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10 **UNITED STATES DISTRICT COURT**
11 **CENTRAL DISTRICT OF CALIFORNIA**

12 LORIS FURLOW,
13 Plaintiff,

14 v.

15 JANSSEN RESEARCH &
16 DEVELOPMENT L.L.C. f/k/a/
17 JOHNSON & JOHNSON
18 PHARMACEUTICAL RESEARCH
19 AND DEVELOPMENT L.L.C.;
20 JOHNSON & JOHNSON; JANSSEN
21 PHARMACEUTICALS, INC. f/k/a
22 ORTHO-MCNEIL-JANSSEN
23 PHARMACEUTICALS, INC.;
24 JANSSEN ORTHO L.L.C.;
25 MITSUBISHI TANABE PHARMA
26 CORPORATION; AND JOHN DOES 1-
27 50,
28 Defendants.

Case No. 2:16-cv-01386

**COMPLAINT FOR DAMAGES
AND
DEMAND FOR JURY TRIAL**

1. **Strict Liability**
2. **Design Defect**
3. **Failure to Warn**
4. **Negligence**
5. **Breach of Express Warranty**
6. **Breach of Implied Warranty**
7. **Fraud**
8. **Misrepresentation**
9. **Fraudulent Concealment**
10. **Negligent Misrepresentation**
11. **Violation of the Fair Business Practices Act of 1975**
12. **Punitive Damages**

25 Plaintiff, Loris Furlow, brings this case against Defendants for injuries suffered as
26 a direct result of Plaintiff's ingestion of the pharmaceutical product Invokana®. Plaintiff
27 alleges as follows:
28

1 **JURISDICTION AND VENUE**

2 1. This Court has subject matter jurisdiction over this action pursuant to 28
3 U.S.C § 1332 because the amount in controversy exceeds \$75,000.00, exclusive of
4 interest and costs, and because Defendants are incorporated and have their principal
5 places of business in states other than the state in which the Plaintiff resides.
6

7
8 2. This Court has jurisdiction over the non-resident Defendants because they
9 have done business in the State of California, have committed a tort in whole or in part
10 in the State of California, and have continuing contacts with the State of California.
11

12 **PARTIES TO THIS COMPLAINT**

13 3. At all times and relevant hereto, Plaintiff Loris Furlow was a citizen of the
14 state of California and resident of Los Angeles, California. Plaintiff was prescribed,
15 purchased, and ingested Invokana®.
16

17 4. Upon information and belief, Defendant JANSSEN RESEARCH &
18 DEVELOPMENT L.L.C. f/k/a/ JOHNSON & JOHNSON PHARMACEUTICAL
19 RESEARCH AND DEVELOPMENT L.L.C. (“JANSSEN R&D”) is a limited liability
20 company organized and existing under the laws of New Jersey and has its principal
21 place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County,
22 New Jersey 08933. Defendant JANSSEN R&D’s sole member is JANSSEN
23 PHARMACEUTICALS, INC., (Centocor, Inc. [now known as Janssen Biotech, Inc.], a
24 Pennsylvania corporation with its principal place of business and nerve center located
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1 at 200 Great Valley Parkway, Malvern, Pennsylvania.), which is a Pennsylvania
2 corporation with a principal place of business at 1125 Trenton-Harbourton Road,
3 Titusville, New Jersey 08560. As part of its business, JANSSEN R&D is involved in the
4 research, development, sales, and marketing of pharmaceutical products including
5 Invokana®. Upon information and belief, and at all relevant times, Defendant,
6 JANSSEN R&D, was in the business of and did research, manufacture, test, advertise,
7 promote, market, sell, and/or distribute the drug Invokana® for use as a drug to treat
8 Type 2 Diabetes.
9
10

11 5. Defendant JOHNSON & JOHNSON ("J&J"), is a fictitious name adopted
12 by Defendant JOHNSON & JOHNSON COMPANY, a New Jersey corporation which
13 has its principal place of business at One Johnson & Johnson Plaza, New Brunswick,
14 Middlesex County, New Jersey 08933. At all times relevant, Defendant J&J was
15 engaged in the business of designing, developing, manufacturing, testing, packaging,
16 promoting, marketing, distributing, labeling, and/or selling Invokana®.
17
18

19 6. Upon information and belief, Defendant JANSSEN
20 PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a
21 ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. ("JANSSEN PHARM")
22 is a Pennsylvania Corporation, having a principal place of business at 1125 Trenton-
23 Harbourton Road, Titusville, New Jersey 08560. As part of its business, JANSSEN
24 PHARM is involved in the research, development, sales, and/or marketing of
25 pharmaceutical products including Invokana®. Upon information and belief, and at all
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1 relevant times, Defendant, JANSSEN PHARM, was in the business of and did design,
2 research, manufacture, test, advertise, promote, market, sell, and/or distribute the drug
3 Invokana® for treatment of Type 2 Diabetes.

4
5 7. Upon information and belief, Defendant JANSSEN ORTHO LLC
6 (“JANSSEN ORTHO”) is a limited liability company organized under the laws of
7 Delaware, having a principal place of business at Stateroad 933 Km 01, Street Statero,
8 Gurabo, Puerto Rico 00778. Defendant JANSSEN ORTHO is a subsidiary of Johnson
9 & Johnson. The only member of JANSSEN ORTHO LLC is OMJ PR Holdings,
10 which is incorporated in Ireland with a principal place of business in Puerto Rico.
11 Accordingly, JANSSEN ORTHO LLC is a citizen of Delaware, Ireland, and Puerto
12 Rico for purposes of determining diversity under 28 U.S.C. § 1332. As part of its
13 business, JANSSEN ORTHO is involved in the research, development, sales, and
14 marketing, and manufacturing of pharmaceutical products including Invokana®. Upon
15 information and belief, and at all relevant times, Defendant, JANSSEN ORTHO, was in
16 the business of and did design, research, manufacture, test, advertise, promote, market,
17 sell, and distribute the drug Invokana® for use as a drug to treat Type 2 Diabetes.

18
19 8. Upon information and belief, Defendant MITSUBISHI TANABE
20 PHARMA CORPORATION (“MTPC”) is a corporation organized and existing under
21 the laws of Japan, having an office and place of business at 2-6-18, Kitahama, Chuo-ku,
22 Osaka 541-8505, Japan. Upon information and belief, Invokana® was first developed
23 by MTPC and later licensed to Janssen Pharmaceuticals.
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1 9. Upon information and belief, Defendants John Does 1-50 are corporations
2 or other legal entities, the names and addresses of residences of which are unknown. At
3 all times alleged herein, Defendants shall include any and all named or unnamed parent
4 companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners,
5 joint ventures, and any organizational units of any kind, their predecessors, successors,
6 successors in interest, assignees, and their officers, directors, employees, agents,
7
8 representatives and any and all other persons acting on their behalf.
9

10 **NATURE OF THE CASE**

11 10. Defendants manufactured, marketed, advertised, distributed, promoted,
12 labeled, tested, and sold Invokana® as a drug to treat Type 2 Diabetes.
13

14 11. On March 29, 2013, Invokana® was approved by the United States Food
15 and Drug Administration (“FDA”) to improve glycemic control in adults with Type 2
16 Diabetes.
17

18 12. Invokana® was the first member of a new class of antidiabetic drugs
19 known as sodium glucose co-transporter 2 (“SGLT2”) inhibitors. SGLT2 inhibitors are
20 designed to work by blocking the reabsorption of glucose by the kidney, increasing
21 glucose excretion, and lowering blood glucose levels in diabetics who have elevated
22 blood glucose levels.
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1 13. Defendants’ marketing materials represent that Invokana® is a once-daily
2 pill that is “proven to lower blood sugar (A1C).”¹ Although Defendants explicitly state
3 that Invokana® is not a weight-loss drug, they nevertheless continue to advertise that
4
5 Invokana® “may help you lose weight.”²

6 14. On May 15 2015, the FDA warned that treatment with SGLT2 inhibitors,
7 including Invokana®, may lead to serious complications, including diabetic
8
9 ketoacidosis—a condition of high levels of acid accumulating in the blood. This
10 condition happens when the body does not have enough insulin to manage glucose
11 levels. The body begins burning fatty acids, which results in a waste product known as
12
13 ketones. These ketones are what trigger the symptoms of ketoacidosis. These symptoms
14 include difficulty breathing, nausea or vomiting, abdominal pain, confusion, fatigue, and
15
16 sleeplessness. Other complications associated with Invokana® include heart attack,
17
18 kidney failure, kidney impairment, kidney stones, urinary tract infections, and abnormal
19 weight loss.

20 15. According to the FDA, a “search of the FDA Adverse Event Reporting
21 System (FAERS) database identified twenty cases of acidosis reported as diabetic
22 ketoacidosis (DKA), ketoacidosis, or ketosis in patients treated with SGLT2 inhibitors
23
24 from March 2013 to June 6, 2014. All patients required emergency room visits or
25

26 _____
27 ¹ What Is Invokana, (last visited Oct. 19, 2015), [http://www.invokana.com/about-](http://www.invokana.com/about-invokana/what-is-invokana)
28 [invokana/what-is-invokana.](http://www.invokana.com/about-invokana/what-is-invokana)

² *Id.*

1 hospitalization to treat their ketoacidosis.”³ However, this information was not portrayed
2 in the warnings section on the Invokana® warning label. The lack of warning of this
3 serious complication resulted in patients ingesting Invokana® and physicians
4 prescribing Invokana® being without sufficient information to make an informed
5 decision regarding the safety of Invokana®.
6

7 16. The Institute for Safe Medication Practices’ (“ISMP”) May 6, 2015
8 edition of Quarter Watch warns about a number of adverse reactions being reported
9 about Invokana®. In the first year after Invokana® was released, more than 450 serious
10 adverse event reports were filed. Many of these reports were related to kidney failure,
11 including fifty-four reports of kidney failure or impairment, fifty-four cases of severe
12 dehydration or fluid imbalance, eleven cases of kidney stones, and fifty-two cases of
13 abnormal weight loss.⁴
14
15

16 17. Defendants’ warning information for Invokana® does not adequately
17 address the increased risk of diabetic ketoacidosis or kidney failure, merely stating
18 that a “possible side effect” of Invokana® is “kidney problems.”⁵
19
20

21 18. Due to the defective nature of Invokana®, persons who were
22 prescribed and ingested it, for even a brief period of time, including the Plaintiff, were
23

24 ³ U.S. Food and Drug Administration, FDA Drug Safety Communication: FDA
25 Warns that SGLT2 Inhibitors for Diabetes May Result in a Serious Condition of too
26 Much Acid in the Blood, May 15, 2015, (last visited Oct. 19, 2015),
<http://www.fda.gov/Drugs/DrugSafety/ucm446845.htm>.

27 ⁴ <http://www.ismp.org/quarterwatch/pdfs/2014Q2.pdf>

28 ⁵ <http://www.invokana.com/medication-guide.pdf>

1 at increased risk for developing serious, and sometimes life-threatening, complications,
2 including kidney failure. Defendants withheld and concealed their knowledge that
3 Invokana® can cause serious, and sometimes life-threatening, complications, including
4 kidney failure from the Plaintiff, other consumers, their physicians, the medical
5 community at large and the general public. Defendants did not adequately warn of
6 increased risk of kidney failure and other serious complications associated with
7 Invokana®, merely indicating that there was a risk for kidney problems, without
8 addressing the specific increased risk of kidney failure or the extent of that risk
9 associated with Invokana®.
10
11

12
13 19. Other safer available alternatives to Invokana® are available for the
14 treatment of Type 2 Diabetes.

15
16 20. Even though safer alternatives to Invokana® are available, consumers,
17 including Plaintiff, who have used Invokana® for the treatment of Type 2 Diabetes have
18 not been adequately warned about the significant risks and lack of benefits associated
19 with Invokana®.
20

21 21. Invokana® is unreasonably dangerous and defective as formulated, putting
22 consumers, including Plaintiff, at an unreasonable risk of suffering injury and death.
23

24 22. As the developers, manufacturers and distributors of Invokana®,
25 Defendants knew or should have known that it was associated with serious
26 complications, including kidney failure.
27
28

1 23. Defendants continued to promote Invokana® as a safe and effective
2 treatment for patients with Type 2 Diabetes despite having knowledge of serious
3 complications, including kidney failure associated with it.
4

5 24. In 2014 alone, \$19.8 million was spent to market Invokana® to
6 doctors and hospitals, making that the second highest amount spent for any
7 pharmaceutical drug in 2014.⁶
8

9 25. Defendants have reaped financial success from Invokana® while placing
10 consumers at risk of severe injury and death. Johnson and Johnson reported 2014
11 domestic sales of Invokana® of \$569 million. As of June 2015, domestic sales had
12 reached a total \$266 million.
13

14 26. Due to the defects in design and warnings, the Invokana® ingested by
15 Plaintiff was unreasonably dangerous at the time it left Defendants' control. The
16 increased risks and subsequent injuries associated with Plaintiff's Invokana® use were
17 the direct and proximate result of Defendants' conduct.
18

19 **PLAINTIFF'S EXPERIENCE AND INJURIES**
20

21 27. Plaintiff Loris Furlow ingested Invokana® as prescribed by her physician
22 for the treatment of Type 2 Diabetes.
23

24 28. After taking Invokana®, on or around April 2014 and March 2015,
25 Plaintiff was admitted to Ronald Reagan UCLA Medical Center for acute kidney injury
26

27 ⁶ Robert Langreth and Caroline Chen, Drug Dollars Seek to Convince Doctors That
28 2nd Choice Is OK, Bloomberg Business (July 2, 2015 11:18 AM),
<http://www.bloomberg.com/news/articles/2015-07-02/doctors-attract-most-cash-from-drugmakers-for-diabetes-clotting>.

1 and acute kidney failure. Plaintiff would not have used Invokana® had Defendants
2 properly disclosed the risks associated with its use, as safer alternatives were available.

3 **FIRST CAUSE OF ACTION**

4 **[Strict Liability]**

5
6 29. Plaintiff incorporates by reference each and every paragraph of this
7 Complaint as if fully set forth herein.

8
9 30. Plaintiff pleads this Court in the broadest sense possible, pursuant to all
10 laws that may apply pursuant to choice of law principles, including the law of the
11 Plaintiff's resident state.

12
13 31. At the time of Plaintiff's injuries, Invokana® was defective and
14 unreasonably dangerous to foreseeable consumers, including Plaintiff.

15
16 32. At all times relevant, the Defendants designed, researched, manufactured,
17 tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired
18 the Defendants who have designed, researched, manufactured, tested, advertised,
19 promoted, marketed sold, and distributed Invokana®, that was used by Plaintiff.

20
21 33. Invokana® was expected to and did reach the Plaintiff without substantial
22 change in the condition in which it was produced, manufactured, sold, distributed, and
23 marketed by the Defendants.

24
25 34. The Invokana® designed, researched, manufactured, tested, advertised,
26 promoted, marketed, sold and distributed by Defendants was defective in design or
27 formulation in that, when it left the hands of the manufacturer and/or suppliers, the
28

1 foreseeable risks exceeded the benefits associated with its design or formulation, it was
2 more dangerous than an ordinary consumer would expect, and it was unreasonably
3 dangerous to its intended users.

4
5 35. Invokana® as designed, researched, manufactured, tested, advertised,
6 promoted, marketed, sold and distributed by Defendants constitutes a defective product
7 which created an unreasonable risk to the health of consumers and to Plaintiff in
8 particular; and Defendants are therefore strictly liable for the injuries sustained by
9 Plaintiff.
10 Plaintiff.

11 36. Plaintiff could not, by the exercise of reasonable care, have discovered
12 Invokana's® defects herein alleged and perceived its danger.
13

14 37. Defendants knew, or should have known that at all times herein
15 mentioned, their Invokana® was in a defective condition, and was and is inherently
16 dangerous and unsafe.
17

18 38. Plaintiff's use of Invokana® was appropriate for the purpose for which it
19 was designed, marketed and distributed, and was in the manner normally intended,
20 namely to help lower blood sugar in adults with Type 2 Diabetes.
21

22 39. The Invokana® designed, researched, manufactured, tested, advertised,
23 promoted, marketed, sold and distributed by Defendants was defective due to
24 inadequate warnings or instructions, as they knew or should have known it created an
25 unreasonable risk of serious and dangerous side effects including, increased risk of
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1 kidney failure, as well as other severe consequences which are permanent and lasting in
2 nature and about which the Defendants failed to warn.

3 40. Invokana® was defective due to Defendants' inadequate post-
4 marketing surveillance and/or their inadequate warnings because after Defendants knew
5 or should have known of the risks of serious side effects including the increased risk of
6 kidney failure, as well as other severe and permanent health consequences from
7 Invokana®. They failed to provide adequate warnings to users or consumers of the
8 product, and continued to improperly advertise, market, and/or promote their product,
9 Invokana®.
10
11

12 41. Defendants are strictly liable for Plaintiff's injuries in the following ways:
13 a) Invokana® as designed, manufactured, sold and supplied by the Defendants, was
14 defectively designed and placed into the stream of commerce in a defective and
15 unreasonably dangerous condition; b) Defendants failed to properly market, design,
16 manufacture, distribute, supply and sell Invokana®; c) Defendants failed to warn and
17 place adequate warnings and instructions on Invokana®; and d) Defendants failed to
18 adequately test Invokana®.
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22 42. As a direct and proximate result of the foregoing, Defendants are strictly
23 liable to Plaintiff for the manufacturing, marketing, promoting, distribution, and selling
24 of a defective product, Invokana®.
25
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1 43. Defendants' defective design, manufacturing defect, and inadequate
2 warnings regarding Invokana® were acts that amount to willful, wanton, and/or
3 reckless conduct by Defendants, warranting an award of punitive damages.
4

5 44. Plaintiff has suffered, and will continue to suffer, injury, emotional
6 distress, harm and economic loss as alleged herein.
7

8 WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter
9 judgment against Defendants jointly and severally for damages, together with costs of
10 this action, and demands trial by jury of all issues raised herein.
11

12 **SECOND CAUSE OF ACTION**

13 **[Design Defect]**

14 45. Plaintiff incorporates by reference each and every paragraph of this
15 Complaint as if fully set forth herein and further alleges as follows:
16

17 46. Defendants were engaged in the business of designing, manufacturing,
18 testing, marketing, distributing and selling Invokana® for the sale to, and use by,
19 members of the public. The Invokana® manufactured and designed by Defendants
20 reached Plaintiff without substantial change and was ingested as directed. The
21 Invokana® was defective and unreasonably dangerous when it entered into the stream
22 of commerce and when used by Plaintiff.
23

24 47. Invokana® is defective in its design, because as designed it is capable of
25 causing serious personal injuries such as those suffered by Plaintiff.
26
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1 48. Invokana® contains defects in its design which render the drug dangerous
2 to consumers, such and Plaintiff, when used as intended or as reasonably foreseeable by
3 Defendants. The defects render Invokana® more dangerous than other drugs which are
4 designed to treat Type 2 Diabetes and cause an unreasonably increased risk of injury,
5 including, but not limited to, life-threatening kidney complications.
6

7 49. Because of the design defects, Invokana® was and is unreasonably
8 dangerous.
9

10 50. As a direct and proximate result of the defective and unreasonably
11 dangerous Invokana® product, Plaintiff suffered injuries and damages, including acute
12 kidney failure.
13

14 WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter
15 judgment against Defendants jointly and severally for damages, together with costs of
16 this action, and demands trial by jury of all issues raised herein.
17

18 **THIRD CAUSE OF ACTION**

19 **[Failure to Warn]**
20

21 51. Plaintiff incorporates by reference each and every paragraph of this
22 Complaint as if fully set forth herein and further alleges as follows:
23

24 52. The Invokana® ingested by Plaintiff was defective and unreasonably
25 dangerous when it left the possession of the Defendants because they provided
26 warnings which were inadequate and insufficient to alert physicians or consumers to the
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28

1 dangerous risks associated with the product, including, without limitation, heart attack,
2 stroke, kidney failure, and diabetic ketoacidosis.

3 53. The Invokana® ingested by Plaintiff was used for its intended purpose.

4
5 54. Defendants knew or reasonably should have known that the warnings
6 provided to users of Invokana® regarding the risks associated with its use were
7 incorrect and misleading because they failed to include sufficiently warn of significant
8 possible side effects associated with its use and the comparative severity, incidence, and
9 duration of such adverse effects.
10

11 55. Plaintiff did not have the same knowledge as Defendants about these
12 significant possible side effects and no adequate warning or other clinically relevant
13 information and data was communicated to Plaintiff or to Plaintiff's physician.
14

15 56. The Defendants had a continuing duty to warn Plaintiff or her doctors of the
16 dangers associated with Invokana®.
17

18 57. Despite the fact that Defendants knew or should have known that
19 Invokana® caused unreasonable and dangerous side effects, they continued to promote
20 and market Invokana® without stating that there were safer, equally effective
21 alternative drug products and/or providing adequate clinically relevant information and
22 data.
23

24
25 58. As a direct and proximate result of the Defendants' failure to warn,
26 Plaintiff has sustained serious and permanent injuries, including acute kidney failure.
27
28

1 WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter
2 judgment against Defendants, jointly and severally for damages, together with costs of
3 this action, and demands trial by jury of all issues raised herein.
4

5 **FOURTH CAUSE OF ACTION**

6 **[Negligence]**

7 59. Plaintiff incorporates by reference each and every paragraph of this
8 Complaint as if fully set forth herein and further alleges as follows:
9

10 60. Defendants owed a duty to the general public, and specifically to
11 Plaintiff, to exercise reasonable care in the design, study, development, manufacture,
12 promotion, sale, marketing, labeling, and distribution of Invokana®.
13

14 61. Defendants failed to exercise reasonable care in the design of Invokana®
15 because as designed, it is capable of causing serious adverse reactions such as those
16 suffered by Plaintiff. Defendants also failed to exercise reasonable care in the
17 marketing and labeling of Invokana® because they failed to warn, that as designed,
18 Invokana® was capable of causing serious adverse reactions such as those suffered by
19 Plaintiff.
20
21

22 62. Defendants were negligent in, but not limited to, designing, manufacturing
23 and selling Invokana® by, *inter alia*, a) failing to use due care in developing, testing,
24 designing and manufacturing Invokana® to avoid the aforementioned risks; b) failing to
25 accompany Invokana® with proper or adequate warnings, or labeling regarding adverse
26 risks associated with its use; c) designing, manufacturing and placing into the stream of
27
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1 commerce a product which was unreasonably dangerous for its reasonably foreseeable
2 use, which Defendants knew or should have known could cause injury to Plaintiff; d)
3 failing to remove Invokana® from the market when Defendants knew or should have
4 known of the likelihood of serious side effects and injury to its users; e) failing to
5 adequately warns users, consumers and physicians about the severity, scope and
6 likelihood of serious complications, including, but not limited to, heart attack, stroke,
7 kidney failure, and diabetic ketoacidosis while taking Invokana®; and f) representing to
8 physicians that Invokana® was safe and effective for use.
9
10

11 63. As a direct and proximate result of the foregoing negligence of Defendants,
12 Plaintiff has suffered pain, hospitalization, and surgery.
13

14 64. Defendants' failure to exercise reasonable care in the design, study,
15 development, manufacture, promotion, sale and marketing of Invokana® was a
16 proximate cause of Plaintiff's injuries.
17

18 WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter
19 judgment against Defendants, jointly and severally for damages, together with costs of
20 this action, and demands trial by jury of all issues raised herein.
21

22 **FIFTH CAUSE OF ACTION**

23 **[Breach of Express Warranty]**
24

25 65. Plaintiff incorporates by reference each and every paragraph of this
26 Complaint as if fully set forth herein and further alleges as follows:
27
28

1 66. Defendants researched, developed, designed, tested, manufactured,
2 distributed, marketed, sold and/or otherwise released into the stream of commerce
3 Invokana®, and directly marketed the product to consumers and healthcare
4 professionals, including Plaintiff.
5

6 67. Invokana® materially failed to conform to those representations made by
7 Defendants in package inserts, and otherwise, concerning its properties and effects.
8 Such failures by Defendants constituted a material breach of express warranties made,
9 directly or indirectly, concerning Invokana® sold to Plaintiff.
10

11 68. As a direct, foreseeable and proximate result of Defendants' breaches of
12 express warranties, Plaintiff suffered serious injury, when Plaintiff's physician, in
13 reasonable reliance upon such express warranties, prescribed Invokana® for Plaintiff.
14

15 69. As a direct and proximate result of Defendants' breach of express
16 warranties, Plaintiff was exposed to Invokana®, and Plaintiff suffered and continues to
17 suffer from the injuries and damages described in this complaint
18

19 WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter
20 judgment against Defendants, jointly and severally for damages, together with costs of
21 this action, and demands trial by jury of all issues raised herein.
22

23 **SIXTH CAUSE OF ACTION**

24 **[Breach of Implied Warranty]**

25 70. Plaintiff incorporates by reference each and every paragraph of this
26 Complaint as if fully set forth herein and further alleges as follows:
27
28

1 71. Defendants impliedly warranted to Plaintiff and all others similarly
2 situated that Invokana® was reasonably fit for its intended use and it was designed,
3 manufactured and sold in accordance with good design, engineering and industry
4 standards.

5
6 72. Invokana® was defective in its manufacture or design and was therefore
7 not fit for its intended use, and was not designed, manufactured or sold in accordance
8 with good design, engineering and industry standards.

9
10 73. Defendants breached the above warranties in that the Invokana® was: a)
11 defective as set forth above, b) was not fit for its intended use, and c) was not designed,
12 manufactured or sold in accordance with good design, engineering and industry
13 standards.

14
15 74. As a direct and proximate result of the foregoing breaches of implied
16 warranties, Plaintiff suffered severe injuries, when Plaintiff ingested Invokana® in
17 reasonable reliance upon the implied warranties.

18
19 75. Plaintiff's losses and injuries are permanent and continuing.

20
21 WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter
22 judgment against Defendants, jointly and severally for damages, together with costs of
23 this action, and demands trial by jury of all issues raised herein.
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SEVENTH CAUSE OF ACTION

[Fraud]

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2
3 76. Plaintiff incorporates by reference each and every paragraph of this
4
5 Complaint as if fully set forth herein and further alleges as follows:

6 77. Defendants owed a duty to provide accurate and complete information
7
8 regarding Invokana®.

9 78. Defendants knew or should have known that Invokana® caused serious
10 complications, including, but not limited to kidney failure.

11 79. Despite their knowledge, Defendants omitted material facts in
12
13 advertisements and other materials available to the public, including Plaintiff and
14 Plaintiff's physician, concerning the safety of Invokana®.

15 80. Defendants intentionally made false and/or misleading representations of
16
17 material facts, and omitted material facts from the consuming public, including Plaintiff
18 and Plaintiff's physician, concerning the safety of Invokana®.

19 81. Defendants' marketing and sale of Invokana® continues to place
20
21 consumers of Invokana® at risk for serious injuries.

22 82. Defendants' statements and omissions were made with the intent that
23
24 members of the public, including Plaintiff and Plaintiff's physician, would rely on
25 them.

26 83. As a direct and proximate result of the Defendants' acts of fraud, Plaintiff
27
28 suffered serious injuries including, but not limited to kidney failure.

1 WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter
2 judgment against Defendants, jointly and severally for damages, together with costs of
3 this action, and demands trial by jury of all issues raised herein.
4

5 **EIGHTH CAUSE OF ACTION**

6 **[Misrepresentation]**

7 84. Plaintiff incorporates by reference each and every paragraph of this
8 Complaint as if fully set forth herein and further alleges as follows:
9

10 85. The Defendants falsely and fraudulently represented to the medical and
11 healthcare community and to the Plaintiff, the FDA, and the public in general, that
12 Invokana® had been tested and was found to be safe and/or effective. These
13 representations were, in fact, false.
14

15 86. When these representations were made, Defendants either knew they were
16 false or willfully, wantonly and recklessly disregarded whether they were true.
17

18 87. Defendants made these representations with the intent of defrauding and
19 deceiving the Plaintiff, the public in general, and the medical and healthcare
20 community, and were intended to induce the medical and healthcare community in
21 particular, to recommend, prescribe, dispense and the general public to purchase
22 Invokana®, both of which evinced a reckless, willful, depraved indifference to the
23 health, safety and welfare of the Plaintiff and the general public.
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1 88. At the time the aforesaid representations were made by the Defendants
2 and at the time Plaintiff used Invokana®, Plaintiff was unaware of the falsity of said
3 representations and reasonably believed them to be true.
4

5 89. In reliance upon these representations, Plaintiff was induced to and did use
6 Invokana®, thereby sustaining severe and permanent personal injuries, and/or being at
7 an increased risk of sustaining severe and permanent personal injuries in the future.
8

9 90. Defendants knew and were aware or should have been aware that
10 Invokana® had not been sufficiently tested, was defective in nature, and/or that it lacked
11 adequate and/or sufficient warnings.
12

13 91. Defendants knew or should have known that Invokana® had a potential
14 to, could, and would cause severe and grievous injury to its users, and that it was
15 inherently dangerous in a manner that exceeded any warnings.
16

17 92. Defendants acted fraudulently, wantonly, and maliciously to the
18 detriment of the Plaintiff and the general public. As a direct and proximate result of one
19 or more of these wrongful acts or omissions of the Defendants, Plaintiff was caused to
20 suffer serious and dangerous side effects including kidney failure, as well as other
21 severe and personal injuries which are permanent and lasting in nature, physical pain
22 and mental anguish, including diminished enjoyment of life, as well as the need for
23 lifelong medical treatment, monitoring and/or medications.
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1 WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter
2 judgment against Defendants, jointly and severally for damages, together with costs of
3 this action, and demands trial by jury of all issues raised herein.
4

5 **NINTH CAUSE OF ACTION**

6 **[Fraudulent Concealment]**

7 93. Plaintiff incorporates by reference each and every paragraph of this
8 Complaint as if fully set forth herein and further alleges as follows:
9

10 94. At all times during the course of dealing between Defendants, Plaintiff,
11 Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety
12 of Invokana® for its intended use.
13

14 95. Defendants knew or were reckless in not knowing that its representations
15 were false.
16

17 96. Defendants fraudulently concealed and intentionally omitted that
18 Invokana® was not as safe as other drugs for the treatment of Type 2 Diabetes; and that
19 the risks of serious complications with Invokana® were higher than those with other
20 forms of treatment for Type 2 Diabetes.
21

22 97. Defendants were under a duty to disclose to Plaintiff, Plaintiff's
23 physicians, hospitals, healthcare providers, and/or the FDA the defective nature of
24 Invokana®, including but not limited to the heightened risks of kidney failure.
25

26 98. Defendants had sole access to material facts concerning the defective
27 nature of the product and its propensity to cause serious and dangerous side effects.
28

1 99. Defendants' concealment and omissions of material facts concerning the
2 safety of Invokana® was made purposefully, willfully, wantonly, and/or recklessly, to
3 mislead Plaintiff, Plaintiff's physicians, hospitals and healthcare providers inducing
4 their reliance on the misrepresentations, their continued use of Invokana®, and to cause
5 them to purchase, prescribe, dispense and/or use Invokana®.
6

7 100. Defendants knew that Plaintiff, and Plaintiff's physicians, hospitals,
8 healthcare providers, and/or the FDA had no way to determine the existence of
9 Defendants' concealment and omissions.
10

11 101. As a direct and proximate result of one or more of the wrongful
12 concealment or omissions of the Defendants, Plaintiff was caused to suffer serious and
13 dangerous side effects including kidney failure, as well as other severe and personal
14 injuries which are permanent and lasting in nature, physical pain and mental anguish,
15 including diminished enjoyment of life, as well as the need for lifelong medical
16 treatment, monitoring and/or medications.
17
18

19 WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter
20 judgment against Defendants, jointly and severally for damages, together with costs of
21 this action, and demands trial by jury of all issues raised herein.
22

23 **TENTH CAUSE OF ACTION**

24 **[Negligent Misrepresentation]**

25
26 102. Plaintiff incorporates by reference each and every paragraph of this
27 Complaint as if fully set forth herein and further alleges as follows:
28

1 103. Defendants had a duty to accurately and truthfully represent to the
2 medical and healthcare community, the Plaintiff and the public, that Invokana® had not
3 been adequately tested and found to be safe and effective. Defendants knew, or
4 should have known, that there were dangerous side effects resulting from the use of
5 Invokana®.
6

7 104. Defendants failed to exercise ordinary care in making representations
8 concerning Invokana® while they were involved its manufacture, sale, testing, quality
9 assurance, quality control, and distribution in interstate commerce, because they
10 negligently misrepresented its unreasonably high risk of dangerous, adverse side
11 effects, including kidney failure and diabetic ketoacidosis.
12
13

14 105. Defendants concealed material information, including adverse information
15 regarding the safety and effectiveness of Invokana®.
16

17 106. Defendants misrepresented their insufficiency of testing which, if properly
18 performed, would have shown that Invokana® had serious side effects.
19

20 107. As a foreseeable, direct, and proximate result of the negligent
21 misrepresentation of Defendants as set forth herein, Plaintiff suffered serious injuries,
22 including acute renal failure.
23

24 WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter
25 judgment against Defendants, jointly and severally for damages, together with costs of
26 this action, and demands trial by jury of all issues raised herein.
27
28

ELEVENTH CAUSE OF ACTION

1
2 **[Violation of the Fair Business Practices Act of 1975 - O.C.G.A. § 10-1-390, *et seq.*]**

3 108. Plaintiff incorporates by reference each and every paragraph of this
4 Complaint as if fully set forth herein.
5

6 109. Plaintiff pleads this Count in the broadest sense available under the law, to
7 include pleading same pursuant to all substantive law that applies to this case, as may
8 be determined by choice of law principles, regardless of whether arising under statute
9 and/or common law.
10

11 110. Plaintiff is a “consumer” under the Fair Business Practices Act of 1975.

12
13 111. Invokana® is merchandise or goods under the Fair Business Practices Act
14 of 1975.

15 112. Defendants are merchants engaged in “consumer acts or practices” and
16 “consumer transactions” in “trade or commerce” under the Fair Business Practices Act
17 of 1975.
18

19 113. Defendants’ sale of Invokana® constitutes an unfair and/or deceptive trade
20 practice in violation of O.C.G.A. § 10-1-390, *et seq.* in that Defendants advertised and
21 promised that Invokana® was of a particular standard, quality, or grade when in fact it
22 was not.
23

24
25 114. As a result of the foregoing acts and omissions, Plaintiff was caused to
26 suffer serious and dangerous side effects including but not limited to, acute renal
27 failure, as well as other severe and personal injuries which are permanent and lasting in
28

1 nature, physical pain and mental anguish, diminished enjoyment of life, and financial
2 expenses for hospitalization and medical care.

3 115. Plaintiff used Invokana® and suffered ascertainable losses as a result of
4
5 Defendants' actions in violation of the consumer protection laws.

6 116. Defendants violated consumer protection laws through their use of false
7
8 and misleading representations or omissions of material fact relating to the safety of
9 Invokana®.

10 117. Defendants uniformly communicated the purported benefits of
11
12 Invokana® while failing to disclose the serious and dangerous side effects related to
13
14 the use of Invokana® and its safety, its efficacy, its usefulness. Defendants made these
15
16 misrepresentations to physicians, the medical community at large, and to patients and
17 consumers, such as Plaintiff.

18 118. Defendants' conduct was also impermissible and illegal in that it created a
19
20 likelihood of confusion and misunderstanding, because they misleadingly, falsely,
21
22 and/or deceptively misrepresented and omitted numerous material facts regarding,
23
24 among other things, the utility, benefits, costs, safety, efficacy, and advantages of
25
26 Invokana®.

27 119. As a result of the foregoing acts and omissions, Plaintiff has suffered and
28
29 incurred damages, including medical expenses and other economic and non-economic
30
31 damages.

1 WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter
2 judgment against Defendants, jointly and severally for damages, together with costs of
3 this action, and demands trial by jury of all issues raised herein.
4

5 **TWELFTH CAUSE OF ACTION**

6 **[Punitive Damages]**

7 120. Plaintiff incorporates by reference each and every paragraph of this
8 Complaint as if fully set forth herein and further alleges as follows:
9

10 121. At all times relevant, Defendants knew or were recklessly indifferent in
11 not knowing that Invokana® was inherently dangerous with respect to the risk of kidney
12 failure.
13

14 122. Defendants misrepresented facts concerning the safety of Invokana® by
15 making false representations about and concealing information regarding Invokana®.
16 Defendants misrepresented and downplayed the risks of serious injuries including
17 kidney failure and diabetic ketoacidosis associated with the use of Invokana®.
18

19 123. Defendants' actions were performed intentionally, willfully, wantonly,
20 and/or purposefully on Plaintiff.
21

22 124. Defendants continued to promote the safety of Invokana®, even after they
23 knew of the risks associated with it.
24

25 125. Defendants' conduct was committed with wanton and willful disregard
26 for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to
27
28

1 punitive damages in an amount appropriate to punish the Defendants and deter them
2 from similar conduct in the future.

3 WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter
4 judgment against Defendants, jointly and severally for damages, together with costs of
5 this action, and demands trial by jury of all issues raised herein.
6

7
8 **PRAYER FOR RELIEF**

9 WHEREFORE, Plaintiff respectfully demands judgment against Defendants for
10 damages allowable by law against Defendants together with interest, costs and
11 attorney's fees as well as all such other relief as the Court may deem proper.
12

13 **DEMAND FOR A JURY TRIAL**

14 Plaintiff respectfully demands a trial by jury on all Counts and as to all issues.

15 RESPECTFULLY SUBMITTED,

16
17 **HEARD ROBINS CLOUD LLP**

18
19 Dated: February 29, 2016

By: /s/ Olga Viner

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