

Melinda Davis Nokes, Bar No. 167787

WEITZ & LUXENBERG, P.C.

1880 Century Park East

Suite 700

Los Angeles, CA 90067

Tel: (310) 247-0921

Fax: (310) 786-9927

Email: mnokes@weitzlux.com

Attorney for Plaintiffs

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA**

BETTY BARKER and SCOTT BARKER,

Plaintiffs,

v.

BRISTOL-MYERS SQUIBB CO.,
ASTRAZENECA LP, and ASTRAZENECA
PHARMACEUTICALS LP and DOES 1 – 100,

Defendants.

**COMPLAINT AND DEMAND
FOR JURY TRIAL**

Civil Case No.:

CIVIL COMPLAINT

Plaintiff BETTY BARKER and Plaintiff-Spouse SCOTT BARKER, by and through their undersigned counsel, brings this action seeking judgment against BRISTOL-MYERS SQUIBB CO., ASTRAZENECA LP, and ASTRAZENECA PHARMACEUTICALS LP, (collectively, Defendants) for injuries and damages caused by Plaintiff's ingestion of FARXIGA, a type 2 diabetes drug in the *gliflozin* class. Plaintiffs allege that at all times hereinafter mentioned:

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

NATURE OF ACTION

1. Defendants, directly or through their agents, apparent agents, servants or employees, designed, manufactured, marketed, advertised, licensed, distributed, and/or sold FARXIGA for the treatment of diabetes.

2. Defendants concealed their knowledge of FARXIGA's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

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

4. After beginning treatment with FARXIGA, and as a direct and proximate result of Defendants' actions and inaction, Plaintiff Betty Barker developed diabetic ketoacidosis. Plaintiff's ingestion of the unreasonably dangerous drug FARXIGA has caused and will continue to cause injury and damage to Plaintiff.

5. Plaintiffs bring this action for personal injuries suffered as a proximate result of being prescribed and ingesting FARXIGA. Plaintiffs accordingly seek compensatory and punitive damages, and all other available remedies as a result of injuries caused by FARXIGA.

PARTIES

6. At all times relevant hereto, Plaintiffs were residents of Bakersfield, California, located in Kern County. Plaintiff Betty Barker ingested and was physically harmed by FARXIGA. Plaintiff Scott Barker was and is her spouse and sues for derivative claims from loss of consortium herein. "Plaintiff," when used in the singular, refers to plaintiff Betty Barker, the plaintiff that ingested FARXIGA and was physically harmed.

7. Defendant BMS is a Delaware corporation with its principal place of business at 345 Park Avenue, New York, New York. BMS is engaged in the business of researching,

1 developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and
2 introducing into interstate commerce, either directly or indirectly through third parties or related
3 entities, its products, including the prescription drug FARXIGA.

4
5 8. Defendant AstraZeneca LP is a Delaware corporation with its principal place of
6 business at 1209 Orange Street, Wilmington, Delaware. AstraZeneca LP is a wholly owned
7 subsidiary of defendant AstraZeneca PLC. AstraZeneca LP is engaged in the business of
8 researching, developing, designing, licensing, manufacturing, distributing, supplying, selling
9 marketing, and introducing into interstate commerce, either directly or indirectly through third
10 parties or related entities, its products, including the prescription drug FARXIGA.

11
12 9. Defendant AstraZeneca Pharmaceuticals LP is a Delaware corporation with its
13 principal place of business at 1209 Orange Street, Wilmington, Delaware. AstraZeneca
14 Pharmaceuticals LP is a wholly owned subsidiary of Defendant AstraZeneca PLC. AstraZeneca
15 Pharmaceuticals LP is engaged in the business of researching, developing, designing, licensing,
16 manufacturing, distributing, supplying, selling marketing, and introducing into interstate
17 commerce, either directly or indirectly through third parties or related entities, its products,
18 including the prescription drug FARXIGA.

19
20 10. Defendants are responsible for designing, developing, manufacturing, marketing,
21 distributing, selling and otherwise introducing FARXIGA into the stream of commerce.

22 **JURISDICTION AND VENUE**

23 11. This Court has subject matter jurisdiction over this action pursuant to 28 USC §
24 1332 because the amount in controversy exceeds \$75,000, exclusive of interest and costs, and
25 because Defendants are incorporated and have their principal places of business in states other
26 than the state in which Plaintiffs are residents and citizens.

1 12. At all times relevant to this action, Defendants engaged, either directly or
2 indirectly, in the business of marketing, promoting, distributing, and selling prescription drug
3 products, including FARXIGA, within the States of California, New York and throughout the
4 country, with a reasonable expectation that the products would be used or consumed in these
5 states, and thus regularly solicited or transacted business in these states.

6 13. At all times relevant to this action, Defendants were engaged in disseminating
7 inaccurate, false, and misleading information about FARXIGA to consumers, including Plaintiff,
8 and to health care professionals in the State of California, with a reasonable expectation that such
9 information would be used and relied upon by consumers and health care professionals
10 throughout the States of California and New York.

11 14. Defendants engaged in substantial business activities in the States of California
12 and New York. At all relevant times, Defendants transacted, solicited, and conducted business in
13 California and New York through their employees, agents, and/or sales representatives and
14 derived substantial revenue from such business.
15

16 15. Defendants conducted meetings, telephone calls, conference calls, webinars, and
17 email communications between the respective companies and also their consultants and agents
18 involving the design, development regulatory actions, marketing and distribution of the drug
19 Farxiga in the State of New York.
20

21 16. Defendant BMS' principal place of business is located at 345 Park Avenue, New
22 York, New York.
23

24 17. Defendants, by its employees or agents attended meetings at BMS' corporate
25 headquarters regarding the research, and/or development, and/or FDA approval, and/or
26 marketing of Farxiga.

27 18. At all relevant times relevant to this action, Defendants were joint venturers and
28 worked together to achieve the common business purpose of selling Farxiga.

1 Bristol-Myers Squibb \$2.7 billion of initial consideration. AstraZeneca has also agreed to
2 pay up to \$1.4 billion in regulatory, launch and sales payments, and various sales-related
3 royalty payments up until 2025, \$600 million of which relates to the approval of Farxiga in
4 the US.

5 23. Defendants' acts in their corporate alliance to market and promote FARXIGA
6 acts took place, in substantial part, in New York. Each Defendant has continuously and
7 systematically entered into transactions, in this District and throughout the United States. The
8 clinical trials referenced in the press releases described above were conducted in numerous
9 locations including the State and City of New York.

11 24. As a *gliflozin* drug, FARXIGA's active ingredient is *dapagliflozin propanediol*.

12 25. SGLT2 inhibitors, including FARXIGA, are indicated for only one use: lowering
13 blood glucose in adults with type 2 diabetes.

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

19 27. Though FARXIGA is indicated for only improved glycemic control in type 2
20 adult diabetics, in order to increase market share Defendants have marketed and continue to
21 market FARXIGA to both healthcare professionals and direct to consumers for off label
22 purposes, including but not limited to weight loss and reduced blood pressure.

24 28. Since FARXIGA's release, the FDA has received a significant number of reports
25 of diabetic ketoacidosis among users of these drugs.

26 29. An analysis of the FDA adverse event database shows that patients taking one of
27 the SGLT2 inhibitors, including FARXIGA, are twice as likely to report ketoacidosis and/or
28 severe kidney damage than those taking non-SGLT2 diabetes drugs to treat diabetes.

1 30. Despite Defendants' knowledge of the increased risk of severe injury among users
2 of FARXIGA, they did not warn patients but instead continued to defend FARXIGA, mislead
3 physicians and the public, and minimize unfavorable findings.

4 31. Consumers, including Plaintiff, who have used FARXIGA for treatment of
5 diabetes, have several alternative safer products available to treat the conditions.

6 32. Defendants knew of the significant risk of diabetic ketoacidosis and kidney
7 damage caused by ingestion of FARXIGA. However, Defendants did not adequately and
8 sufficiently warn consumers, including Plaintiff, or the medical community of the severity of
9 such risks.
10

11 33. To the contrary, Defendants conducted nationwide sales and marketing
12 campaigns to promote FARXIGA, and they willfully deceived Plaintiff, Plaintiff's health care
13 professionals, the medical community, and the general public as to the health risks and
14 consequences of the use of FARXIGA.
15

16 34. As a direct result of Defendants' above described conduct, Plaintiff was
17 prescribed and began taking FARXIGA to treat type II diabetes.

18 35. Plaintiff ingested and used FARXIGA as prescribed and in a foreseeable manner.

19 36. The FARXIGA used by Plaintiff was provided in a condition substantially the
20 same as the condition in which it was manufactured and sold.

21 37. Plaintiff agreed to initiate treatment with FARXIGA in an effort to reduce blood
22 sugar and hemoglobin A1c levels. In doing so, Plaintiff relied on claims made by Defendants
23 that FARXIGA was safe and effective for the treatment of diabetes.
24

25 38. Instead, FARXIGA can cause severe injuries, including diabetic ketoacidosis and
26 acute kidney failure.

27 39. Plaintiff was prescribed, purchased, ingested, and exposed to FARXIGA in Kern
28 County, California. As a result of ingesting FARXIGA, Plaintiff suffered personal and economic

1 injuries, which developed and occurred in Kern County, California and Plaintiff sought and
2 received treatment for the effects attendant thereto.

3 40. Plaintiff began taking FARXIGA on or about March 11, 2015 at the age of fifty-
4 six years old.

5 41. On July 2, 2015, approximately four months after beginning treatment with
6 FARXIGA, and as a direct and proximate result thereof, Plaintiff Betty Barker suffered diabetic
7 ketoacidosis and dehydration and was admitted to Mercy Hospital Southwest.

8 42. Plaintiff was hospitalized until July 3, 2015 and was told to discontinue
9 FARXIGA upon discharge.

10 43. Defendants knew or should have known the risks associated with using
11 FARXIGA, including the risk of developing diabetic ketoacidosis and dehydration.

12 44. While Defendants did not warn about the risks of DKA, on May 15, 2015, the
13 FDA issued a safety announcement covering the SGLT2 inhibitor class, warning about the risk
14 of diabetic ketoacidosis and advising that the FDA would continue to evaluate the safety issue.
15

16 45. As part of their continued evaluation, on December 4, 2015 the FDA issued a new
17 safety communication disclosing they had found 73 adverse events reported between March
18 2013 and May 2015 that required hospitalization due to ketoacidosis related to SGLT2 inhibitors.
19 The FDA noted adverse event reports “include only reports submitted to FDA, so there are likely
20 additional cases about which we are unaware.”
21

22 46. In light of the data disclosed in the December 4, 2015 safety communication, the
23 FDA changed the label for FARXIGA and the other SGLT2 inhibitors to include a warning
24 “about the risks of too much acid in the blood” and urged patients taking SGLT2 inhibitors to
25 stop taking the drug and seek immediate medical attention if they have any symptoms of
26 ketoacidosis.
27
28

1 47. As part of their December 4, 2015 Safety Communication and label change, the
2 FDA further required all manufacturers of SGLT2 inhibitors, including Defendants, to conduct a
3 postmarketing study wherein the manufacturers would analyze spontaneous postmarketing
4 reports of ketoacidosis in patients treated with SGLT2 inhibitors, including specialized follow-up
5 to collect additional information, over a 5-year period.

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

- 8
- 9 a. Hall, *Hall - 2015 -Case report of Ketoacidosis associated with Canagliflozin (Invokana).pdf*, March 5-8 ENDO CONFERENCE(2015).
 - 10 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).
 - 11 c. Julia Hine et al., *SGLT inhibition and euglycaemic diabetic ketoacidosis*, THE LANCET DIABETES & ENDOCRINOLOGY (2015).
 - 12 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).
 - 13 e. Anne L. Peters et al., *Euglycemic Diabetic Ketoacidosis: A Potential Complication of Treatment With Sodium-Glucose Cotransporter 2 Inhibition*, DIABETES CARE dc150843 (2015).
 - 14 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).

15 49. Along with the above described ketone related injuries, SGLT-2 inhibitors, and
16 FARXIGA in particular, also dramatically increase the likelihood of a patient developing kidney
17 failure.

18 50. FARXIGA by its very mechanism of action causes dehydration and osmotic
19 diuresis. Osmotic diuresis is the increase of urination rate caused by the presence of certain

1 substances in the small tubes of the kidneys. The excretion occurs when substances such as
2 glucose enter the kidney tubules and cannot be reabsorbed.

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

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

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

12 54. FARXIGA causes osmotic diuresis due to its very mechanism of action, by
13 forcing the kidneys to work harder and push more glucose through their tubules than the kidneys
14 are intended to do. This continued heightened state the kidneys are put in when a patient is on
15 FARXIGA makes kidney injury a higher likelihood, even for those with normal kidney function
16 at the beginning of FARXIGA therapy.

17 55. On June 14, 2016, the FDA issued a drug safety communication about
18 dapagliflozin, warning that FARXIGA can cause acute kidney injury. The drug safety
19 communication linked 28 patients with acute kidney injury and use of FARXIGA, with
20 hospitalization, intensive care unit admission, and death resulting from the injury in some cases.

21 56. Defendant was aware of the potential for FARXIGA and other drugs in the
22 SGLT-2 inhibitor class to cause kidney failure prior to FARXIGA's approval. For example,
23 Invokana's medical review, submitted with Invokana's NDA approval documents in 2012 and
24 publicly released nearly a year before Farxiga was approved, disclosed a nearly three-fold
25
26
27
28

1 increase (1.7% compared to 0.6%) in acute renal failure for patients taking the higher dose of
2 Invokana compared to those taking placebo, even in patients whose kidney function was normal.

3 57. Defendants knew that the likelihood of renal adverse effects such as acute renal
4 failure was nearly tripled in patients with near normal kidney function taking a drug in the same
5 class with a nearly identical mechanism of action and more than doubled in patients with even
6 moderately impaired kidney function.

7
8 58. At the time of the FDA Advisory Committee meeting, the FDA renal review
9 questioned Invokana's role in causing adverse events related to the kidneys, when it noted "the
10 long term renal consequences of canagliflozin's effect on the eGFR are unknown....It seems
11 prudent to assume that the volume depletion and corresponding reduction in eGFR ...places
12 patients at increased risk for clinically significant episodes of acute kidney injury." The idea that
13 FARXIGA, a drug with the same mechanism of action and a substantially similar chemical
14 makeup, could cause the same kinds of problems as Invokana should have occurred to a prudent
15 pharmaceutical manufacturer.

16
17 59. The development of Plaintiff's injuries was preventable and resulted directly from
18 Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and
19 publicize alarming safety signals, suppression of information revealing serious and life-
20 threatening risks, willful and wanton failure to provide adequate instructions, and willful
21 misrepresentations concerning the nature and safety of FARXIGA. Both Defendants' conduct
22 and the marketing and promotional defects complained of herein were substantial factors in
23 bringing about and exacerbating Plaintiff's injuries.

24
25 60. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants'
26 conduct.

27
28 61. At all times material hereto, Defendants, by and through their agents, servants and
employees, negligently, recklessly and carelessly marketed, distributed and sold FARXIGA

1 both off-label and without adequate instructions or warning of serious side effects and
2 unreasonably dangerous risks.

3 62. Plaintiff would not have used FARXIGA had Defendants properly disclosed the
4 risks associated with its drug. Thus, had the defendants properly disclosed the risks associated
5 with FARXIGA, Plaintiff would have avoided the risk of developing the injuries complained of
6 herein by not ingesting FARXIGA.

7 63. Defendants, through their affirmative misrepresentations and omissions, actively
8 concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with
9 taking FARXIGA.

10 64. As a result of Defendants' actions, Plaintiff and Plaintiff's prescribing physicians
11 were unaware, and could not reasonably have known or learned through reasonable diligence,
12 that Plaintiff had been exposed to the risks identified herein, and that those risks were the direct
13 and proximate result of Defendants' acts, omissions, and misrepresentations, both separately
14 and collectively.

15 65. As a direct and proximate result of Defendants' negligence, wrongful conduct,
16 Plaintiff suffered severe and permanent physical and emotional injuries. Plaintiff has endured
17 pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including
18 significant expenses for medical care and treatment which will continue in the future. Plaintiffs
19 seek actual, compensatory, and punitive damages from all Defendants.

20
21
22 **COUNT I**

23 **PRODUCT LIABILITY – FAILURE TO WARN (STRICT LIABILITY)**

24 66. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

25 67. Defendants have engaged in the business of designing, developing, researching,
26 testing, licensing, manufacturing, packaging, labeling, promoting, marketing, selling, and/or
27 distributing FARXIGA. Through that conduct, Defendants knowingly and intentionally placed
28

1 FARXIGA into the stream of commerce with full knowledge that it would reach consumers,
2 such as Plaintiff, who ingested the drug.

3 68. Defendants researched, developed, designed, tested, manufactured, inspected,
4 labeled, distributed, marketed, promoted, sold, and otherwise released FARXIGA into the stream
5 of commerce. In the course of same, Defendants directly advertised, marketed, and promoted
6 FARXIGA to health care professionals, Plaintiff, and other consumers, and therefore had a duty
7 to warn of the risks associated with the use of FARXIGA.
8

9 69. Defendants had a duty to warn Plaintiff and her doctors regarding the nature,
10 likelihood and severity of risks associated with FARXIGA, including but not limited to renal
11 failure, renal impairment and ketoacidosis.
12

13 70. Defendants knew, or in the exercise of reasonable care, should have known about
14 the risk of renal failure, renal impairment and ketoacidosis. In 2015, multiple *published* case
15 reports identified additional DKA events in patients treated with SGLT2 inhibitors. These
16 reports include:

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

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

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

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

28 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

1 *contraindication*, 33 THE AMERICAN JOURNAL OF EMERGENCY
2 MEDICINE 604.e3-604.e4 (2015).

3 71. FARXIGA, as supplied by Defendants, was defective due to inadequate warnings
4 or instructions. Defendants knew or should have known that the product created significant risks
5 of serious bodily harm to consumers, as alleged herein, and they failed to adequately warn
6 consumers and/or their health care professionals of such risks.

7 72. In addition to the above list of published cases of DKA, before May 2015,
8 Defendants also received multiple *internal* adverse event reports associating DKA and kidney
9 failure in patients taking FARXIGA.

10 73. Defendants failed to provide warnings or instructions that a manufacturer
11 exercising reasonable care would have provided concerning the risk of renal failure, renal
12 impairment and ketoacidosis in light of the above referenced published reports and *internally*
13 reported adverse events. Because of this, FARXIGA was defective and unsafe such that it was
14 unreasonably dangerous when it left Defendants' possession and/or control, was distributed by
15 the defendants, and when ingested by Plaintiff. The FARXIGA label did not contain warnings
16 sufficient to alert consumers, including Plaintiff, to the dangerous risks and reactions associated
17 with FARXIGA, including the development of Plaintiff's injuries.

18 74. This defect caused serious injury to Plaintiff, who used FARXIGA for its
19 intended purpose and in a reasonably anticipated manner.

20 75. At all times herein mentioned, Defendants had a duty to properly inspect,
21 package, label, market, promote, sell, distribute, supply, warn, and take such other steps as are
22 necessary to ensure FARXIGA did not cause users to suffer from unreasonable and dangerous
23 risks.

24 76. Defendants negligently and recklessly marketed, labeled, distributed, and
25 promoted FARXIGA.
26
27
28

1 77. Defendants had a continuing duty to warn Plaintiff of the dangers associated with
2 FARXIGA and failed to provide warnings or instructions that a manufacturer exercising
3 reasonable care would have provided concerning the risks of renal failure, renal impairment and
4 ketoacidosis.

5 78. Defendants, as sellers or distributors of prescription drugs, are held to the
6 knowledge of an expert in the field.

7 79. Defendants failed to update the warnings based on information received from
8 product surveillance and literature review after FARXIGA was first approved by the FDA and
9 marketed, sold and consumed in the United States and elsewhere.

10 80. A manufacturer exercising reasonable care would have updated its warnings on
11 the basis of the *published* and *internal* reports of injuries.

12 81. Plaintiff and her healthcare providers could not have discovered any defects in
13 FARXIGA through the exercise of reasonable care, and instead, Plaintiff relied upon the skill,
14 superior knowledge, and judgment of Defendants.

15 82. The warnings that were given by Defendants failed to properly warn physicians of
16 the risks associated with FARXIGA, subjecting Plaintiff to risks that exceed the benefits to the
17 Plaintiff. Plaintiff, individually and through her physicians, reasonably relied upon the skill,
18 superior knowledge and judgment of Defendants.

19 83. Defendants were aware of the probable consequences of the aforesaid conduct.
20 Despite the facts that the defendants knew or should have known that FARXIGA caused serious
21 injuries, they failed to exercise reasonable care to warn of the severity of the dangerous risks
22 associated with its use. The dangerous propensities of FARXIGA, as referenced above, were
23 known to Defendants, or scientifically knowable to them, through appropriate research and
24 testing by known methods, at the time they marketed, distributed, supplied, or sold the product.
25
26
27
28

1 Such information was not known to ordinary physicians who would be expected to prescribe the
2 drug for their patients.

3 84. FARXIGA, as supplied by Defendants, respectively, was unreasonably dangerous
4 when used by consumers, including Plaintiff, in a reasonably and intended manner without
5 knowledge of this risk of serious bodily harm.
6

7 85. Each of the defendants knew or should have known that the limited warnings
8 disseminated with FARXIGA were inadequate, but they failed to communicate adequate
9 information on the dangers and safe use of their product, taking into account the characteristics
10 of and the ordinary knowledge common to physicians who would be expected to prescribe the
11 drugs. In particular, Defendants failed to communicate warnings and instructions to doctors that
12 were appropriate and adequate to render their products safe for ordinary, intended, and
13 reasonably foreseeable uses, including the common, foreseeable, and intended use of the
14 products for treatment of diabetes.
15

16 86. Defendants communicated information to health care professionals that failed to
17 contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that
18 would enable health care professionals to prescribe FARXIGA safely for use by patients for the
19 purposes for which it is intended. In particular, the defendants:
20

21 a. disseminated information that was inaccurate, false, and
22 misleading, and which failed to communicate accurately or adequately the
23 comparative severity, duration, and extent of the risk of injuries with use
24 of FARXIGA;

25 b. continued to aggressively promote FARXIGA even after
26 Defendants knew or should have known of the unreasonable risks from
27 use;

28 c. failed to accompany their product with proper or adequate
warnings or labeling regarding adverse side effects and health risks
associated with the use of FARXIGA and the comparative severity of such
adverse effects;

d. failed to provide warnings, instructions or other information that
accurately reflected the symptoms, scope, and severity of the side effects

1 and health risks, including but not limited to those associated with the
2 severity of FARXIGA's effect on renal function and propensity to cause
ketoacidosis;

3 e. failed to adequately warn users, consumers, and physicians about
4 the need to monitor renal function in patients that do not already suffer
from renal impairment; and;

5 f. overwhelmed, downplayed, or otherwise suppressed, through
6 aggressive marketing and promotion, the risks associated with the use of
FARXIGA.

7 87. To this day, Defendants have failed to adequately and accurately warn of the true
8 risks of injuries associated with the use of FARXIGA.

9 88. Due to these deficiencies and inadequacies, FARXIGA was unreasonably
10 dangerous and defective as advertised, sold, labeled, and marketed by Defendants, respectively.

11 89. Had Plaintiff or her healthcare provider received adequate warnings regarding the
12 risks associated with the use of FARXIGA, Plaintiff would not have used it.

13 90. Defendants are liable to Plaintiffs for injuries caused by their negligent or willful
14 failure to provide adequate warnings or other clinically relevant information and data regarding
15 the appropriate use of FARXIGA and the risks associated.

16 91. As a foreseeable, direct, and proximate consequence of Defendants' actions,
17 omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related
18 health complications.
19

20 92. In addition, as a result of the injuries caused by Defendants, Plaintiff requires and
21 will continue to require healthcare and services. Plaintiffs have incurred and will continue to
22 incur medical and related expenses. Plaintiff also has suffered and will continue to suffer
23 diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of
24 premature death, aggravation of preexisting conditions, activation of latent conditions, and other
25 losses and damages. Plaintiff's direct medical losses and costs include physician care,
26
27
28

1 monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical
2 pain and suffering.

3 WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs'
4 favor for compensatory and punitive damages, together with interest, costs herein incurred,
5 attorneys' fees, and all such other and further relief as this Court deems just and proper.
6 Plaintiffs also demand that the issues contained herein be tried by a jury.
7

8 **COUNT II**

9 **NEGLIGENCE**

10 93. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

11 94. Defendants directly or indirectly caused FARXIGA, to be sold, distributed,
12 packaged, labeled, marketed, promoted, and/or used by Plaintiff.

13 95. Defendants owed Plaintiff and other consumers a duty to exercise reasonable care
14 when designing, manufacturing, marketing, advertising, distributing, and selling FARXIGA,
15 including the duty to take all reasonable steps necessary to ensure their drugs were not
16 unreasonably dangerous to its consumers and users, and to warn Plaintiff and other consumers of
17 the dangers associated with FARXIGA.
18

19 96. At all times material hereto, Defendants had actual knowledge, or in the
20 alternative, should have known through the exercise of reasonable and prudent care, of the
21 hazards and dangers of FARXIGA.
22

23 97. Defendants had a duty to disclose to health care professionals the causal
24 relationship or association of FARXIGA to the development of Plaintiff's injuries.

25 98. Defendants' duty of care owed to consumers, health care professionals, and
26 patients included providing accurate information concerning: (1) the clinical safety and
27
28

1 effectiveness profiles of FARXIGA, and (2) appropriate, complete, and accurate warnings
2 concerning the adverse effects of FARXIGA, including the injuries suffered by Plaintiff.

3 99. During the time that Defendants designed, manufactured, packaged, labeled,
4 promoted, distributed, and/or sold FARXIGA, they knew, or in the exercise of reasonable care
5 should have known, that their products were defective, dangerous, and otherwise harmful to
6 Plaintiff.
7

8 100. Defendants knew, or in the exercise of reasonable care should have known, that
9 the use of FARXIGA could cause or be associated with Plaintiff's injuries and thus created a
10 dangerous and unreasonable risk of injury to users of the products.

11 101. Defendants knew that many health care professionals were prescribing
12 FARXIGA, and that numerous patients developed serious side effects including but not limited
13 to diabetic ketoacidosis.
14

15 102. Defendants breached their duty of reasonable care and failed to exercise ordinary
16 care in the design, research, development, manufacture, marketing, supplying, promotion,
17 marketing, advertisement, packaging, sale, testing, quality assurance, quality control, sale, and
18 distribution of FARXIGA in interstate commerce, in that the defendants knew and had reason to
19 know that a consumer's use and ingestion of FARXIGA created a significant risk of suffering
20 unreasonably dangerous health related side effects, including Plaintiff's injuries, and failed to
21 prevent or adequately warn of the severity of these risks and injuries.
22

23 103. Defendants were further negligent in that they manufactured and produced a
24 defective product containing *dapagliflozin*, and *dapagliflozin propanediol*, respectively, and they
25 knew and were aware of the defects inherent in their product, failed to act in a reasonably
26 prudent manner in designing, testing, and marketing their product, and failed to provide adequate
27 warnings of their product's defects and risks.
28

1 104. Defendants failed to exercise due care under the circumstances, and their
2 negligence includes the following acts and omissions:

- 3 a. failing to properly and thoroughly test FARXIGA before releasing the
4 drugs to market;
- 5 b. failing to properly and thoroughly analyze the data resulting from the pre-
6 marketing tests of FARXIGA;
- 7 c. failing to conduct sufficient post-market testing and surveillance of
8 FARXIGA;
- 9 d. designing, manufacturing, marketing, advertising, distributing, and selling
10 FARXIGA to consumers, including Plaintiff, without an adequate warning
11 of the significant and dangerous risks of the medication and without
12 proper instructions to avoid foreseeable harm;
- 13 e. failing to accompany their product with proper or adequate warnings or
14 labeling regarding adverse side effects and health risks associated with the
15 use of FARXIGA and the comparative severity of such adverse effects;
- 16 f. failing to provide warnings, instructions or other information that
17 accurately reflected the symptoms, scope, and severity of the side effects
18 and health risks, including but not limited to those associated with the
19 severity of FARXIGA's effect on acid balance and renal function;
- 20 g. failing to adequately warn users, consumers, and physicians about the
21 need to monitor renal function in patients that do not already suffer from
22 renal impairment;
- 23 h. failing to exercise due care when advertising and promoting FARXIGA;
24 and
- 25 i. negligently continuing to manufacture, market, advertise, and distribute
26 FARXIGA after they knew or should have known of its adverse effects.

27 105. Defendants had a duty to create a product that was not unreasonably dangerous
28 for its normal, common, and intended use.

 106. Defendants negligently and carelessly breached this duty of care to Plaintiff
because FARXIGA was and is unreasonably defective in design as follows:

- a. FARXIGA unreasonably increases the risks of developing Plaintiff's
injuries as complained of herein;
- b. FARXIGA was not reasonably safe as intended to be used;
- c. FARXIGA are more dangerous than an ordinary consumer would expect
and more dangerous than other risks associated with like products;

- d. FARXIGA contained insufficient, incorrect, and defective warnings in that they failed to alert health care professionals and users, including Plaintiff, of the severity of the risks of adverse effects;
- e. FARXIGA was not safe for its intended use;
- f. FARXIGA was not adequately tested; and/or
- g. FARXIGA's risks exceeded any benefit of the drug.

107. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of the defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution and sale of FARXIGA.

108. Plaintiff did not know the nature and extent of the injuries that could result from ingestion and use of FARXIGA.

109. Defendants' negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiff suffered, and will continue to suffer, as described herein.

110. Defendants' conduct, as described above, was reckless. The defendants' actions and inaction risked the lives of consumers and users of their product, including Plaintiff.

111. Defendants' FARXIGA was expected to, and did, reach the intended consumers, handlers and persons coming into contact with the drug without substantial change in the condition in which it was researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants.

112. At all times relevant hereto, FARXIGA was manufactured, designed and labeled in an unsafe, defective and inherently dangerous condition, which was dangerous for use by the public and in particular by Plaintiff.

113. Plaintiff used FARXIGA for its intended purposes and in a manner normally intended: to treat diabetes.

114. The harm caused by FARXIGA far outweighed the benefits, rendering FARXIGA more dangerous and less effective than an ordinary consumer or health care

1 professionals would expect and more dangerous than alternative products. Defendants could
2 have designed FARXIGA, to make them less dangerous. When the defendants manufactured
3 FARXIGA, the state of the industry's scientific knowledge was such that a less risky design was
4 attainable.

5
6 115. At the time FARXIGA left Defendants' control, there was a practical, technically
7 feasible, and safer alternative design that would have prevented the harm without substantially
8 impairing the reasonably anticipated or intended function of FARXIGA. This was demonstrated
9 by the existence of other diabetes medications that had a more established safety profile and a
10 considerably lower risk profile.

11
12 116. Plaintiff could not, in the reasonable exercise of care, have discovered the defects
13 of FARXIGA and perceived the danger.

14
15 117. The defects in FARXIGA were substantial contributing factors in causing
16 Plaintiff's injuries. But for the defendants' acts and omissions, Plaintiff would not have
17 suffered the injuries complained of herein.

18
19 118. As a foreseeable, direct, and proximate consequence of Defendants' actions,
20 omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related
21 health complications.

22
23 119. In addition, as a result of the injuries caused by Defendants, Plaintiff requires and
24 will continue to require healthcare and services. Plaintiffs have incurred and will continue to
25 incur medical and related expenses. Plaintiff also has suffered and will continue to suffer
26 diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of
27 premature death, aggravation of preexisting conditions, activation of latent conditions, and other
28 losses and damages. Plaintiff's direct medical losses and costs include physician care,

1 monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical
2 pain and suffering.

3 WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs'
4 favor for compensatory and punitive damages, together with interest, costs herein incurred,
5 attorneys' fees, and all such other and further relief as this Court deems just and proper.
6 Plaintiffs also demand that the issues contained herein be tried by a jury.
7

8 **COUNT III**

9 **WILLFUL AND WANTON CONDUCT OR GROSS NEGLIGENCE**

10 120. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

11 121. The wrongs done by Defendants were aggravated by malice, fraud, and grossly
12 negligent disregard for the rights of others, the public, and Plaintiff, in that the defendants'
13 conduct was specifically intended to cause substantial injury to Plaintiff. When viewed
14 objectively from Defendants' standpoint at the time of the conduct, considering the probability
15 and magnitude of the potential harm to others, the defendants' conduct involved an extreme
16 degree of risk.
17

18 122. Defendants were actually, subjectively aware of the risk involved, but
19 nevertheless proceeded with complete indifference to or a conscious disregard for to the rights,
20 safety, or welfare of others. Moreover, Defendants made material representations that were
21 false, with actual knowledge of or reckless disregard for their falsity, with the intent that the
22 representations be acted on by Plaintiff and her healthcare providers.
23

24 123. Plaintiff relied on Defendants' representations and suffered injuries as a
25 proximate result of this reliance.
26

27 124. Plaintiffs therefore assert claims for exemplary damages.
28

1 125. Plaintiffs also allege that the acts and omissions of Defendants, whether taken
2 singularly or in combination with others, constitute gross negligence that proximately caused the
3 injuries to Plaintiff.

4 126. Plaintiffs are entitled to an award of punitive and exemplary damages based upon
5 Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and
6 conduct, and the defendants' reckless disregard for the public safety and welfare. Defendants
7 intentionally and fraudulently misrepresented facts and information to both the medical
8 community and the general public, including Plaintiff, by making intentionally false and
9 fraudulent misrepresentations about the safety of FARXIGA. Defendants intentionally
10 concealed the true facts and information regarding the serious risks of harm associated with the
11 ingestion of FARXIGA, and intentionally downplayed the type, nature, and extent of the
12 adverse side effects of ingesting FARXIGA, despite their knowledge and awareness of these
13 serious side effects and risks.

14 127. Defendants had knowledge of, and were in possession of evidence demonstrating
15 that FARXIGA caused serious side effects. Notwithstanding their knowledge, Defendants
16 continued to market FARXIGA by providing false and misleading information with regard to
17 their product's safety to regulatory agencies, the medical community, and consumers of
18 FARXIGA.

19 128. Although Defendants knew or recklessly disregarded the fact that FARXIGA
20 cause debilitating and potentially lethal side effects, the defendants continued to market,
21 promote, and distribute FARXIGA to consumers, including Plaintiff, without disclosing these
22 side effects when there were safer alternative methods for treating diabetes.

23 129. Defendants failed to provide adequate warnings that would have dissuaded health
24 care professionals from prescribing FARXIGA and consumers from purchasing and ingesting
25
26
27
28

1 FARXIGA, thus depriving both from weighing the true risks against the benefits of prescribing,
2 purchasing, or consuming FARXIGA.

3 130. Defendants knew of FARXIGA's defective nature as set forth herein, but
4 continued to design, manufacture, market, distribute, sell, and/or promote the drugs to maximize
5 sales and profits at the expense of the health and safety of the public, including Plaintiff, in a
6 conscious, reckless, or negligent disregard of the foreseeable harm caused by FARXIGA.
7

8 131. Defendants' acts, conduct, and omissions were willful and malicious. The
9 defendants committed these acts with knowing, conscious, and deliberate disregard for the
10 rights, health, and safety of Plaintiff and other users of FARXIGA and for the primary purpose
11 of increasing Defendants' profits from the sale and distribution of FARXIGA. Defendants'
12 outrageous and unconscionable conduct warrants an award of exemplary and punitive damages
13 against all defendants in an amount appropriate to punish and make an example out of each.
14

15 132. Prior to the manufacture, sale, and distribution of FARXIGA, Defendants knew
16 that FARXIGA was in a defective condition and knew that those who were prescribed the
17 medications would experience and did experience severe physical, mental, and emotional
18 injuries. Further, each defendant, through their officers, directors, managers, and agents, knew
19 that FARXIGA presented a substantial and unreasonable risk of harm to the public, including
20 Plaintiff. As such, Defendants unreasonably subjected consumers of FARXIGA to risk of
21 injury.
22

23 133. Despite their knowledge, Defendants, acting through their officers, directors and
24 managing agents, for the purpose of enhancing the defendants' profits, knowingly and
25 deliberately failed to remedy the known defects in FARXIGA and failed to adequately warn the
26 public, including Plaintiff, of the extreme risk of injury occasioned by said defects. Defendants
27 and their respective agents, officers, and directors intentionally proceeded with the
28

1 manufacturing, sale, distribution, and marketing of FARXIGA knowing these actions would
2 expose persons to serious danger in order to advance the defendants' pecuniary interest and
3 monetary profits.

4 134. Defendants' conduct was committed with willful and conscious disregard for the
5 safety of Plaintiffs, entitling Plaintiffs to exemplary damages.

6 WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs'
7 favor for compensatory and punitive damages, together with interest, costs herein incurred,
8 attorneys' fees, and all such other and further relief as this Court deems just and proper.
9 Plaintiffs also demand that the issues contained herein be tried by a jury.

11 **COUNT IV**

12 **LOSS OF CONSORTIUM**

13 130. Plaintiffs incorporate by reference each proceeding and succeeding paragraph as
14 though set forth fully at length herein.

15 131. Plaintiff-Spouse SCOTT BARKER is the husband of BETTY BARKER, and was
16 her lawful husband on all material and relevant dates.

17 132. As a direct and proximate result of the negligence and other acts omissions of
18 Defendants, described within the previous Counts of this Complaint, Plaintiff -Spouse has
19 suffered a loss of consortium, society, affections and services of his wife, BETTY BARKER, as
20 well as other economic damages.

21 WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs'
22 favor for compensatory and punitive damages, together with interest, costs herein incurred,
23 attorneys' fees, and all such other and further relief as this Court deems just and proper.
24 Plaintiffs also demand that the issues herein contained be tried by a jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment against the Defendants, and each of them, individually, jointly, and severally, as follows:

1. Judgment in favor of plaintiffs and against all defendants, for damages in such amount as may be proven at trial;
2. Compensation for both economic and non-economic losses including but not limited to medical expenses, loss of earnings, loss of consortium, pain and suffering, mental anguish and emotional distress in such amounts as may be proven at trial;
3. Punitive and/or exemplary damages;
4. Interest;
5. Attorneys' fees, expenses, and costs of this action; and
6. Such further relief as this Court deems necessary, just and proper.

Dated: June 27, 2016

Respectfully submitted,

WEITZ & LUXENBERG, P.C.
Attorneys for PLAINTIFFS

By: _____ /s/ _____
Melinda Davis Nokes

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

JURY DEMAND

Plaintiffs demand trial by jury on all issues within this Complaint.

Dated: June 27, 2016

Respectfully submitted,

WEITZ & LUXENBERG, P.C.
Attorneys for PLAINTIFFS

By: _____ /s/
Melinda Davis Nokes

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Betty Barker & Scott Barker

(b) County of Residence of First Listed Plaintiff KERN

(EXCEPT IN U.S. PLAINTIFF CASES)

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

MELINDA DAVIS NOKES, WEITZ & LUXENBERG P.C
1880 CENTURY PARK EAST, SUITE 700, LOS ANGELES, CA 90067
mnokes@weitzlux.com P: 310-247-0921

DEFENDANTS

BRISTOL-MYERS SQUIBB CO., ASTRAZENECA LP,
ASTRAZENECA PHARMACEUTICALS LP, & DOES 1-100

County of Residence of First Listed Defendant NEW YORK

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship: Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation.

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

Click here for: Nature of Suit Code Descriptions.

Large table with categories: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding
2 Removed from State Court
3 Remanded from Appellate Court
4 Reinstated or Reopened
5 Transferred from Another District (specify)
6 Multidistrict Litigation - Transfer
8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

28:1332pl

Brief description of cause: Product Liability

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE LORNA G. SCHOFIELD

DOCKET NUMBER 17-MD-2776 (LGS)

DATE 06/27/2017

SIGNATURE OF ATTORNEY OF RECORD

Handwritten signature of attorney

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFF JUDGE MAG. JUDGE