IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION	**MDL NO. 2750** **Master Docket No. 3:16-md-2750**
DOROTHY FRANCO, **Plaintiff,**	**JUDGE BRIAN R. MARTINOTTI** **JUDGE LOIS H. GOODMAN**
v.	**DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 4**
JANSSEN PHARMACEUTICALS, INC., AND JOHNSON & JOHNSON CO., **Defendants.**	**Civil Action No. _____**

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff files this Complaint pursuant to CMO No. 4, and is bound by the rights, protections and privileges and obligations of that CMO. Further, in accordance with CMO No. 4, Plaintiff hereby designates the United States District Court for the District of Connecticut as the place of remand as this case may have originally been filed there.

Plaintiff, DOROTHY FRANCO, brings this case against Defendants for injuries suffered as a direct result of Plaintiff's ingestion of the pharmaceutical product INVOKANA. Plaintiff alleges as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of INVOKANA (at times referred to herein as "the subject product") for the treatment of diabetes.

2. Defendants Janssen Pharmaceuticals ("JANSSEN") and Johnson & Johnson, Co. ("JOHNSON & JOHNSON") concealed, and continue to conceal, their knowledge of INVOKANA's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

3. As a result of the defective nature of INVOKANA, persons who were prescribed and ingested INVOKANA, including Plaintiff, have suffered and may continue to suffer severe and permanent personal injuries, including diabetic ketoacidosis, stroke, heart attack, and severe kidney damage.

4. After beginning treatment with INVOKANA, and as a direct and proximate result of Defendants' actions and inaction, Plaintiff developed dehydration and acute renal failure. Plaintiff's ingestion of the defective and unreasonably dangerous drug INVOKANA has caused and will continue to cause injury and damage to Plaintiff.

5. Plaintiff brings this action for personal injuries suffered as a proximate result of being prescribed and ingesting INVOKANA. Plaintiff accordingly seeks compensatory and punitive damages, monetary restitution, and all other available remedies as a result of injuries caused by INVOKANA.

PARTIES

6. Plaintiff DOROTHY FRANCO is a citizen and resident of the State of Connecticut.

7. Plaintiff DOROTHY FRANCO took Invokana in March 2015.

8. Defendant JANSSEN is a Pennsylvania corporation with its principal place of business at 1125 Trenton Harbourton Road, Titusville, New Jersey, and is a wholly owned subsidiary of Defendant JOHNSON & JOHNSON. JANSSEN is registered to do business in

throughout the United States, including Connecticut. JANSSEN is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug INVOKANA.

9. Defendant JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey. JOHNSON & JOHNSON is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug INVOKANA.

JURISDICTION

10. This Court has jurisdiction pursuant to 28 U.S.C. § l332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000 exclusive of interest and costs.

11. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. §l391(a) because, at all times material hereto, Plaintiff resided in this district and Defendants conducted substantial business in this district.

FACTUAL BACKGROUND

12. This case involves the prescription drug Invokana, which is manufactured, sold, distributed and promoted by the Defendants JANSSEN and JOHNSON & JOHNSON as a treatment for Type 2 Diabetes Mellitus.

13. Defendant JANSSEN, a wholly owned subsidiary of JOHNSON & JOHNSON, acquired the marketing rights to INVOKANA in North America, and marketed, advertised, distributed, and sold INVOKANA in the United States.

14. As of 2012 there were approximately 29.1 million Americans who had diabetes and 28 million Americans within that group who have Type II diabetes.[1] Over time, high blood sugar levels can increase the risk for serious complications, including heart disease, blindness, nerve and kidney damage.

15. There are many prescription medication options for Type II diabetes. The first drug generally prescribed for Type II diabetes patients is metformin. Metformin was the first diabetes drug approved by the FDA and is still the most prescribed drug treatment option available today. Metformin works by improving the patient's sensitivity to insulin so the body uses insulin more effectively.

16. Along with Metformin, several other drug classes are available today as treatment options to patients who have Type II diabetes. Some examples of these other drug classes are sulfonylureas, including Glucotrol (generic: glipizide) and Amaryl (glimepiride); meglitinides, including Prandin (repaglinide) and Starlix (nateglinide); thiazolidinediones, including Avandia (rosiglitazone) and Actos (pioglitazone); DPP-4 inhibitors, including Januvia (sitagliptin) and Tradjenta (linagliptin); and GLP-1 receptor agonists which include Byetta (exenatide) and Victoza (liraglutide).

17. Type II diabetes drugs generally reduce blood sugar by eliminating some of the sugar in your blood (GLP-1 receptor agonists, DPP-4 inhibitors), making the body more

[1] The Center for Disease Control and Prevention's 2014 National Diabetes Statistics Report; http://www.cdc.gov/media/releases/2014/p0610-diabetes-report.html, last accessed on October 5, 2016.

sensitive to insulin (thiazolidinediones and metformin), or helping the patient's body secrete more insulin (sulfonylureas and meglitinides).

18. Because diabetes is a chronic disease, diabetes drugs are designed for long-term use. Patients have been known to take one drug for many years before being prescribed a different drug. With such long-term use, comes a similar focus on long-term safety. Being able to safely use a diabetes drug along with knowledge about effects of cumulative dosage is paramount with these drugs. In its QuarterWatch publication for the second quarter of 2014, the Institute for Safe Medication Practices ("ISMP") stated "[a] common-sense criterion for diabetes drugs is that they should reflect inherently low risks since it takes years for either progression of the disease or possible but yet-unproven benefits of treatment to be manifest."[2]

19. Defendants submitted their New Drug Application for Invokana on May 31, 2012.

20. Invokana was the first in a new class of Type II diabetes drugs called sodium glucose co-transporter 2 ("SGLT-2") inhibitors. SGLT-2 inhibitors introduced a novel way to control Type II diabetes by involving the kidneys in the process of reducing the patient's blood sugars.

21. SGLT-2 is a protein in humans that facilitates glucose reabsorption in the kidneys. SGLT-2 inhibitors reduce blood sugar levels by reducing glucose reabsorption through the user's kidneys and increasing glucose excretion through the user's urine.

22. Invokana works by blocking the reabsorption of glucose by the kidney, increasing glucose excretion, and lowering blood glucose levels in diabetics who have elevated blood glucose levels.

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[2] Institute for Safe Medicine Practices, *QuarterWatch: Monitoring FDA MedWatch Reports*, May 6, 2015 – Data from 2014 Quarter 2, Available online at http://www.ismp.org/QuarterWatch/pdfs/2014Q2.pdf, last accessed October 5, 2016.

23. According to Janssen's own website, "INVOKANA® works with your kidneys to help you lose some sugar through the process of urination."[3]

24. However, SGLT2 inhibitors, including Invokana, are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. As a result, excess glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease.

25. Though Invokana is indicated for only improved glycemic control in type 2 adult diabetics, Defendants have marketed and continued to market Invokana for off label purposes, including but not limited to weight loss, reduced blood pressure, and improved glycemic control in type 1 diabetics.

26. Since Invokana's release, the FDA has received a significant number of reports of diabetic ketoacidosis among users of Invokana.

27. An analysis of the FDA adverse event database shows that patients taking Invokana are several times more likely to report diabetic ketoacidosis than those taking non-SGLT2 diabetes drugs to treat diabetes.

28. Invokana's safety and effectiveness were evaluated in nine clinical trials involving over 10,285 patients with Type II diabetes. The trials showed improvement in hemoglobin A1c levels (a measure of blood sugar control) and fasting plasma glucose (blood sugar) levels.

29. As part of the approval of Invokana, FDA required Janssen Pharmaceuticals to conduct a separate clinical trial to assess a signal of a serious risk of major adverse cardiovascular events with antidiabetic medications, including Invokana. FDA required Janssen to complete two double blind studies to evaluate the cardiovascular risk.

[3] https://www.invokana.com/about-invokana/how-invokana-works last visited October 5, 2016.

30. Responsive information to FDA's request for Defendants to investigate the cardiovascular risk of Invokana was provided during a January 10, 2013 meeting of the FDA Endocrinologic and Metobolic Drugs Advisory Committee. During that meeting, testimony from a statistical assessment of the cardiovascular safety of Invokana revealed that researchers found a hazard ratio of 6.49 for cardiac events during the first 30 days of the Canagliflozin Cardiovascular Assessment Study ("CANVAS"), a study sponsored by Defendant Janssen Pharmaceuticals. Stated another way, Defendants' own study found that patients on Invokana had a 649% higher probability of suffering a cardiovascular event in the first 30 days of use than did patients who were on the placebo.

31. FDA required Defendants to continue their CANVAS study and continue investigating the proclivity of cardiovascular events and reduction of kidney function from use of Invokana. Defendants' CANVAS study is anticipated to be completed in June, 2017.

32. Defendants received final FDA approval for Invokana on March 29, 2013 in oral tablet doses of 100 mg and 300 mg. Invokana's indications for use statement was "[a]s an adjunct to diet and exercise to improve glycemic control in adults with Type II diabetes mellitus."

33. Even though Invokana was not approved until nearly three months into the year, Defendants spent $12 million on advertising for Invokana between January and October 2013, the most money spent marketing any pharmaceutical drug in the United States during that time period.

34. In an effort to increase their market share and distinguish Invokana from other Type II diabetes drugs, Defendants marketed (and continue to market) Invokana off label for weight loss.

35. As discussed above, there are several different types of diabetes drugs on the market. Most of the drugs available have no discernable effect on a patient's weight, and several of these drugs even can cause weight gain. Because weight loss is typically a main component of treatment in Type II diabetes, a Type II diabetes drug that could cause weight loss would be of substantial benefit to patients, healthcare providers, and the manufacturer of that drug.

36. Other diabetes drugs help body metabolize blood sugar but Invokana is designed to have the body urinate sugar out of the system via the kidneys. This forces blood sugar thru the kidneys, overworking the kidneys as there is not a corresponding reduction in blood sugar thru other mechanisms. This constant stream of sugars in the urine overworks the kidneys, leading to eventual failure and ketoacidosis.

37. At all times relevant, Defendants extensively marketed Invokana off label as a weight loss drug to the public and healthcare providers. For example, in the clinical research results section on their website specifically directed to healthcare providers, Defendants included a prominent tab titled "Body Weight Change." The first statement on the tab said "Invokana® monotherapy demonstrated statistically significant reductions in body weight vs. placebo at 26 weeks." Then there was a graph claiming a 2.2% increase in weight loss for those on 100 mg doses (a mean of 5.5 pounds) and a 3.3% increase in weight loss for those on 300 mg doses (a mean of 7.5 pounds).

38. These reductions in weight are not inconsequential. The CDC[4], American Diabetes Association[5], Mayo Clinic[6], and the National Institute of Diabetes and Digestive and

[4] http://www.cdc.gov/diabetes/managing/health.html, last accessed on October 5, 2016.

[5] http://www.diabetes.org/living-with-diabetes/recently-diagnosed/where-do-i-begin/weight-loss.htmllast accessed on October 5, 2016.

[6] http://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/diabetes-diet/art-20044295, last accessed on October 5, 2016.

Kidney Diseases ("NIDDK")[7] all recommend weight loss as part of Type II diabetes treatment. And statements like, "You don't have to lose a lot of weight to start seeing results. Just losing 10-15 pounds can make a difference," from the same American Diabetes Association website are common knowledge in the diabetes community.

39. On Defendants' website directed to consumers, in a large chart promoting the alleged benefits of Invokana, Defendants claim, "Invokana® is not for weight loss, but may help you lose weight."[8] Again on Defendants Frequently Asked Questions website directed to consumers, the following question is posed: "If INVOKANA® helps my body get rid of some sugar, can it also help me lose weight?" The answer Defendants provide states, "Although INVOKANA® is not a weight-loss medicine, and each person is different, people can experience reduction in weight."[9]

40. Defendants also provided a checklist of questions for a new patient to ask their doctor about Invokana. Many of the questions relate to steering the conversation towards the patient's weight. Questions a prospective patient are supposed to ask their doctor include:

a. Should I consider losing weight? If so, how much?

b. What are the most important lifestyle changes I can make to help improve my numbers?

c. What type of exercise is best for me? Are there any forms of exercise I should avoid?

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[7] http://www.niddk.nih.gov/health-information/health-topics/weight-control/Pages/default.aspx, last accessed on October 5, 2016.

[8] https://www.invokana.com/about-invokana/what-is-invokana?&utm_source=google&utm_medium=cpc&utm_campaign=Branded&utm_content=Weight+Loss&utm_term=%252Binvokana+%252Bweight+%252Bloss&gclid=CPnA8piZxM8CFUqmNwodELIPtQ&gclsrc=ds, last accessed October 5, 2016.

[9] https://www.invokana.com/about-invokana/faq, last accessed October 5, 2016.

d. How is INVOKANA® different from other types of medications I'm taking/have tried?[10]

41. On information and belief, these direct-to-consumer advertisements are intended to play on the psyche of a Type II diabetes patient, as Type II diabetes patients are generally looking to lose weight to augment their prescription regimen to help control their diabetes.

42. On information and belief, Defendants intend for healthcare providers and the public to see the alleged added benefit of weight loss and choose Invokana over other Type II diabetes drugs, when in fact these alleged weight loss benefits are one of the catalysts to the serious injuries alleged herein.

43. Defendants' website for Invokana claims that over four million prescriptions have been written for Invokana.

44. As a result of their heavy marketing of Invokana, Defendants turned a new drug with zero market share in March 2013 into a drug that did $278 million in sales in the first quarter of 2015.

45. Indeed, Defendants published advertisements on their company websites and issued press releases announcing favorable information about Invokana. For example, the FDA's approval of Invokana on March 29, 2013 was announced on the Johnson & Johnson web site. On March 14, 2016, Johnson & Johnson issued a press release announcing "First Real-World Evidence Comparing an SGLT2 Inhibitor with DPP-4 Inhibitors Shows Adults with Type 2 Diabetes Achieve Greater Blood Glucose Control with INVOKANA® (canagliflozin)". The former announcement did not contain warnings about ketoacidosis, serious infections, etc., while the latter announcement mentioned these conditions.

[10] https://www.invokana.com/sites/www.invokana.com/files/DTCDoctorDiscussionGuideV2.pdf, last accessed October 5, 2016.

46. Through these advertisements, press releases, publications and web sites, Johnson and Johnson has purposefully directed activities nationally including towards residents of Connecticut.

47. Invokana's sales nearly tripled from $94 million in sales from the first quarter of 2014, and is nearly 40% more than Invokana's sales from the previous quarter of 2014 which totaled $201 million.

48. Defendants' marketing is misleading in that it overstates Invokana's efficacy while downplaying the serious adverse events. Defendants should have and would have discovered the risk of serious cardiovascular events, such as myocardial infarctions, through studies prior to Invokana's approval.

49. Along with the above described serious injuries, less than two years after Invokana's approval, multiple pieces of medical literature have linked SGLT-2 inhibitors with increased ketone production, including:

a. Kohei Kaku et al., *Efficacy and safety of monotherapy with the novel sodium/glucose cotransporter-2 inhibitor tofogliflozin in Japanese patients with type 2 diabetes mellitus: a combined Phase 2 and 3 randomized, placebo- controlled, double-blind, parallel-group comparative study*, 13 CARDIOVASCULAR DIABETOLOGY (2014);

b. Sunder Mudaliar et al., *Changes in Insulin Sensitivity and Insulin Secretion with the Sodium Glucose Cotransporter 2 Inhibitor Dapagliflozin*, 16 DIABETES TECHNOLOGY & THERAPEUTICS 137–144 (2014); and,

c. Yutaka Seino, *Luseogliflozin for the treatment of type 2 diabetes*, 15 EXPERT OPINION ON PHARMACOTHERAPY 2741–2749 (2014)

50. Increased ketone production can lead to a serious and potentially deadly disease called diabetic ketoacidosis (also known as DKA).

51. DKA, a subset of ketoacidosis or ketosis in diabetic patients, is a type of acidosis that typically occurs when insulin levels are inadequate to meet the body's basic metabolic

requirements. Insulin deficiency leads to formation of free fatty acids due to breakdown of triglycerides and amino acids, which get converted to highly acidic ketone bodies, leading to acidosis. Physical symptoms include nausea, vomiting, and abdominal pain that can progress to cerebral edema, coma, and death. DKA most commonly occurs in patients with type 1 diabetes and is almost always accompanied by high blood sugar levels.

52. The hallmark symptoms for a differential diagnosis of DKA are high blood sugars and having type 1 diabetes. The DKA events that have been linked to SGLT-2 inhibitors were not typical for DKA because the patients had Type II diabetes and their blood sugar levels, when reported, were only slightly increased compared to typical cases of DKA.

53. This type of DKA is referred to as euglycemic diabetic ketoacidosis, where the patient's blood sugar is below 200 mg/dl when diagnosed.

54. After approval of Invokana, the FDA received multiple adverse event reports linking Invokana with DKA. Specifically, the FDA received 20 adverse event reports of ketoacidosis in patients treated with SGLT-2 inhibitors from March, 2013 to June 6, 2014, and the FDA continues to receive additional adverse event reports post-June 2014.

55. As a result of the adverse event reports linking Invokana with DKA, and little more than two years after Invokana's approval, on May 15, 2015 FDA issued a safety communication to the public and the medical community that identified SGLT-2 inhibitors as a cause of DKA. This safety communication put particular emphasis on Invokana. The FDA indicated it was continuing to investigate the safety issue.

56. As the manufacturers of Invokana, Defendants knew or should have known that Invokana use was associated with ketoacidosis. Instead, Defendants promoted, and continue to promote, Invokana as a safe and effective treatment for Type II diabetes.

57. Case reports from Invokana's own clinical trials showed the link between Invokana and elevated ketones. At least 4 cases of ketoacidosis or heightened ketones were present in Defendants' submissions to the FDA. Because of how rare an event DKA is in patients with Type II diabetes, a reasonable and prudent manufacturer would have investigated the causal link in these case reports.

58. In 2015, multiple published case reports identified additional DKA events in patients treated with SGLT-2s. These reports include:

a. Hall, *2015-Case report of Ketoacidosis associated with Canagliflozin (Invokana).pdf*, March 5-8 ENDO CONFERENCE (2015).

b. Tomohide Hayami et al., *Case of ketoacidosis by a sodium-glucose cotransporter 2 inhibitor in a diabetic patient with a low-carbohydrate diet*, JOURNAL OF DIABETES INVESTIGATION n/a–n/a (2015).

c. Julia Hine et al., *SGLT inhibition and euglycaemic diabetic ketoacidosis*, THE LANCET DIABETES & ENDOCRINOLOGY (2015).

d. Nobuya Inagaki et al., *Efficacy and safety of canagliflozin alone or as add-on to other oral antihyperglycemic drugs in Japanese patients with type 2 diabetes: A 52-week open-label study*, 6 JOURNAL OF DIABETES INVESTIGATION 210–218 (2015).

e. Anne L. Peters et al., *Euglycemic Diabetic Ketoacidosis: A Potential Complication of Treatment With Sodium-Glucose Cotransporter 2 Inhibition*, DIABETES CARE dc150843 (2015).

f. Reginald St. Hilaire & Heather Costello, *Prescriber beware: report of adverse effect of sodium-glucose cotransporter 2 inhibitor use in a patient with contraindication*, 33 THE AMERICAN JOURNAL OF EMERGENCY MEDICINE 604.e3–604.e4 (2015).

59. Despite Defendants' knowledge of the risks of cardiovascular and ketoacidosis injuries as described above, Invokana's label fails to contain a warning for either event.

60. Along with the above described cardiovascular and ketone related injuries, SGLT-2 inhibitors, and Invokana in particular, also dramatically increase the likelihood of a patient developing kidney failure.

61. Invokana by its very mechanism of action causes dehydration and osmotic diuresis. Osmotic diuresis is the increase of urination rate caused by the presence of certain substances in the small tubes of the kidneys. The excretion occurs when substances such as glucose enter the kidney tubules and cannot be reabsorbed.

62. Because Invokana blocks sugar from being reabsorbed by the kidneys, the kidneys expel the sugar in the patient's urine. A buildup of sugar in the tubes leading from the kidneys leads to acute kidney (or "renal") failure.

63. Osmotic diuresis leads to volume depletion, which is water loss and salt loss. Volume depletion is distinct from dehydration, which relates only to water loss.

64. Volume depletion leads to decreased renal perfusion, meaning the kidneys do not push the fluid through its vessels as well as they should. Unimpeded, decreased renal perfusion leads to acute renal injury, including kidney failure which necessitates dialysis and, unencumbered, may require kidney transplants.

65. Invokana causes osmotic diuresis by forcing the kidneys to work harder and push more glucose through their tubules than the kidneys are intended to do. This continued heightened state the kidneys are put in when a patient is on Invokana makes kidney injury a higher likelihood, even for those with normal kidney function at the beginning of Invokana therapy.

66. Defendants were aware of the potential for Invokana to cause kidney failure prior to Invokana's approval. In fact, Invokana's medical review, submitted with Invokana's NDA

approval documents, disclosed a nearly three-fold increase (1.7% compared to 0.6%) in acute renal failure for patients taking the higher dose of Invokana compared to those taking placebo, even in patients whose kidney function was normal.

67. Defendants knew that the likelihood of renal adverse effects such as acute renal failure was nearly tripled in patients with near normal kidney function and more than doubled in patients with even moderately impaired kidney function.

68. At the time of the FDA Advisory Committee meeting, the FDA renal review questioned Invokana's role in causing adverse events related to the kidneys when it noted "the long term renal consequences of canagliflozin's effect on the eGFR ("epidermal growth factor receptor" or the cell-surface receptor for members of the epidermal growth factor family) are unknown.…It seems prudent to assume that the volume depletion and corresponding reduction in eGFR …places patients at increased risk for clinically significant episodes of acute kidney injury."

69. Invokana's risks substantially outweigh its benefits. Usage of Invokana reduced hemoglobin A1C levels (the test by which diabetics can measure their average blood sugars over a few month time period) by only by 0.62% for the 100 mg dosage and by 0.77% for the 300 mg dosage, which published medical literature has described as a very weak reduction.

70. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Invokana (canagliflozin) for use as a type of prescription medication prescribed to help lower blood sugar levels in adults with diabetes mellitus Type II.

71. The weight loss they claim is a benefit is instead a byproduct of the osmotic diuresis discussed above. Put another way, the weight loss is by and large water weight, and the

user is suffering from volume depletion. Once the user's fluids are corrected, their water weight comes back.

72. As part of their marketing of Invokana, Defendants widely disseminated direct-to- consumer advertising campaigns that were designed to influence patients, including Plaintiff, to make inquiries to their prescribing physician about Invokana and/or request prescriptions for Invokana.

73. In the course of these direct to consumer advertisements, Defendants overstated the efficacy of Invokana with respect to reducing hemoglobin A1c values, failed to adequately disclose the risks of severe injuries as described herein, and misleadingly promoted Invokana for weight loss, all without disclosing potentially life-threatening and fatal consequences of which Defendants knew or should have known.

74. Further, IMSP identified 457 domestic serious adverse events with canagliflozin as the primary suspect drug for the 12 months ending with March 31, 2014. IMSP states this was a higher total than for 92% of the drugs they regularly monitor.

75. Defendants admitted they knew of these adverse events and the likelihood that Invokana would cause them. When provided an opportunity to respond to the data IMSP had collected, Janssen told IMSP that **the specific adverse effects we observed in postmarketing reports were generally consistent with those seen in clinical trials**."

76. IMSP concluded with the question of whether the "drug does more good than harm in long-term treatment." In answering this question, IMSP stated, "[T]he data were still of insufficient duration to establish whether the drug had a measurable clinical benefit on the complications of Type II diabetes. The current data are also insufficient to address unanswered questions raised in the FDA reviews about whether long-term use might result in a steady decline

in kidney function, increased risk of bone fractures, or more cardiovascular events. By contrast, we observe clear evidence of harm to some patients in terms of hypersensitivity reactions and an array of renal adverse effects."

77. At all times relevant to this action, The Invokana Medication Guide, prepared and distributed by Defendants and intended for U.S. patients to whom Invokana has been prescribed, failed to warn and disclose to patients that Invokana may cause DKA, kidney failure, or cardiac events such as myocardial infarctions.

78. The Invokana used by Plaintiff was provided to him in a condition substantially the same as the condition in which it was manufactured and sold.

79. As a result of Defendants' actions, Plaintiff and her prescribing physicians were unaware, and could not reasonably have known or learned through reasonable diligence, that Plaintiff had been exposed to the risks identified herein, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

80. As a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of INVOKANA, Plaintiff suffered severe and permanent physical and emotional injuries. Plaintiff has endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiff seeks actual, compensatory, and punitive damages from Defendants.

81. Plaintiff has suffered from mental anguish from the knowledge that he may suffer life-long complications as a result of the injuries caused by INVOKANA.

82. The Defendants, their agents, servants, and/or employees, were negligent in the design, manufacture, sale, labeling, warnings, marketing, promotion, quality assurance, quality control, and distribution of Invokana in that, among other things, they:

a. Manufactured, produced, promoted, formulated, created, tested, and/or designed Invokana without thoroughly testing it and without due care;

b. Failed to analyze pre-marketing test data of Invokana;

c. Failed to conduct sufficient post-marketing and surveillance of Invokana;

d. Failed to provide adequate training and instruction to medical care providers for the appropriate use of Invokana;

e. Falsely and misleadingly over promoted, advertised and marketed Invokana as set forth herein including overstating efficacy, minimizing risk and stating that blood monitoring and dose adjustments were not necessary for safe and effective use to influence patients, such as the Plaintiff, to purchase and consume Invokana;

f. Manufacturing, producing, promoting, formulating, creating and/or designing Invokana without thoroughly testing it;

g. Manufacturing, producing, promoting, formulating, creating and/or designing Invokana without adequately testing it;

h. Not conducting sufficient testing programs to determine whether or not Invokana was safe for use; in that the Defendants herein knew or should have known that Invokana was unsafe or unfit for use by reason of the dangers to its users;

i. Selling Invokana without making proper and sufficient tests to determine the dangers to its users;

j. Negligently failing to adequately and correctly warn the Plaintiff, the Plaintiff's physicians, the public, the medical and healthcare profession, and the FDA of the dangers of Invokana;

k. Failing to provide adequate instructions regarding safety precautions to be followed by users such as the Plaintiff, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Invokana;

l. Failing to test Invokana and/or failing to adequately, sufficiently and properly test Invokana;

m. Negligently advertising and recommending the use of Invokana without sufficient knowledge as to its dangerous propensities;

n. Negligently representing that Invokana was safe for use for its intended purpose, when, in fact, it was unsafe;

o. Negligently designing Invokana in a manner which was dangerous to its users;

p. Negligently manufacturing Invokana in a manner which was dangerous to users;

q. Negligently producing Invokana in a manner which was dangerous to its users;

r. Negligently assembling Invokana in a manner which was dangerous to its users;

s. Concealing information from the Plaintiff and the public, in knowing that Invokana was unsafe, dangerous, and/or non-conforming with FDA regulations;

t. Placing an unsafe product into the stream of commerce.

83. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' drug, Invokana.

84. Plaintiff's use of Invokana caused Plaintiff to suffer serious and life threatening injuries as detailed below.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

85. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

86. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of INVOKANA into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

87. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of INVOKANA into interstate commerce in that Defendants knew or should have known that using INVOKANA created a high risk of unreasonable, dangerous side effects, including stroke, heart attack, ketoacidosis, and severe kidney damage, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

88. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Manufacturing, producing, promoting, formulating, creating, and/or designing INVOKANA without thoroughly testing it;

b. Manufacturing, producing, promoting, formulating, creating, and/or designing INVOKANA without adequately testing it;

c. Not conducting sufficient testing programs to determine whether or not INVOKANA was safe for use; in that Defendants herein knew or should have known that INVOKANA was unsafe and unfit for use by reason of the dangers to its users;

d. Selling INVOKANA without making proper and sufficient tests to determine the dangers to its users;

e. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of INVOKANA;

f. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, INVOKANA;

g. Failing to test INVOKANA and/or failing to adequately, sufficiently and properly test INVOKANA.

h. Negligently advertising and recommending the use of INVOKANA without sufficient knowledge as to its dangerous propensities;

i. Negligently representing that INVOKANA was safe for use for its intended purpose, when, in fact, it was unsafe;

j. Negligently representing that INVOKANA had equivalent safety and efficacy as other forms of treatment for diabetes;

k. Negligently designing INVOKANA in a manner which was dangerous to its users;

l. Negligently manufacturing INVOKANA in a manner which was dangerous to its users;

m. Negligently producing INVOKANA in a manner which was dangerous to its users;

n. Negligently assembling INVOKANA in a manner which was dangerous to its users;

o. Concealing information from the Plaintiff in knowing that INVOKANA was unsafe, dangerous, and/or non-conforming with FDA regulations;

p. Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of INVOKANA compared to other forms of treatment for diabetes.

89. Defendants underreported, underestimated and downplayed the serious dangers of INVOKANA.

90. Defendants negligently compared the safety risk and/or dangers of INVOKANA with other forms of treatment for diabetes.

91. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of INVOKANA in that they:

a. Failed to use due care in designing and manufacturing INVOKANA so as to avoid the aforementioned risks to individuals when INVOKANA was used for treatment for diabetes;

b. Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of INVOKANA;

c. Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of INVOKANA;

d. Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning INVOKANA;

e. Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

f. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of INVOKANA;

g. Failed to warn Plaintiff, prior to actively encouraging the sale of INVOKANA, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

h. Were otherwise careless and/or negligent.

92. Despite the fact that Defendants knew or should have known that INVOKANA caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell INVOKANA to consumers, including the Plaintiff, DOROTHY FRANCO.

93. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

94. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiff suffered and/or will continue to suffer.

95. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including dehydration and acute renal failure, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

96. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

97. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of of TEN MILLION DOLLARS ($10,000,000.00).

SECOND CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY)

98. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

99. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently

acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed INVOKANA as hereinabove described that was used by the Plaintiff, DOROTHY FRANCO.

100. That INVOKANA was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

101. At those times, INVOKANA was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

102. The INVOKANA designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of INVOKANA.

103. The INVOKANA designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

104. At all times herein mentioned, INVOKANA was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

105. Defendants knew, or should have known that at all times herein mentioned its INVOKANA was in a defective condition, and was and is inherently dangerous and unsafe.

106. At the time of the Plaintiff's use of INVOKANA, INVOKANA was being used for the purposes and in a manner normally intended, namely to control high blood sugar in people with type 2 diabetes.

107. Defendants with this knowledge voluntarily designed its INVOKANA in a dangerous condition for use by the public, and in particular the Plaintiff.

108. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

109. Defendants created a product unreasonably dangerous for its normal, intended use.

110. The INVOKANA designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that INVOKANA left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

111. The INVOKANA designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' INVOKANA was manufactured.

112. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

113. The Plaintiff could not, by the exercise of reasonable care, have discovered INVOKANA'S defects herein mentioned and perceived its danger.

114. The INVOKANA designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including stroke, heart attack, ketoacidosis, and severe kidney damage, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

115. The INVOKANA designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

116. The INVOKANA designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, stroke, heart attack, ketoacidosis, and severe kidney damage, as well as other severe and permanent health consequences from INVOKANA, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, INVOKANA.

117. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, INVOKANA.

118. Defendants' defective design, manufacturing defect, and inadequate warnings of INVOKANA were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

119. That said defects in Defendants' drug INVOKANA were a substantial factor in causing Plaintiff's injuries.

120. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including dehydration and acute renal failure, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

121. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

122. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

123. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

124. At all times material hereto, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing, promoting, selling, and/or distributing INVOKANA, which is unreasonably dangerous and defective, thereby placing INVOKANA into the stream of commerce.

125. Defendants expressly represented to Plaintiff DOROTHY FRANCO, other consumers, Plaintiff's physicians, and the medical community, by and through statements made

and written materials disseminated by Defendants or their authorized agents or sales representatives, that INVOKANA:

a. was safe and fit for its intended purposes;

b. was of merchantable quality;

c. did not produce any dangerous side effects, and

d. had been adequately tested and found to be safe and effective for the treatment of diabetes.

126. These express representations include incomplete prescribing information that purports, but fails, to include the true risks associated with use of INVOKANA. In fact, Defendants knew or should have known that the risks identified in INVOKANA's prescribing information and package inserts do not accurately or adequately set forth the drug's true risks. Despite this, Defendants expressly warranted INVOKANA as safe and effective for use.

127. Defendants advertised, labeled, marketed, and promoted INVOKANA, representing the quality to health care professionals, Plaintiff, and the public in such a way as to induce INVOKANA's purchase or use, thereby making an express warranty that INVOKANA would conform to the representations. More specifically, the prescribing information for INVOKANA did not and does not contain adequate information about the true risks of developing the injuries complained of herein.

128. Despite this, Defendants expressly represented that INVOKANA was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat diabetes. Portions of the prescribing information relied upon by Plaintiff and her health care professionals, including the "Warnings and Precautions" section,

purport to expressly include the risks associated with the use of INVOKANA, but those risks are neither accurately nor adequately set forth.

129. The representations about INVOKANA contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

130. INVOKANA does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries. Therefore, Defendants breached the aforementioned warranties.

131. At all relevant times, INVOKANA did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

132. Neither Plaintiff nor her prescribing health care professionals had knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning INVOKANA.

133. Plaintiff, other consumers, Plaintiff's physicians, and the medical community justifiably and detrimentally relied upon Defendants' express warranties when prescribing and ingesting INVOKANA.

134. Had the prescribing information for INVOKANA accurately and adequately set forth the true risks associated with the use of such product, including Plaintiff's injuries, rather than expressly excluding such information and warranting that the product was safe for its intended use, Plaintiff could have avoided the injuries complained of herein.

135. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered dehydration and acute renal failure. In

addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

136. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

137. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

138. Defendants manufactured, distributed, advertised, promoted, and sold INVOKANA.

139. At all relevant times, Defendants knew of the use for which INVOKANA was intended, and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

140. Defendants were aware that consumers, including Plaintiff DOROTHY FRANCO, would use INVOKANA for treatment of type 2 diabetes and for other purposes, including but not limited to weight loss, reduced blood pressure, and improved glycemic control in type 1 diabetics.

141. INVOKANA was neither safe for its intended use nor of merchantable quality, as impliedly warranted by Defendants, in that INVOKANA has dangerous propensities when used as intended and can cause serious injuries, including stroke, heart attack, ketoacidosis, and severe kidney damage.

142. At all relevant times, Defendants intended that INVOKANA be used in the manner used by Plaintiff, and Defendants impliedly warranted it to be of merchantable quality, safe, and fit for such use, despite the fact that INVOKANA was not adequately tested.

143. Defendants were aware that consumers, including Plaintiff, would use INVOKANA as marketed by Defendants. As such, Plaintiff was a foreseeable user of INVOKANA.

144. Upon information and belief, Plaintiff and/or her health care professionals were at all relevant times in privity with Defendants.

145. INVOKANA was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Plaintiff's injuries.

146. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell INVOKANA only if it was indeed of merchantable quality and safe and fit for its intended use.

147. Defendants breached their implied warranty to consumers, including Plaintiff that INVOKANA was not of merchantable quality, nor was it safe and fit for its intended use.

148. Plaintiff and her physicians reasonably relied upon Defendants' implied warranty for INVOKANA when prescribing and ingesting INVOKANA.

149. Plaintiff's use of INVOKANA was as prescribed and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

150. INVOKANA was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

151. Defendants breached the warranties of merchantability and fitness for its particular purpose because INVOKANA was unduly dangerous and caused undue injuries, including Plaintiff's injuries.

152. The harm caused by INVOKANA far outweighed its alleged benefit, rendering INVOKANA more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products.

153. Neither Plaintiff nor her health care professionals reasonably could have discovered or known of the risk of serious injury and death associated with INVOKANA.

154. Defendants' breach of these implied warranties caused Plaintiff's injuries.

155. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered dehydration and acute renal failure. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

156. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FIFTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(FRAUDULENT MISREPRESENTATION)

157. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

158. Defendants made fraudulent misrepresentations with respect to INVOKANA in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that INVOKANA had been tested and found to be safe and effective for the treatment of diabetes; and

b. Upon information and belief, Defendants represented that INVOKANA was safer than other alternative medications.

c. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of INVOKANA to Plaintiff DOROTHY FRANCO, other consumers, Plaintiff's physicians, and the medical community.

159. The representations were made by the Defendants with the intent that doctors and patients, including Plaintiff and her physicians, rely upon them.

160. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, Plaintiff's physicians, and the medical community to induce and encourage the sale of INVOKANA.

161. Plaintiff, her doctors, and others relied upon these representations.

162. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered dehydration and acute renal failure. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has

incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

163. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SIXTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(FRAUDULENT CONCEALMENT)

164. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

165. Throughout the relevant time period, Defendants knew that INVOKANA was defective and unreasonably unsafe for its intended purpose, and intentionally and willfully failed to disclose and/or suppressed information regarding the true nature of the risks of use of INVOKANA.

166. Defendants fraudulently concealed information with respect to INVOKANA in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that INVOKANA was safe and fraudulently withheld and concealed information about the severity of the substantial risks of using INVOKANA; and

b. Upon information and belief, Defendants represented that INVOKANA was safer than other alternative medications and fraudulently concealed

information which demonstrated that INVOKANA was not safer than alternatives available on the market.

c. Defendants were under a duty to Plaintiff, DOROTHY FRANCO, to disclose and warn of the defective and dangerous nature of INVOKANA because:

d. Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of INVOKANA;

e. Defendants knowingly made false claims and omitted important information about the safety and quality of INVOKANA in the documents and marketing materials Defendants provided to physicians and the general public; and

f. Defendants fraudulently and affirmatively concealed the defective and dangerous nature of INVOKANA from Plaintiff.

167. As the designers, manufacturers, sellers, promoters, and/or distributors of INVOKANA, Defendants had unique knowledge and special expertise regarding INVOKANA. This placed them in a position of superiority and influence over Plaintiff and her healthcare providers. As such, Plaintiff and her healthcare providers reasonably placed their trust and confidence in Defendants and in the information disseminated by Defendants.

168. The facts concealed or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or use INVOKANA.

169. The concealment and/or non-disclosure of information by Defendants about the severity of the risks caused by INVOKANA was intentional, and the representations made by Defendants were known by them to be false.

170. The concealment of information and the misrepresentations about INVOKANA were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon

them so that Plaintiff would request and purchase INVOKANA and her health care providers would prescribe and recommend INVOKANA.

171. Plaintiff, her doctors, and others reasonably relied on Defendants' representations and were unaware of the substantial risk posed by INVOKANA.

172. Had Defendants not concealed or suppressed information regarding the severity of the risks of INVOKANA, Plaintiff and her physicians would not have prescribed or ingested the drug.

173. Defendants, by concealment or other action, intentionally prevented Plaintiff and her health care professionals from acquiring material information regarding the lack of safety of INVOKANA, thereby preventing Plaintiff from discovering the truth. As such, Defendants are liable for fraudulent concealment.

174. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered dehydration and acute renal failure. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

175. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SEVENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENT MISREPRESENTATION)

176. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

177. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning INVOKANA, to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

178. Defendants disseminated to health care professionals and consumers -through published labels, marketing materials, and otherwise - information that misrepresented the properties and effects of INVOKANA with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe or ingest INVOKANA.

179. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of INVOKANA, knew or reasonably should have known that health care professionals and consumers of INVOKANA rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of prescribing or ingesting INVOKANA.

180. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of INVOKANA were accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was negligently and

materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff DOROTHY FRANCO.

181. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of INVOKANA, knew or reasonably should have known that health care professionals would write prescriptions for INVOKANA in reliance on the information disseminated by Defendants, and that the patients receiving prescriptions for INVOKANA would be placed in peril of developing serious and potential life threatening injuries if the information disseminated by Defendants and relied upon was materially inaccurate, misleading, or otherwise false.

182. From the time INVOKANA was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety of INVOKANA. Defendants made material misrepresentations to Plaintiff, her health care professionals, the healthcare community, and the general public, including:

a. stating that INVOKANA had been tested and found to be safe and effective for the treatment of diabetes;

b. concealing, misrepresenting, and actively downplaying the severe and life-threatening risks of harm to users of INVOKANA, when compared to comparable or superior alternative drug therapies; and

c. misrepresenting INVOKANA's risk of unreasonable, dangerous, adverse side effects.

183. Defendants made the foregoing representations without any reasonable ground for believing them to be true.

184. These representations were made directly by Defendants, their sales representative, and other authorized agents, and in publications and other written materials directed to health care professionals, medical patients, and the public.

185. Defendants made these representations with the intent to induce reliance thereon, and to encourage the prescription, purchase, and use of INVOKANA.

186. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff, the truth regarding Defendants' claims that INVOKANA had been tested and found to be safe and effective for treating diabetes.

187. The misrepresentations made by Defendants, in fact, were false and known by Defendants to be false at the time the misrepresentations were made.

188. Defendants failed to exercise ordinary care in making their representations concerning INVOKANA and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of INVOKANA.

189. Defendants engaged in a nationwide marketing campaign, over-promoting INVOKANA in written marketing literature, in written product packaging, and in direct-to-consumer advertising via written and internet advertisements and television commercial ads. Defendants' over-promotion was undertaken by touting the safety and efficacy of INVOKANA while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening risks of harm to users of INVOKANA, when compared to comparable or superior alternative drug therapies. Defendants negligently misrepresented INVOKANA's risk of unreasonable and dangerous adverse side effects.

190. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of INVOKANA, including Plaintiff. Defendants had knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

191. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered dehydration and acute renal failure. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

192. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(FRAUD AND DECEIT)

193. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

194. Defendants conducted research and used INVOKANA as part of their research.

195. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, Plaintiff DOROTHY FRANCO, Plaintiff's doctors, hospitals, healthcare professionals, and/or the FDA that INVOKANA was safe and effective for use as a means to control high blood sugar in people with type 2 diabetes.

196. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

197. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as Plaintiff's respective healthcare providers and/or the FDA.

198. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

199. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drug INVOKANA was safe and effective for use to control high blood sugar in people with type 2 diabetes.

200. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug INVOKANA carried the same risks, hazards, and/or dangers as other forms of treatment control high blood sugar in people with type 2 diabetes.

201. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that INVOKANA was not injurious to the health and/or safety of its intended users.

202. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that INVOKANA was as potentially

injurious to the health and/or safety of its intended as other forms of treatment to control high blood sugar in people with type 2 diabetes.

203. These representations were all false and misleading.

204. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that INVOKANA was not safe as a means of treatment for controlling high blood sugar in people with type 2 diabetes.

205. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of INVOKANA, specifically but not limited to INVOKANA not having dangerous and serious health and/or safety concerns.

206. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiff, regarding the safety of INVOKANA, specifically but not limited to INVOKANA being a safe means of controlling high blood sugar in people with type 2 diabetes.

207. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of INVOKANA and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use INVOKANA.

208. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that

INVOKANA was fit and safe for use as treatment to control high blood sugar in people with type 2 diabetes.

209. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that INVOKANA was fit and safe for use as treatment for controlling high blood sugar in people with type 2 diabetes.

210. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that INVOKANA did not present serious health and/or safety risks.

211. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that INVOKANA did not present health and/or safety risks greater than other forms of treatment for controlling high blood sugar in people with type 2 diabetes.

212. That these representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

213. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe INVOKANA.

214. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of INVOKANA to the public at large, the Plaintiff in

particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of treatment for controlling high blood sugar in people with type 2 diabetes.

215. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of INVOKANA by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of INVOKANA.

216. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on INVOKANA and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

217. Defendants, through their public relations efforts, which included but were not limited to public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as Plaintiffs respective healthcare professionals would rely upon the information being disseminated.

218. Defendants utilized direct to consumer adverting to market, promote, and/or advertise INVOKANA.

219. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment for controlling high blood sugar in people with type 2 diabetes.

220. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of INVOKANA.

221. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.

222. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of INVOKANA, Plaintiff would not have purchased, used and/or relied on Defendants' drug INVOKANA.

223. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

224. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including dehydration and acute renal failure, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

225. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

226. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

PUNITIVE DAMAGES ALLEGATIONS

227. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

228. Plaintiff DOROTHY FRANCO is entitled to punitive damages because Defendants misrepresented and/or withheld information and materials from the FDA, the medical community and the public at large, including the Plaintiff, concerning the safety profile, and, more specifically the serious side effects and/or complications associated with INVOKANA.

229. In respect to the FDA, physicians, and consumers, Defendant downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks associated with the use of INVOKANA, despite available information that INVOKANA was likely to cause serious side effects and/or complications.

230. In respect to the FDA, physicians, and consumers, Defendant downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks associated with the use of INVOKANA, despite available information that INVOKANA was likely to cause serious side effects and/or complications.

231. Defendants' failure to provide the necessary materials and information to the FDA, as well as their failure warn physicians and consumers of the serious side effects and/or complications, was reckless and without regard for the public's safety and welfare.

232. Defendants were or should have been in possession of evidence demonstrating that INVOKANA causes serious side effects. Nevertheless, Defendant continued to market INVOKANA by providing false and misleading information with regard to safety and efficacy.

233. Defendants failed to provide the FDA, physicians and consumers with available materials, information and warnings that would have ultimately dissuaded physicians from prescribing INVOKANA to consumers, from purchasing and consuming INVOKANA, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming INVOKANA.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Judgment for Plaintiff and against Defendants;

2. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

4. Awarding Plaintiff reasonable attorneys' fees;

5. Awarding Plaintiff the costs of these proceedings; and

6. Such other and further relief as this Court deems just and proper.

PLAINTIFF

By Counsel

Respectfully submitted,

/s/ P. Gregory Haddad
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