community. Indeed, the

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[31] Gier B, Matveyenko AV, Kirakossian D, Dawson D, Dry SM, Butler PC. 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*. 2012;61(5): 1250-1262.

[32] ID

[33] Butler AE, Campbell-Thompson M, Gurlo T, Dawson DW, Atkinson M, Butler PC. Marked Expansion of Exocrine and Endocrine Pancreas with Incretin Therapy in Humans with increased Exocrine Pancreas Dysplasia and the potential for Glucagon-producing Neuroendocrine Tumors. Diabetes. 2013 Mar 22. [Epub ahead of print]

[34] 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

manufacturers of the Drugs do not even mention 'pancreatic cancer' in their drugs' respective product inserts.

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

82. The current warnings for the Drugs 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.

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

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

85. As the manufacturers and distributors of the Drugs, Defendants knew or should have known that the Drugs' usage were associated with pancreatic cancer.

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

87. Victoza's global sales reached $1.044 billion during 2011 and the first two sales quarters of 2012 have already reached $748 million.[35]

[35]http://webmedia.novonordisk.com/nncom/images/investors/investor_presentations/2012/Interim_report/PR120809_H1_UK.pdf (Victoza 2011 sales amount converted from 804 million Euros to

Footnote continued on next page

88. Januvia is also one of the top selling drugs in the country, and further, Januvia is one of the Merck Defendant's best sellers with $1.977 billion in sales the first two quarter's of 2012 alone.[36]

89. Janumet and Byetta have likewise been highly successful drugs, making hundreds of millions, if not billions, of dollars for the Defendants.

90. While Defendants have enjoyed great financial success from their blockbuster drugs, they continue to place American citizens at risk of developing deadly pancreatic cancer.

91. Consumers, including Plaintiff, who have used the Drugs for treatment of their type 2 diabetes or otherwise 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 the Drugs' therapy.

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

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

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

95. At all times relevant hereto, the Defendants have directly marketed the

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Footnote continued from previous page
1,044 million US dollars and 2012 quarters converted 576 Euros to 748 US dollars using Google Currency Converter accessed October 25, 2012)

[36] http://www.merck.com/investors/financials/sec-filings/home.html (Merck & Co., Inc. Form10Q filed 08/07/2012).

Drugs to the consuming public throughout the United States, including Plaintiffs.

96. 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 Drugs as dictated by good pharmaceutical science standards.

97. Defendants both over-promoted the Drugs and under-warned about their risks, including:

a. in print advertising;

b. on their websites and blogs;

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

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

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

99. Defendants failed to provide proper and full information as to the safety of the Drugs.

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

101. Defendants have never sought to enlarge their warnings to include a warning about pancreatic cancer risks associated with the use of the Drugs.

102. Instead, Defendants marketed (and continue to market) the Drugs as having a low risk of side effects and continue to minimize the Drugs' deadly side effects.

103. 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.

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

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

106. 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 Drugs and would have used and prescribed other methods for diabetes control if they had been so informed.

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

108. 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.

109. 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.

110. 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.

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

ACTIONS FOR SURVIVAL AND WRONGFUL DEATH

112. If applicable, in the event the Injured Party named herein is deceased, Plaintiffs bring this action as a survival action, as the successor(s) in interest of Decedent, pursuant to California Code of Civil Procedure § 377.30, and as a wrongful death action, pursuant to California Code of Civil Procedure § 377.60, and/or other applicable state law.

CAUSES OF ACTION

COUNT I

STRICT LIABILITY-FAILURE TO WARN

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

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

115. The Plaintiff was administered the Drugs for their intended purposes.

116. The Plaintiff could not have discovered any defect in the Drugs through the exercise of care.

117. 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 the Drugs were incomplete and inadequate.

118. 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.

119. 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 Drugs, as it became or could have become available to Defendants.

120. Defendants marketed, promoted, distributed and sold unreasonably dangerous and defective prescription drugs, Victoza, Byetta, Janumet, and/or Januvia, to health care providers empowered to prescribe and dispense the Drugs 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 Drugs, which resulted in injury to Plaintiff.

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

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

123. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff and 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 Drugs including, among other things, their tendency to increase the risk of, and/or cause, promote, or otherwise accelerate, 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 Drugs even after they knew or should have known of the unreasonable risks of developing pancreatic cancer from ingestion of the Drugs.

124. 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 Drugs, and/or that there existed safer and more or equally effective alternative drug products.

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

126. Defendants' actions described above were performed willfully,

intentionally, and with reckless disregard of the life and safety of the Plaintiff and the public.

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

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

COUNT II

STRICT PRODUCTS LIABILITY - DESIGN DEFECT

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

130. Defendants are the manufacturers, designers, distributers, sellers and suppliers of the Drugs, who sold The Drugs in the course of business.

131. The Drugs 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.

132. The Drugs administered to Plaintiff was defective in design or formulation in the following respects:

a. When it left the hands of the Defendants, these drugs were unreasonably dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff or Plaintiff's physicians;
b. Any benefit of these Drugs were 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 Drugs sold by the Defendants was unreasonably dangerous;
d. There are no patients for whom the benefits of the Drugs 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 Drugs is a safer and more efficacious drug than other drug products in its class; and/or

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

133. The Drugs administered to Plaintiff were defective at the time they were distributed by the Defendants or left their control.

134. The foreseeable risks associated with the design or formulation of the Drugs include, but are not limited to, the fact that the design or formulation of the Drugs are 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.

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

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

137. 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

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

139. Defendants had a duty to exercise reasonable care in the manufacture,

sale and/or distribution of the Drugs into the stream of commerce, including a duty to ensure that the products did not cause users to suffer from unreasonable, dangerous side effects.

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

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

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

143. 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.

144. 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.

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

COUNT IV

BREACH OF IMPLIED WARRANTY

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

147. At all times mentioned in this Complaint, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and sold the Drugs, and prior to the time the Drugs were

prescribed to Plaintiff, Defendants impliedly warranted to Plaintiff, and Plaintiff's physicians and healthcare providers, that the Drugs were of merchantable quality and safe for the use for which they were intended.

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

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

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

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

COUNT V

BREACH OF EXPRESS WARRANTY

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

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

154. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which the Drugs were to be used and warranted the

same to be in all respects, fit, safe, and effective and proper for such purpose. The Drugs were unaccompanied by adequate warnings of their dangerous propensities that were either known or knowable at the time of distribution.

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

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

COUNT VI

PUNITIVE DAMAGES

(As Permitted by Applicable State Law)

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

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

166. Defendants knew of the Drugs' 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 Drugs.

167. Defendants intentionally concealed or recklessly failed to disclose to the public, including Plaintiff, the potentially life-threatening side effects of the Drugs to ensure their continued and increased sales. Defendants failed to provide

warnings that would have dissuaded physicians from prescribing the Drugs and consumers from purchasing and consuming the Drugs, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming the Drugs.

168. 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 to the extent permitted by applicable state law in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

COUNT VII

LOSS OF CONSORTIUM

(Only Applicable if Consortium Plaintiff(s) Named)

169. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

170. Plaintiff was at all times relevant hereto the spouse, child, and/or parent of the Decedent.

171. For the reasons set forth herein, Plaintiff has been caused, presently and in the future, to suffer the loss of the Injured Party's companionship and society, and accordingly, the Plaintiff has been caused great mental anguish.

COUNT VIII

WRONGFUL DEATH

(Only Applicable if Injured Party is Deceased)

172. Plaintiffs hereby incorporate by reference all paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

173. Plaintiff is the adult child, parent, spouse and/or surviving heir and successor-in-interest to the Injured Party, who used Defendants' Drugs and was injured and died as a result. Said Injured Party was prescribed, supplied with, received, took, used and consumed said Drugs as tested, studied, researched,

evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants.

174. The injuries and damages the Plaintiff and Injured Party were caused by the wrongful acts, omissions, and fraudulent misrepresentations of Defendants.

175. As a result of the conduct of Defendants and the use of Defendants' Drugs, the Injured Party suffered catastrophic and ultimately fatal injuries.

176. As a result of the death of the Decedent, Plaintiff was deprived of love, companionship, comfort, affection, society, solace and or moral support of the Injured Party.

177. Plaintiff is entitled to recover economic and non-economics damages against all Defendants for wrongful death directly and legally caused by the defects in defendants' Drugs and the negligent conduct, acts, errors, omissions and intentional and negligent misrepresentations of Defendants, and each of them.

178. The representative/administrator/successor-in-interest of the Injured Party's estate further pleads all wrongful death damages allowed by statute and law in the state or states in which the causes of action accrued.

COUNT IX

SURVIVAL ACTION

(Only Applicable if Injured Party is Deceased)

179. Plaintiffs hereby incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

180. As a direct and proximate result of the Defendants' conduct, and failure to comply with applicable standards, as outlined above, the Injured Party suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and loss of earnings as well

as loss of ability to earn money prior to the Injured Party's death.

181. The representative/administrator/successor-in-interest of the Injured Party's estate brings this claim on behalf of the Injured Party's estate and the Injured Party's beneficiaries for damages.

182. The representative/administrator/successor-in-interest of the Injured Party's estate further pleads all survival damages allowed by statute and law in the state or states in which the causes of action accrued.

PRAYER FOR RELIEF AND, AS APPLICABLE,

PRAYER FOR RELIEF FOR SURVIVAL AND WRONGFUL DEATH

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. Economic damages, including, as applicable, wage loss and loss of earning capacity, in an amount to be determined at trial of this action;
3. Medical expenses, including for past and future treatment, in an amount to be determined at trial of this action;
4. Non-economic damages, including pain and suffering;
5. If applicable, all wrongful death and/or survival damages;
6. If applicable, burial and funeral expenses;
7. If applicable, loss of consortium, companionship, and society;
8. Punitive damages alleged against Defendants, including Plaintiff's attorney fees, in excess of $75,000.00;
9. All pre- and post-judgment interest at the highest legal rate available under relevant law;
10. Attorneys' fees, expenses, and costs of this action; and
11. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

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

Dated: November 26, 2013

RESPECTFULLY SUBMITTED,

By:

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