IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF KENTUCKY

Donna Royse, Individually and as Representative of the Estate of Terry Royse; Plaintiff	Case No. _____
vs.	JURY TRIAL DEMANDED
Janssen Pharmaceuticals, Inc., Janssen Research and Development, LLC, Janssen Ortho, LLC, Johnson & Johnson Co., Mitsubishi Tanabe Pharma Development America, Inc., Tanabe Research Laboratories U.S.A., Inc., Mitsubishi Tanabe Pharma Development America, Inc., Eli, Lilly and Company, Boehringer Ingelheim Pharmaceuticals, Inc., Bristol-Myers Squibb Co, Astrazeneca LP, Astrazeneca Pharmaceuticals LP Defendants	

PLAINTIFF'S ORIGINAL COMPLAINT
AND JURY DEMAND

Plaintiff Donna Royse, Individually and as Representative of the Estate of Terry Royse, Deceased (collectively "Plaintiff" and Terry Royse hereinafter "Decedent"), respectfully submits this Complaint and Jury Demand in which she individually and collectively complain against Defendants Janssen Pharmaceuticals, Inc., Janssen Research and Development, LLC, Janssen Ortho, LLC, Johnson & Johnson Co., Mitsubishi Tanabe Pharma Development America, Inc., Tanabe

Research Laboratories U.S.A., Inc., Mitsubishi Tanabe Pharma Development America, Inc., Eli Lilly and Company, Boehringer Ingelheim Pharmaceuticals, Inc., Bristol-Myers Squibb Co, Astrazeneca LP, and Astrazeneca Pharmaceuticals LP (collectively "Defendants"), for serious and permanent injuries caused by Decedent's ingestion of SLGT2 INHIBITOR,[1] a drug in the *gliflozin* class, and seeking compensatory and punitive damages, equitable relief, statutory attorney's fees and costs, pre- and post-judgment interest and such other and further relief deemed just and proper; and, in support thereof Plaintiff alleges the following based upon her best knowledge, information and belief. Additionally, this filing is made before the receipt of medical records in order to preserve Plaintiff's legal rights.

I.
BRIEF SUMMARY OF CLAIMS ASSERTED HEREIN

1. Defendants, directly or through their agents, apparent agents, servants or employees, designed, manufactured, marketed, advertised, licensed, distributed, and/or sold SLGT2 INHIBITOR for the treatment of diabetes.

2. Defendants concealed, and continue to conceal, their knowledge of SLGT2 INHIBITOR's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

3. As a result of the defective nature of SLGT2 INHIBITOR, persons who were prescribed and ingested SLGT2 INHIBITOR, including Decedent, have suffered and may continue to suffer severe and permanent personal injuries,

[1] Invokana® is a registered trademark of Johnson & Johnson Co., U.S. Trademark and Patent Office, Serial No. 85592280, Registration No. 4369669, filing date: 2012-04-09, Registration date: 2013-07-16. (See https://trademarks.justia.com/855/92/SLGT2 Inhibitor-85592280.html). (Site last visited 7/16/16). Throughout this Original Complaint Ivokana, Jardiance, Farxiga, and Invokamet shall be referred to collectively as ("SLGT2 INHIBITOR").

including stroke, heart attack, severe kidney damage, diabetic ketoacidosis, respiratory failure, and death.

4. After beginning treatment with SLGT2 INHIBITOR, and as a direct and proximate result of Defendants' actions and inaction, Decedent suffered kidney failure, respiratory failure and death. Decedent's ingestion of the defective and unreasonably dangerous drug SLGT2 INHIBITOR has caused and will continue to cause injury and damage to Plaintiff.

5. This is an action in which Plaintiff asserts claims for strict products liability, including design defect and failure to warn, negligence, willful and wanton conduct and/or gross negligence, breach of express and implied warranties, fraudulent misrepresentation, negligent misrepresentation, negligent design, fraudulent concealment, and fraud against: Janssen Pharmaceuticals, Inc., ("JANSSEN"), Janssen Research and Development, LLC, ("JANSSEN R&D"); Janssen Ortho, LLC, ("JANSSEN ORHTO"); Johnson & Johnson Co., ("JOHNSON & JOHNSON"); Mitsubishi Tanabe Pharma Development America, Inc., ("TANABE DEVELOPMENT"); Tanabe Research Laboratories U.S.A., Inc., ("TANABE RESEARCH"); Mitsubishi Tanabe Pharma Development America, Inc., ("TANABE HOLDINGS"); Eli Lilly and Company ("LILLY"); Boehringer Ingelheim Pharmaceuticals, Inc. ("BIP"); Bristol-Myers Squibb Co ("BMS"); Astrazeneca LP ("ASTRAZENECA"); and Astrazeneca Pharmaceuticals LP ("ASTRAZENECA PHARMACEUTICALS") jointly and severally.

6. Plaintiff brings this action for serious and permanent personal injuries suffered as a proximate result of Decedent having been prescribed and ingesting SLGT2 INHIBITOR. Plaintiff accordingly seeks compensatory and punitive

damages, monetary restitution, equitable relief, statutory attorney's fees and costs, pre- and post-judgment interest and such other and further relief and all other available remedies as a result of injuries caused by SLGT2 INHIBITOR.

II.
JURISDICTION AND VENUE

7. The United States District Court for the Eastern District of Kentucky has original subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a) because there is complete diversity among all properly joined and served parties and the amount in controversy exceeds $75,000, exclusive of interest and costs.

8. Venue is proper, pursuant to 28 U.S.C. section 1391(b), because Plaintiff and Decedent are and were citizens of Kentucky at all times pertinent herein; and because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district.

III.
PARTIES

9. At all times relevant hereto, Plaintiff Donna Royse, Individually and as Representative of the Estate of Terry Royse was and is a resident and citizen of Montgomery County, Kentucky. Decedent was a resident and citizen of Montgomery County, Kentucky when he was prescribed, purchased, ingested, and exposed to SLGT2 INHIBITOR. As a result of ingesting SLGT2 INHIBITOR, Decedent, Terry Royse suffered physical injuries and other personal and economic injuries, which developed and occurred in the foregoing locale, and he sought treatment for the effects attendant thereto in said locale as well. For purposes of 28 U.S.C. § 1332(c)(1), Plaintiff is therefore deemed to be a citizen of Kentucky.

10. Defendants JANSSEN and JANSSEN R&D are Pennsylvania corporations with principal places of business at 1125 Trenton Harbourton Road, Titusville, New Jersey 08560, and each company is a wholly owned subsidiary of Defendant JOHNSON & JOHNSON. JANSSEN and JANSSEN R&D are engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Invokana and Invokamet. For the purposes of 28 U.S.C. § 1332(c)(1), JANSSEN and JANSSEN R&D are deemed to be a citizen of Pennsylvania and New Jersey.

11. Defendant JANSSEN ORTHO, LLC is a Delaware company with a principal place of business at State Road 933 Km 01, Gurabo, Puerto Rico 00778. JANSSEN ORTHO is registered to do business throughout the United States and may be served through its registered agent c/o The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. JANSSEN ORTHO is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Invokamet. For the purposes of 28 U.S.C. § 1332(c)(1), BIP is therefore deemed to be a citizen of Delaware.

12. Defendant JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. JOHNSON & JOHNSON is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing,

supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Invokana. For the purposes of 28 U.S.C. § 1332(c)(1), JOHNSON & JOHNSON is therefore deemed to be a citizen of New Jersey.

13. Defendant MITSUBISHI TANABE PHARMA DEVELOPMENT AMERICA, INC., is a Delaware corporation, with a principal place of business at 525 Washington Boulevard, Suite 400, Jersey City, New Jersey 07310. Tanabe Development licenses pharmaceuticals and drug therapies including SLGT2 Inhibitor for its parent corporation, Tanabe and conducts clinical development activity for obtaining marketing approval of drugs in the U.S., including Invokana, and provides administration support for the U.S. affiliates. For the purposes of 28 U.S.C. § 1332(c)(1), TANABE DEVELOPMENT is therefore deemed to be a citizen of New Jersey and Delaware.

14. Defendant TANABE RESEARCH LABORATORIES U.S.A., INC. is a California corporation, with a principal place of business 4540 Towne Centre Court, San Diego, California 92121. TANABE RESEARCH conducts pharmaceutical research, including with respect to Invokana. For the purposes of 28 U.S.C. § 1332(c)(1), TANABE RESEARCH is therefore deemed to be a citizen of California.

15. Defendant MITSUBISHI TANABE PHARMA HOLDINGS AMERICA, INC. is a Delaware corporation, with a principal place of business at 525 Washington Boulevard, Suite 400, Jersey City, NJ 07310. Tanabe Holdings is a subsidiary of Tanabe and a holding company for U.S. subsidiaries. For the purposes of 28 U.S.C. § 1332(c)(1), TANABE HOLDINGS is therefore deemed to be a citizen of New Jersey and Delaware.

16. Defendant ELI LILLY AND COMPANY is an Indiana corporation with its principal place of business at 893 S Delaware St, Indianapolis, IN 46225. Lilly is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Jardiance. For the purposes of 28 U.S.C. § 1332(c)(1), LILLY is therefore deemed to be a citizen of Indiana.

17. Defendant BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. is a Delaware corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, CT 06877. BIP is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Jardiance. For the purposes of 28 U.S.C. § 1332(c)(1), BIP is therefore deemed to be a citizen of Connecticut.

18. Defendant BRISTOL-MYERS SQUIBB CO, 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, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Farxiga. For the purposes of 28 U.S.C. § 1332(c)(1), BMS is therefore deemed to be a citizen of New York.

19. Defendant ASTRAZENECA LP is a Delaware corporation with its principal place of business at 1209 Orange Street, Wilmington, Delaware.

Astrazeneca LP is a wholly owned subsidiary of defendant Astrazeneca PLC. Astrazeneca LP is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Farxiga. For the purposes of 28 U.S.C. § 1332(c)(1), ASTRAZENECA is therefore deemed to be a citizen of Delaware.

20. Defendant ASTRAZENECA PHARMACEUTICALS LP is a Delaware corporation with its principal place of business at 1209 Orange Street, Wilmington, Delaware. Astrazeneca Pharmaceuticals LP is a wholly owned subsidiary of Defendant Astrazeneca PLC. Astrazeneca Pharmaceuticals LP is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Farxiga. For the purposes of 28 U.S.C. § 1332(c)(1), ASTRAZENECA PHARMACEUTICALS is therefore deemed to be a citizen of Delaware.

IV.
FACTUAL BACKGROUND

1. Defendant TANABE, in collaboration with Defendant JOHNSON & JOHNSON, and Defendants JANSSEN and JANSSEN R&D, wholly owned subsidiaries of JOHNSON & JOHNSON, designed and developed the diabetes drug, Invokana.

2. Defendants JANSSEN and JANSSEN R&D, wholly owned subsidiaries of JOHNSON & JOHNSON, acquired the marketing rights to Invokana in North America, and marketed, advertised, distributed, and sold Invokana in the United States, including in the State of Kentucky.

3. In March 2013, the United States Food and Drug Administration ("FDA") approved Invokana (*canagliflozin*) for the treatment of type 2 diabetes.

4. *Canagliflozin* is a member of the *gliflozin* class of pharmaceuticals, also known as sodium-glucose cotransporter 2 ("SGLT2") inhibitors, and is marketed in the United States by Defendants under the name Invokana.

5. On January 8, 2014, the FDA approved Farxiga (dapagliflozin) for use in treatment of type 2 diabetics. Farxiga is a part of the *gliflozin* drug class, and was one of the first *gliflozins* approved for use in the United States. The *gliflozin* class is referred to generally as SGLT2 (short for "Sodium Glucose Cotransporter 2") inhibitors.

6. As a *gliflozin* drug, Farxiga's active ingredient is *dapagliflozin propanediol*.

7. On August 1, 2014, the FDA approved Jardiance (dapagliflozin) for use in treatment of type 2 diabetics. Jardiance is a part of the *gliflozin* drug class, and was one of the first *gliflozins* approved for use in the United States. The *gliflozin* class is referred to generally as SGLT2 (Sodium Glucose Cotransporter 2) inhibitors.

8. On August 8, 2014, the FDA approved Invokamet, a fixed-dose therapy combining canagliflozin and metformin hydrochloride in a single tablet, for the treatment of adults with type 2 diabetes. Invokament was designed to provide the clinical attributes of Invokana, the first sodium glucose co-transporter 2 inhibitor

available in the United States, together with metformin, which was commonly prescribed early in the treatment of type 2 diabetes. Invokamet was the first fixed-dose combination of an SGLT2 inhibitor with metformin approved in the United States.

9. SGLT2 inhibitors are primarily used for treating type 2 diabetes. Invokana was the first SGLT2 inhibitor approved for use by the FDA.

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

11. Though SLGT2 INHIBITOR is indicated for only improved glycemic control in type 2 adult diabetics, Defendants have marketed and continue to market SLGT2 INHIBITOR for off label purposes, including but not limited to weight loss, and reduced blood pressure.

12. Since SLGT2 INHIBITOR's release, the FDA has received a significant number of reports of diabetic ketoacidosis and kidney infection among users of SLGT2 INHIBITOR.

13. On May 15, 2015, the FDA issued a Public Health Advisory linking SGLT2 inhibitors to diabetic ketoacidosis, a sudden onset condition which can result in organ failure and even death.

14. An analysis of the FDA adverse event database shows that patients taking SLGT2 INHIBITOR are several times more likely to report diabetic ketoacidosis than those taking non-SGLT2 diabetes drugs to treat diabetes.

15. Despite Defendants' knowledge of the increased risk of severe injury among SLGT2 INHIBITOR users, Defendants did not warn patients, including Decedent, but instead continued to defend SLGT2 INHIBITOR, mislead physicians and the public, and minimize unfavorable findings.

16. Notwithstanding their actual knowledge of mounting concerns and documented patient problems, Defendants aggressively conducted nationwide sales and marketing campaigns to promote the sale of SLGT2 INHIBITOR and willfully deceived Decedent, his health care professionals, the medical community, and the general public as to the health risks and consequences of the use of the SLGT2 INHIBITOR.

17. Defendants' failure to warn about diabetic ketoacidosis is particularly detrimental to those taking the drug because in many cases of SLGT2 INHIBITOR-induced ketoacidosis, the patient's glucose levels are not elevated, as is typically the case. This phenomenon leaves diagnosing doctors in a quandary, and often leads to the ketoacidosis being missed and untreated.

18. Recently, on December 4, 2015, it was the FDA that updated Invokana's warning label to warn of too much acid in the blood (ketoacidosis), and serious urinary tract infections, which can develop into full blown kidney infections.

19. Consumers, including Decedent, who have used SLGT2 INHIBITOR for treatment of diabetes, have several alternative safer products available to treat the conditions.

20. Defendants knew of the significant risk of severe injury caused by ingestion of SLGT2 INHIBITOR. However, Defendants did not adequately and

sufficiently warn consumers, including Decedent, or the medical community of the severity of such risks.

21. To the contrary, Defendants conducted nationwide sales and marketing campaigns to promote the sale of SLGT2 INHIBITOR and willfully deceived Decedent, his health care professionals, the medical community, and the general public as to the health risks and consequences of the use of the SLGT2 INHIBITOR.

22. As a direct result, Decedent were prescribed and began taking SLGT2 INHIBITOR, primarily to treat diabetes.

23. Decedent ingested and used SLGT2 INHIBITOR as prescribed and in a foreseeable manner.

24. The SLGT2 INHIBITOR used by Decedent was provided to him in a condition substantially the same as the condition in which it was manufactured and sold.

25. Decedent agreed to initiate treatment with SLGT2 INHIBITOR in an effort to reduce his blood glucose levels. In doing so, Decedent relied on claims made by Defendants that SLGT2 INHIBITOR was safe and effective for the treatment of diabetes.

26. Instead, SLGT2 INHIBITOR can, and in the case of the Decedent did, cause severe injuries, including respiratory failure, kidney damage/failure, and death.

27. After beginning treatment SLGT2 INHIBITOR, and as a direct and proximate result thereof, Decedent suffered serious and permanent injuries. In turn, and as a direct and proximate result of Decedent's use of SLGT2 INHIBITOR, Plaintiff suffered damages as set out below.

28. Defendants knew or should have known the risks associated with the use of SLGT2 INHIBITOR, including the risk of developing kidney damage/failure, respiratory failure and other serious conditions.

29. The development of Decedent's injuries was preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life threatening risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of SLGT2 INHIBITOR. This conduct and the product defects complained of herein were substantial factors in bringing about and exacerbating Plaintiff's injuries.

30. Plaintiff's injuries and Decedent's death were reasonably foreseeable consequences of Defendants' conduct and SLGT2 INHIBITOR's defects.

31. At all times material hereto, Defendants, by and through their agents, servants and employees, negligently, recklessly and carelessly marketed, distributed and sold SLGT2 INHIBITOR without adequate instructions or warning of its serious side effects and unreasonably dangerous risks, including but not limited to the risk of developing serious side effects.

32. Decedent would not have used SLGT2 INHIBITOR had Defendants properly disclosed the risks associated with the drug. Thus, had Defendants properly disclosed the risks associated with SLGT2 INHIBITOR, Decedent would have avoided the risk of developing the injuries complained of herein by not ingesting SLGT2 INHIBITOR.

33. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Decedent and his physicians the true and significant risks associated with taking SLGT2 INHIBITOR.

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

35. As a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of SLGT2 INHIBITOR, Decedent, and Plaintiff as the Representative of Decedent, suffered severe and permanent physical and emotional injuries. Plaintiff has endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiff seeks actual, compensatory, and punitive damages from Defendants, in addition to all appropriate other forms of compensation and relief.

V.
CAUSES OF ACTION

COUNT I
STRICT PRODUCTS LIABILITY
DESIGN DEFECT

1. Plaintiff restates the allegations set forth above as if fully rewritten herein.

2. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed SLGT2 INHIBITOR, including the SLGT2 INHIBITOR used by Decedent, which was in a defective and unreasonably dangerous condition.

3. Defendants expected SLGT2 INHIBITOR to reach, and it did in fact reach, Decedent without substantial change in the condition in which it was manufactured and sold by the Defendants.

4. At all times relevant hereto, Defendants' SLGT2 INHIBITOR was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition and was dangerous for use by the public and in particular by Decedent.

5. At all times relevant to this action, SLGT2 INHIBITOR, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by the Defendants, was defective in design and formulation in one or more of the following particulars:

a. When placed in the stream of commerce, SLGT2 INHIBITOR contained unreasonably dangerous design defects and was not

reasonably safe as intended to be used, subjecting Decedent to risks that exceeded the benefits of the drug;

b. When placed in the stream of commerce, SLGT2 INHIBITOR was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the treatment of diabetes;

c. SLGT2 INHIBITOR was insufficiently tested;

d. SLGT2 INHIBITOR caused harmful side effects that outweighed any potential utility;

e. Defendants were aware at the time SLGT2 INHIBITOR was marketed that ingestion of SLGT2 INHIBITOR would result in an increased risk of severe kidney damage, and other injuries;

f. Inadequate post-marketing surveillance; and/or

g. There were safer alternative designs and formulations that were not utilized.

6. SLGT2 INHIBITOR was defective, failed to perform safely, and was unreasonably dangerous when used by ordinary consumers, including Decedent, as intended and in a reasonably foreseeable manner.

7. SLGT2 INHIBITOR, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in its design or formulation, in that it was unreasonably dangerous and its foreseeable risks exceeded the alleged benefits associated with SLGT2 INHIBITOR's design or formulation.

8. SLGT2 INHIBITOR, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in design or formulation in that it posed a greater likelihood of injury than other diabetes drugs and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

9. At all times relevant to this action, Defendants knew or had reason to know that SLGT2 INHIBITOR was in a defective condition and was inherently dangerous and unsafe when used in the manner instructed, provided, and/or promoted by Defendants.

10. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and otherwise ensure that SLGT2 INHIBITOR was not unreasonably dangerous for its normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

11. When Defendants placed SLGT2 INHIBITOR into the stream of commerce, they knew it would be prescribed to treat diabetes, and they marketed and promoted SLGT2 INHIBITOR as safe for treating diabetes.

12. Decedent was prescribed, purchased, and used SLGT2 INHIBITOR. Decedent used SLGT2 INHIBITOR for its intended purpose and in the manner recommended, promoted, marketed, and reasonably anticipated by Defendants.

13. Neither Decedent nor his health care professionals, by the exercise of reasonable care, could have discovered the defects and risks associated with SLGT2 INHIBITOR before Decedent's ingestion of SLGT2 INHIBITOR.

14. The harm caused by SLGT2 INHIBITOR far outweighed its benefit, rendering SLGT2 INHIBITOR more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products. Defendants could have designed SLGT2 INHIBITOR to make it less dangerous. When Defendants designed SLGT2 INHIBITOR, the state of the industry's scientific knowledge was such that a less risky design was attainable.

15. At the time SLGT2 INHIBITOR left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm Decedent suffered without substantially impairing the reasonably anticipated or intended function of SLGT2 INHIBITOR. This was demonstrated by the existence of other diabetes medications that had a more established safety profile and a considerably lower risk profile.

16. Defendants' defective design of SLGT2 INHIBITOR was willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of SLGT2 INHIBITOR.

17. Defendants' conduct was motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of SLGT2 INHIBITOR.

18. The defects in SLGT2 INHIBITOR were substantial producing and/or contributing factors in causing Decedent's injuries. But for Defendants' acts and omissions, Decedent would not have suffered the injuries complained of herein.

19. Due to the unreasonably dangerous condition of SLGT2 INHIBITOR, Defendants are liable for Decedent's injuries.

20. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of SLGT2 INHIBITOR, including Decedent, with knowledge of the safety problems associated with SLGT2 INHIBITOR, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

21. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe and permanent injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses prior to his death. Decedent suffered diminished capacity for the enjoyment of life, a diminished quality of life, premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Decedent endured mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor on this Count for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT II
STRICT PRODUCTS LIABILITY
FAILURE TO WARN

22. Plaintiff restates the allegations set forth above as if fully rewritten herein.

23. Defendants have engaged in the business of designing, developing, researching, testing, licensing, manufacturing, packaging, labeling, promoting, marketing, selling, and/or distributing SLGT2 INHIBITOR. Through that conduct, Defendants knowingly and intentionally placed SLGT2 INHIBITOR into the stream of commerce with full knowledge that it reaches consumers, such as Decedent, who ingested it.

24. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released SLGT2 INHIBITOR into the stream of commerce. In the course of same, Defendants directly advertised, marketed, and promoted SLGT2 INHIBITOR to the FDA, health care professionals, Decedent, and other consumers, and therefore had a duty to warn of the risks associated with the use of SLGT2 INHIBITOR.

25. Defendants expected SLGT2 INHIBITOR to reach, and it did in fact reach, prescribing health care professionals and consumers, including Decedent and his prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

26. SLGT2 INHIBITOR, as manufactured and/or supplied by Defendants, was defective due to inadequate warnings or instructions. Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or the health care professionals of such risks.

27. SLGT2 INHIBITOR was defective and unsafe such that it was unreasonably dangerous when it left Defendants' possession and/or control, was distributed by Defendants, and ingested by Decedent. SLGT2 INHIBITOR contained

warnings insufficient to alert consumers, including Decedent, to the dangerous risks and reactions associated with SLGT2 INHIBITOR, including the development of Decedent's injuries.

28. This defect caused serious injury to Decedent, who used SLGT2 INHIBITOR for its intended purpose and in a reasonably anticipated manner.

29. At all times herein mentioned, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take such other steps as are necessary to ensure SLGT2 INHIBITOR did not cause users to suffer from unreasonable and dangerous risks.

30. Defendants negligently and recklessly labeled, distributed, and promoted SLGT2 INHIBITOR.

31. Defendants had a continuing duty to warn Decedent of the dangers associated with SLGT2 INHIBITOR.

32. Defendants, as manufacturers, sellers, or distributors of prescription drugs, are held to the knowledge of an expert in the field.

33. Decedent could not have discovered any defects in SLGT2 INHIBITOR through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

34. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the facts that Defendants knew or should have known that SLGT2 INHIBITOR caused serious injuries, they failed to exercise reasonable care to warn of the severity of the dangerous risks associated with its use. The dangerous propensities of SLGT2 INHIBITOR, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and

testing by known methods, at the time they distributed, supplied, or sold the product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their patients.

35. SLGT2 INHIBITOR, as manufactured and/or supplied by Defendants, was unreasonably dangerous when used by consumers, including Decedent, in a reasonably and intended manner without knowledge of this risk of serious bodily harm.

36. Defendants knew or should have known that the limited warnings disseminated with SLGT2 INHIBITOR were inadequate, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug. In particular, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for treatment of diabetes.

37. Defendants communicated to health care professionals information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drug safely for use by patients for the purposes for which it is intended. In particular, Defendants:

a. disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or

adequately the comparative severity, duration, and extent of the risk of injuries with use of SLGT2 INHIBITOR;

b. continued to aggressively promote SLGT2 INHIBITOR even after Defendants knew or should have known of the unreasonable risks from use;

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 SLGT2 INHIBITOR 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 and health risks, including but not limited to those associated with the severity of SLGT2 INHIBITOR's effect on renal function;

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

f. overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the risks associated with the use of SLGT2 INHIBITOR.

38. To this day, Defendants have failed to adequately and accurately warn of the true risks of injuries associated with the use of SLGT2 INHIBITOR.

39. Due to these deficiencies and inadequacies, SLGT2 INHIBITOR was unreasonably dangerous and defective as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by the Defendants.

40. Had Defendants properly disclosed and disseminated the risks associated with SLGT2 INHIBITOR, Decedent would have avoided the risk of developing injuries as alleged herein.

41. The Defendants are liable to Decedent for injuries caused by their negligent or willful failure to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of SLGT2 INHIBITOR and the risks associated with its use.

42. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, which were producing and/or contributing causes thereof, Decedent suffered severe and permanent injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses prior to his death. Decedent suffered diminished capacity for the enjoyment of life, a diminished quality of life, premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Decedent endured mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor on this Count for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further

relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT III
COMMON LAW NEGLIGENCE

43. Plaintiff restates the allegations set forth above as if fully rewritten herein.

44. Defendants directly or indirectly caused SLGT2 INHIBITOR to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Decedent.

45. The Defendants owed Decedent and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling SLGT2 INHIBITOR, including the duty to take all reasonable steps necessary to ensure the product was not unreasonably dangerous to its consumers and users, and to warn Defendant and other consumers of the dangers associated with SLGT2 INHIBITOR.

46. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of SLGT2 INHIBITOR.

47. Defendants had a duty to disclose to health care professionals the causal relationship or association of SLGT2 INHIBITOR to the development of Decedent' injuries.

48. Defendants' duty of care owed to consumers, health care professionals, and patients included providing accurate information concerning: (1) the clinical safety and effectiveness profiles of SLGT2 INHIBITOR, and (2) appropriate,

complete, and accurate warnings concerning the adverse effects of SLGT2 INHIBITOR, including the injuries suffered by Decedent.

49. During the time that Defendants designed, manufactured, packaged, labeled, promoted, distributed, and/or sold SLGT2 INHIBITOR, Defendants knew, or in the exercise of reasonable care should have known, that their product was defective, dangerous, and otherwise harmful to Decedent.

50. Defendants knew, or in the exercise of reasonable care should have known, that the use of SLGT2 INHIBITOR could cause or be associated with Decedent's injuries and thus created a dangerous and unreasonable risk of injury to users of the products.

51. Defendants knew that many health care professionals were prescribing SLGT2 INHIBITOR, and that many patients developed serious side effects including but not limited to severe kidney damage and respiratory failure.

52. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, marketing, advertisement, packaging, sale, testing, quality assurance, quality control, sale, and distribution of SLGT2 INHIBITOR in interstate commerce, in that Defendants knew and had reason to know that a consumer's use and ingestion of SLGT2 INHIBITOR created a significant risk of suffering unreasonably dangerous health related side effects, including Decedent's injuries, and failed to prevent or adequately warn of the severity of these risks and injuries.

53. Defendants were further negligent in that they manufactured and produced a defective product containing *canagliflozin*, knew and were aware of the

defects inherent in the product, failed to act in a reasonably prudent manner in designing, testing, and marketing the products, and failed to provide adequate warnings of the product's defects and risks.

54. The Defendants failed to exercise due care under the circumstances, and their negligence includes the following acts and omissions:

a. failing to properly and thoroughly test SLGT2 INHIBITOR before releasing the drug to market;

b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of SLGT2 INHIBITOR;

c. failing to conduct sufficient post-market testing and surveillance of SLGT2 INHIBITOR;

d. designing, manufacturing, marketing, advertising, distributing, and selling SLGT2 INHIBITOR to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of SLGT2 INHIBITOR and without proper instructions to avoid foreseeable harm;

e. failing to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of SLGT2 INHIBITOR and the comparative severity of such adverse effects;

f. failing to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to

those associated with the severity of SLGT2 INHIBITOR's effect on renal function;

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

h. failing to exercise due care when advertising and promoting SLGT2 INHIBITOR; and,

i. negligently continuing to manufacture, market, advertise, and distribute SLGT2 INHIBITOR after the Defendants knew or should have known of its adverse effects.

55. Defendants knew and/or should have known that it was foreseeable that consumers such as Decedent would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution and sale of SLGT2 INHIBITOR.

56. Decedent did not know the nature and extent of the injuries that could result from ingestion and use of SLGT2 INHIBITOR.

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

58. Defendants' conduct, as described above, was reckless. Defendants' actions and inaction risked the lives of consumers and users of their products, including Decedent.

59. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe and

permanent injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses prior to his death. Decedent suffered diminished capacity for the enjoyment of life, a diminished quality of life, premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Decedent endured mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor on this Count for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT IV
WILLFUL AND WANTON CONDUCT AND/OR
GROSS NEGLIGENCE

60. Plaintiff restates the allegations set forth above as if fully rewritten herein.

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

62. Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with complete indifference to or a conscious disregard for to

the rights, safety, or welfare of others. Moreover, Defendants made material representations that were false, with actual knowledge of or reckless disregard for their falsity, with the intent that the representations be acted on by Decedent and his healthcare providers.

63. Decedent relied on Defendants' representations and suffered injuries as a proximate result of this reliance.

64. Plaintiff therefore assert claims for exemplary damages.

65. Plaintiff also allege that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Decedent.

66. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Decedent, by making intentionally false and fraudulent misrepresentations about the safety of SLGT2 INHIBITOR. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of SLGT2 INHIBITOR, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting SLGT2 INHIBITOR, despite their knowledge and awareness of these serious side effects and risks.

67. Defendants had knowledge of, and were in possession of evidence demonstrating that SLGT2 INHIBITOR caused serious side effects. Notwithstanding Defendants' knowledge, Defendants continued to market the drug by providing false

and misleading information with regard to the product's safety to regulatory agencies, the medical community, and consumers of SLGT2 INHIBITOR.

68. Although Defendants knew or recklessly disregarded the fact that SLGT2 INHIBITOR causes debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute SLGT2 INHIBITOR to consumers, including Decedent, without disclosing these side effects when there were safer alternative methods for treating diabetes.

69. Defendants failed to provide adequate warnings that would have dissuaded health care professionals from prescribing SLGT2 INHIBITOR and consumers from purchasing and ingesting SLGT2 INHIBITOR, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing, or consuming SLGT2 INHIBITOR.

70. Defendants knew of SLGT2 INHIBITOR's defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell, and/or promote the drug to maximize sales and profits at the expense of the health and safety of the public, including Decedent, in a conscious, reckless, or negligent disregard of the foreseeable harm caused by SLGT2 INHIBITOR.

71. Defendants' acts, conduct, and omissions were willful, wanton and malicious. Defendants committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Decedent and other SLGT2 INHIBITOR users and for the primary purpose of increasing Defendants' profits from the sale and distribution of SLGT2 INHIBITOR. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages

against Defendants in an amount appropriate to punish and make an example out of Defendants.

72. Prior to the manufacture, sale, and distribution of SLGT2 INHIBITOR, Defendants knew that the drug was in a defective condition and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the drug presented a substantial and unreasonable risk of harm to the public, including Decedent. As such, Defendants unreasonably subjected consumers of SLGT2 INHIBITOR to risk of injury or death.

73. Despite their knowledge, Defendants, acting through their officers, directors and managing agents, for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in SLGT2 INHIBITOR and failed to adequately warn the public, including Decedent, of the extreme risk of injury occasioned by said defects. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of SLGT2 INHIBITOR knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

74. Defendants' conduct was committed with willful and conscious disregard for the safety of Decedent, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor on this Count for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further

relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT V
BREACH OF EXPRESS WARRANTY

75. Plaintiff restate the allegations set forth above as if fully rewritten herein.

76. At all times material hereto, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing, promoting, selling, and/or distributing SLGT2 INHIBITOR, which is unreasonably dangerous and defective, thereby placing SLGT2 INHIBITOR into the stream of commerce.

77. Defendants expressly represented to Decedent, other consumers, Decedent's physicians, and the medical community, by and through statements made and written materials disseminated by Defendants or their authorized agents or sales representatives, that SLGT2 INHIBITOR:

a. was safe and fit for its intended purposes;

b. was of merchantable quality;

c. did not produce any dangerous side effects; and,

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

78. These express representations include incomplete prescribing information that purports, but fails, to include the true risks associated with use of SLGT2 INHIBITOR. In fact, Defendants knew or should have known that the risks identified in SLGT2 INHIBITOR's prescribing information and package inserts do

not accurately or adequately set forth the drug's true risks. Despite this, Defendants expressly warranted SLGT2 INHIBITOR as safe and effective for use.

79. Defendants advertised, labeled, marketed, and promoted SLGT2 INHIBITOR, representing the quality to health care professionals, Decedent, and the public in such a way as to induce SLGT2 INHIBITOR's purchase or use, thereby making an express warranty that SLGT2 INHIBITOR would conform to the representations. More specifically, the prescribing information for SLGT2 INHIBITOR did not and does not contain adequate information about the true risks of developing the injuries complained of herein.

80. Despite this, Defendants expressly represented that SLGT2 INHIBITOR was safe and effective, that it was safe and effective for use by individuals such as Decedent, and/or that it was safe and effective to treat diabetes. Portions of the prescribing information relied upon by Plaintiff and his health care professionals, including the "Warnings and Precautions" section, purport to expressly include the risks associated with the use of SLGT2 INHIBITOR, but those risks are neither accurately nor adequately set forth.

81. The representations about SLGT2 INHIBITOR contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

82. SLGT2 INHIBITOR does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries. Therefore, Defendants breached the aforementioned warranties.

83. At all relevant times, SLGT2 INHIBITOR did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

84. Neither Decedent nor his prescribing health care professionals had knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning SLGT2 INHIBITOR.

85. Decedent, other consumers, Decedent's physicians, and the medical community justifiably and detrimentally relied upon Defendants' express warranties when prescribing and ingesting SLGT2 INHIBITOR.

86. Had the prescribing information for SLGT2 INHIBITOR accurately and adequately set forth the true risks associated with the use of such product, including Decedent's injuries, rather than expressly excluding such information and warranting that the product was safe for its intended use, Decedent could have avoided the injuries complained of herein.

87. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe and permanent injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses prior to his death. Decedent suffered diminished capacity for the enjoyment of life, a diminished quality of life, premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Decedent endured mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor on this Count for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT VI
BREACH OF IMPLIED WARRANTY

88. Plaintiff restates the allegations set forth above as if fully rewritten herein.

89. Defendants manufactured, distributed, advertised, promoted, and sold SLGT2 INHIBITOR.

90. At all relevant times, Defendants knew of the use for which SLGT2 INHIBITOR was intended, and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

91. Defendants were aware that consumers, including Decedent, would use SLGT2 INHIBITOR for treatment of type 2 diabetes and for other purposes, including but not limited to weight loss, and reduced blood pressure.

92. SLGT2 INHIBITOR was neither safe for its intended use nor of merchantable quality, as impliedly warranted by Defendants, in that SLGT2 INHIBITOR has dangerous propensities when used as intended and can cause serious injuries, including stroke, heart attack, ketoacidosis, severe kidney damage, and respiratory failure.

93. At all relevant times, Defendants intended that SLGT2 INHIBITOR be used in the manner used by Decedent, and Defendants impliedly warranted it to be

of merchantable quality, safe, and fit for such use, despite the fact that SLGT2 INHIBITOR was not adequately tested.

94. Defendants were aware that consumers, including Decedent, would use SLGT2 INHIBITOR as marketed by Defendants. As such, Decedent was a foreseeable user of SLGT2 INHIBITOR.

95. Upon information and belief, Decedent and/or his health care professionals were at all relevant times in privity with Defendants.

96. SLGT2 INHIBITOR was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Decedent's injuries.

97. Decedent and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell SLGT2 INHIBITOR only if it was indeed of merchantable quality and safe and fit for its intended use.

98. Defendants breached their implied warranty to consumers, including Decedent. SLGT2 INHIBITOR was not of merchantable quality, nor was it safe and fit for its intended use.

99. Decedent and his physicians reasonably relied upon Defendants' implied warranty for SLGT2 INHIBITOR when prescribing and ingesting SLGT2 INHIBITOR.

100. Decedent's use of SLGT2 INHIBITOR was as prescribed and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

101. SLGT2 INHIBITOR was expected to reach and did in fact reach consumers, including

102. Decedent, without substantial change in the condition in which it was manufactured and sold by Defendants.

103. Defendants breached the warranties of merchantability and fitness for its particular purpose because SLGT2 INHIBITOR was unduly dangerous and caused undue injuries, including Decedent's injuries.

104. The harm caused by SLGT2 INHIBITOR far outweighed its alleged benefit, rendering SLGT2 INHIBITOR more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products.

105. Neither Decedent nor his health care professionals reasonably could have discovered or known of the risk of serious injury and death associated with SLGT2 INHIBITOR.

106. Defendants' breach of these implied warranties caused Decedent's injuries.

107. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe and permanent injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses prior to his death. Decedent suffered diminished capacity for the enjoyment of life, a diminished quality of life, premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Decedent endured mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor on this Count for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT VII
FRAUDULENT MISREPRESENTATION

108. Plaintiff restates the allegations set forth above as if fully rewritten herein.

109. Defendants made fraudulent misrepresentations with respect to SLGT2 INHIBITOR in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that SLGT2 INHIBITOR had been tested and found to be safe and effective for the treatment of diabetes; and,

b. upon information and belief, Defendants represented that SLGT2 INHIBITOR was safer than other alternative medications.

110. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of SLGT2 INHIBITOR to Decedent, other consumers, Decedent's physicians, and the medical community.

111. The representations were made by the Defendants with the intent that doctors and patients, including Decedent and his physicians, rely upon them.

112. Defendants' representations were made with the intent of defrauding and deceiving Decedent, other consumers, Decedent's physicians, and the medical community to induce and encourage the sale of SLGT2 INHIBITOR.

113. Decedent, his doctors, and others relied upon these representations.

114. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe and permanent injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses prior to his death. Decedent suffered diminished capacity for the enjoyment of life, a diminished quality of life, premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Decedent endured mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor on this Count for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT VIII
NEGLIGENT MISREPRESENTATION

115. Plaintiff restates the allegations set forth above as if fully rewritten herein.

116. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning SLGT2 INHIBITOR, to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

117. Defendants disseminated to health care professionals and consumers — through published labels, marketing materials, and otherwise — information that misrepresented the properties and effects of SLGT2 INHIBITOR with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe or ingest SLGT2 INHIBITOR.

118. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of SLGT2 INHIBITOR, knew or reasonably should have known that health care professionals and consumers of SLGT2 INHIBITOR rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of prescribing or ingesting SLGT2 INHIBITOR.

119. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of SLGT2 INHIBITOR were accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

120. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of SLGT2 INHIBITOR, knew or reasonably should have known that health care professionals would write prescriptions for SLGT2 INHIBITOR in

reliance on the information disseminated by Defendants, and that the patients receiving prescriptions for SLGT2 INHIBITOR would be placed in peril of developing serious and potential life threatening injuries if the information disseminated by Defendants and relied upon was materially inaccurate, misleading, or otherwise false.

121. From the time SLGT2 INHIBITOR was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety of SLGT2 INHIBITOR. Defendants made material misrepresentations to Decedent, his health care professionals, the healthcare community, and the general public, including:

a. stating that SLGT2 INHIBITOR had been tested and found to be safe and effective for the treatment of diabetes;

b. concealing, misrepresenting, and actively downplaying the severe and life-threatening risks of harm to users of SLGT2 INHIBITOR, when compared to comparable or superior alternative drug therapies; and,

c. misrepresenting SLGT2 INHIBITOR's risk of unreasonable, dangerous, adverse side effects.

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

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

124. Defendants made these representations with the intent to induce reliance thereon, and to encourage the prescription, purchase, and use of SLGT2 INHIBITOR.

125. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Decedent, the truth regarding Defendants' claims that SLGT2 INHIBITOR had been tested and found to be safe and effective for treating diabetes.

126. The misrepresentations made by Defendants, in fact, were false and known by

127. Defendants to be false at the time the misrepresentations were made.

128. Defendants failed to exercise ordinary care in making their representations concerning SLGT2 INHIBITOR and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of SLGT2 INHIBITOR.

129. Defendants engaged in a nationwide marketing campaign, over-promoting SLGT2 INHIBITOR in written marketing literature, in written product packaging, and in direct-to-consumer advertising via written and internet advertisements and television commercial ads. Defendants' over-promotion was undertaken by touting the safety and efficacy of SLGT2 INHIBITOR while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening risks of harm to users of SLGT2 INHIBITOR, when compared to comparable or superior alternative drug therapies. Defendants negligently misrepresented SLGT2 INHIBITOR's risk of unreasonable and dangerous adverse side effects.

130. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of SLGT2 INHIBITOR, including Decedent. Defendants had knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

131. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe and permanent injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses prior to his death. Decedent suffered diminished capacity for the enjoyment of life, a diminished quality of life, premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Decedent endured mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor on this Count for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT IX
NEGLIGENT DESIGN

132. Plaintiff restates the allegations set forth above as if fully rewritten herein.

133. At all relevant times, Defendants owed a duty to consumers, including Decedent and his health care professionals, to exercise reasonable care in the design of SLGT2 INHIBITOR.

134. Defendants negligently and carelessly breached this duty of care to Decedent because SLGT2 INHIBITOR was and is unreasonably defective in design as follows:

a. SLGT2 INHIBITOR unreasonably increased the risks of developing Decedent' injuries as complained of herein;

b. SLGT2 INHIBITOR was not reasonably safe as intended to be used;

c. SLGT2 INHIBITOR was more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with like products;

d. SLGT2 INHIBITOR contained insufficient, incorrect, and defective warnings in that it failed to alert health care professionals and users, including Decedent, of the severity of the risks of adverse effects;

e. SLGT2 INHIBITOR was not safe for its intended use;

f. SLGT2 INHIBITOR was not adequately tested; and/or

g. SLGT2 INHIBITOR's risks exceeded any benefit of the drug.

135. Defendants' SLGT2 INHIBITOR 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.

136. At all times relevant hereto, SLGT2 INHIBITOR 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 Decedent.

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

138. Decedent used SLGT2 INHIBITOR for its intended purposes and in a manner normally intended: to treat diabetes.

139. The harm caused by SLGT2 INHIBITOR far outweighed the benefits, rendering the SLGT2 INHIBITOR more dangerous and less effective than an ordinary consumer or health care professionals would expect and more dangerous than alternative products. Defendants could have designed SLGT2 INHIBITOR to make it less dangerous. When Defendants manufactured the SLGT2 INHIBITOR, the state of the industry's scientific knowledge was such that a less risky design was attainable.

140. At the time SLGT2 INHIBITOR left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of SLGT2 INHIBITOR. This was demonstrated by the existence of other diabetes medications that had a more established safety profile and a considerably lower risk profile.

141. Decedent could not, in the reasonable exercise of care, have discovered the defects of SLGT2 INHIBITOR and perceived its danger.

142. The defects in SLGT2 INHIBITOR were substantial contributing factors in causing

143. But for Defendants' acts and omissions, Decedent would not have suffered the injuries complained of herein.

144. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe and permanent injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses prior to his death. Decedent suffered diminished capacity for the enjoyment of life, a diminished quality of life, premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Decedent endured mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor on this Count for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT X
FRAUDULENT CONCEALMENT

145. Plaintiff restates the allegations set forth above as if fully rewritten herein.

146. Throughout the relevant time period, Defendants knew that SLGT2 INHIBITOR was defective and unreasonably unsafe for its intended purpose, and

intentionally and willfully failed to disclose and/or suppressed information regarding the true nature of the risks of use of SLGT2 INHIBITOR.

147. Defendants fraudulently concealed information with respect to SLGT2 INHIBITOR in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that SLGT2 INHIBITOR was safe and fraudulently withheld and concealed information about the severity of the substantial risks of using SLGT2 INHIBITOR; and,

b. upon information and belief, Defendants represented that SLGT2 INHIBITOR was safer than other alternative medications and fraudulently concealed information which demonstrated that SLGT2 INHIBITOR was not safer than alternatives available on the market.

148. Defendants were under a duty to Decedent to disclose and warn of the defective and dangerous nature of SLGT2 INHIBITOR because:

a. Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of SLGT2 INHIBITOR;

b. Defendants knowingly made false claims and omitted important information about the safety and quality of SLGT2 INHIBITOR in the documents and marketing materials Defendants provided to physicians and the general public; and.

c. Defendants fraudulently and affirmatively concealed the defective and dangerous nature of SLGT2 INHIBITOR from Decedent.

149. As the designers, manufacturers, sellers, promoters, and/or distributors of SLGT2 INHIBITOR, Defendants had unique knowledge and special expertise regarding SLGT2 INHIBITOR. This placed them in a position of superiority and influence over Plaintiff and his healthcare providers. As such, Decedent and his healthcare providers reasonably placed their trust and confidence in Defendants and in the information disseminated by Defendants.

150. The facts concealed or not disclosed by Defendants to Decedent were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or use SLGT2 INHIBITOR.

151. The concealment and/or non-disclosure of information by Defendants about the severity of the risks caused by SLGT2 INHIBITOR was intentional, and the representations made by Defendants were known by them to be false.

152. The concealment of information and the misrepresentations about SLGT2 INHIBITOR were made by Defendants with the intent that doctors and patients, including Decedent, rely upon them so that Decedent would request and purchase SLGT2 INHIBITOR and his health care providers would prescribe and recommend SLGT2 INHIBITOR.

153. Decedent, his doctors, and others reasonably relied on Defendants' representations and were unaware of the substantial risk posed by SLGT2 INHIBITOR

154. Had Defendants not concealed or suppressed information regarding the severity of the risks of SLGT2 INHIBITOR, Decedent and his physicians would not have prescribed or ingested the drug.

155. Defendants, by concealment or other action, intentionally prevented Decedent and their health care professionals from acquiring material information regarding the lack of safety of SLGT2 INHIBITOR, thereby preventing Decedent from discovering the truth. As such, Defendants are liable for fraudulent concealment.

156. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe and permanent injuries and other related health complications. In addition, Decedent required healthcare and services prior to his death. Decedent incurred medical and related expenses. Decedent suffered diminished capacity for the enjoyment of life, a diminished quality of life, premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Decedent endured mental and physical pain and suffering prior to his death.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor on this Count for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT XI
FRAUD

157. Plaintiff restates the allegations set forth above as if fully rewritten herein.

158. Defendants intentionally, willfully, and knowingly, fraudulently misrepresented to Decedent, their prescribing health care professionals, the health care industry, and consumers that SLGT2 INHIBITOR had been adequately tested in clinical trials and was found to be safe and effective as a diabetes treatment.

159. Defendants knew or should have known at the time they made their fraudulent misrepresentations that their material misrepresentations and omissions were false regarding the dangers and risk of adverse health events associated with use of SLGT2 INHIBITOR. Defendants made their fraudulent misrepresentations willfully, wantonly, and with reckless disregard and depraved indifference for the safety and well-being of the users of SLGT2 INHIBITOR, such as Decedent.

160. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the health care industry and consumers, including Decedent and his prescribing health care professionals, so as to induce them to recommend, prescribe, dispense, or purchase SLGT2 INHIBITOR, despite the risk of severe life threatening injury, which Defendants knew were caused by the products.

161. Defendants fraudulently and intentionally concealed material information, as aforesaid. Defendants knew that SLGT2 INHIBITOR was defective and unreasonably unsafe for its intended purpose and intentionally failed to disclose information regarding the true nature of the product's risks.

162. Defendants fraudulently and intentionally failed to disclose and warn of the severity of the injuries described herein, which were known by Defendants to result from use of SLGT2 INHIBITOR.

163. Defendants fraudulently and intentionally suppressed information about the severity of the risks and injuries associated with SLGT2 INHIBITOR from physicians and patients, including Decedent and his prescribing physicians, used sales and marketing documents that contained information contrary to Defendants' internally held knowledge regarding the aforesaid risks and injuries, and overstated the efficacy and safety of the SLGT2 INHIBITOR. For example:

a. SLGT2 INHIBITOR was not as safe and effective as other diabetes drugs given its intended use;

b. ingestion of SLGT2 INHIBITOR does not result in a safe and more effective method of diabetes treatment than other available treatments;

c. the risks of harm associated with the use of the SLGT2 INHIBITOR was greater than the risks of harm associated with other forms of diabetes drug therapies;

d. the risk of adverse events with SLGT2 INHIBITOR was not adequately tested and was known by Defendants, but Defendants knowingly failed to adequately test the product;

e. Defendants knew that the risks of harm associated with the use of SLGT2 INHIBITOR was greater than the risks of harm associated with other forms of diabetes drug therapies, yet knowingly made material misrepresentations and omissions of

fact on which Plaintiff relied when ingesting SLGT2 INHIBITOR;

f. the limited clinical testing revealed that SLGT2 INHIBITOR had an unreasonably high risk of injury, including Decedent' injuries, above and beyond those associated with other diabetes drug therapies;

g. Defendants intentionally and knowingly failed to disclose and concealed the adverse events discovered in the clinical studies and trial results;

h. Defendants had knowledge of the dangers involved with the use of SLGT2 INHIBITOR, which dangers were greater than those associated with other diabetes drug therapies;

i. Defendants intentionally and knowingly failed to disclose that patients using SLGT2 INHIBITOR could suffer severe kidney damage and *sequelae,* and would require monitoring while treating with SLGT2 INHIBITOR drug therapy; and/or

j. SLGT2 INHIBITOR was defective, and caused dangerous and adverse side effects, including the specific injuries described herein.

164. Defendants had access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who ingest SLGT2 INHIBITOR, information that was not publicly disseminated or made available, but instead was actively suppressed by the Defendants.

165. Defendants' intentional concealment and omissions of material fact concerning the safety of SLGT2 INHIBITOR was made with purposeful, willful, wanton, fraudulent, and reckless disregard for the health and safety of Decedent, and with reckless intent to mislead, so as to cause Decedent' prescribing health care professionals to purchase, prescribe, and/or dispense SLGT2 INHIBITOR, and to cause Decedent to rely on Defendants' fraudulent misrepresentations that SLGT2 INHIBITOR was a safe and effective diabetes drug therapy.

166. At the time Decedent purchased and used SLGT2 INHIBITOR, Decedent was unaware that Defendants had made misrepresentations and omissions, and instead Decedent reasonably believed Defendants' representations to constitute true, complete, and accurate portrayal of SLGT2 INHIBITOR's safety and efficacy.

167. Defendants knew and had reason to know that SLGT2 INHIBITOR could and would cause serious personal injury to the users of the products, and that the products were inherently dangerous in a manner that exceeded any purported warnings given by Defendants.

168. In reliance on Defendants' false and fraudulent misrepresentations, Decedent was induced to use and in fact used SLGT2 INHIBITOR, thereby sustaining injuries and damages. Defendants knew and had reason to know that Decedent and their health care professionals did not have the ability to determine the true facts intentionally concealed and suppressed by Defendants, and that Decedent and their health care professionals would not have prescribed and ingested SLGT2 INHIBITOR if the true facts regarding the drug had not been concealed by Defendants.

169. During the marketing and promotion of SLGT2 INHIBITOR to health care professionals, neither Defendants nor the co-promoters who were detailing SLGT2 INHIBITOR on Defendants' behalf, warned health care professionals, including Decedent' prescribing health care professionals, that SLGT2 INHIBITOR caused or increased the risk of harm of severe kidney damage.

170. Decedent reasonably relied upon Defendants' misrepresentations, where knowledge of the concealed facts was critical to understanding the true dangers inherent in the use of SLGT2 INHIBITOR.

171. Defendants willfully, wrongfully, and intentionally distributed false information, assuring Decedent, the public, Decedent's health care professionals, and the health care industry that SLGT2 INHIBITOR was safe for use as a means of diabetes treatment. Upon information and belief, Defendants intentionally omitted, concealed, and suppressed the true results of Defendants' clinical tests and research.

172. Defendants' conduct was intentional and reckless. Defendants risked the lives of consumers and users of SLGT2 INHIBITOR, including Decedent. Defendants knew of SLGT2 INHIBITOR's safety problems, and suppressed this knowledge from the general public. Defendants' intentional and reckless conduct warrants an award of punitive damages.

173. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe and permanent injuries and other related health complications. In addition, Decedent required healthcare and services prior to his death. Decedent incurred medical and related expenses. Decedent suffered diminished capacity for the enjoyment of life, a diminished quality of life, premature death, and other losses and damages.

Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Decedent endured mental and physical pain and suffering prior to his death.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor on this Count for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT XII
LOSS OF CONSORTIUM

174. Plaintiff restates the allegations set forth above as if fully rewritten herein.

175. At all relevant times Plaintiff Donna Royse was and is the spouse of Decedent Terry Royse. As a result of the death of Decedent, as set forth above, Plaintiff Donna Royse has suffered loss of consortium, including but not limited to, mental anguish and the loss of her husband's support, service, society, companionship, comfort, affection, love and solace. As a result of the injuries sustained by Plaintiff, as set forth above, Plaintiff suffered the loss of her husband.

COUNT XIII
VIOLATION OF STATE UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAWS

176. Plaintiff restates the allegations set forth above as if fully rewritten herein.

177. SLGT2 Inhibitor is a product pursuant to the Kentucky Rev. Stat. § 367.100-367.300, and other applicable state consumer protection statutes (the

"Acts"). Defendants knew, or should have known SLGT2 Inhibitor was defective in design and manufacture and its use created the risk of causing serious and life threatening injuries in patients, yet, Defendants knowingly, willfully, and intentionally failed to inform and warn the medical community and the consuming public, including Decedent, of these risks.

178. In violation of the Acts, Defendants engaged in deception, fraud, false pretense, false promise, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts regarding the risk of harm associated with the use of SLGT2 Inhibitor, with the intent that others rely upon such concealment, suppression, or omission, in connection with its sale or advertisement. Defendants omitted and concealed material facts from Decedent and his physicians and healthcare providers in product packaging, labeling, medical advertising, and promotional campaigns and materials, regarding the safety and use SLGT2 Inhibitor. Moreover, Defendants downplayed and understated the serious nature of the risks and dangers associated with the use of SLGT2 Inhibitor to increase their sales, to reap millions of dollars in profits from sales of their products, and to secure a greater market share.

179. Defendants' statements and omissions were undertaken with the intent that the FDA, physicians, healthcare providers, and consumers, including Plaintiff and Decedent, would rely on the Defendants' false and deceptive statements and omissions.

180. Decedent's physicians and healthcare providers prescribed SLGT2 Inhibitor to Plaintiff, who suffered ascertainable losses of money and property as a

result of Defendants' fraudulent methods, acts, practices, and sale of SLGT2 Inhibitor.

181. Defendants' promotion and release SLGT2 Inhibitor into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts with the intent that others, including Plaintiff and Decedent, would rely upon such concealment, suppression, or omission in connection with the sale or advertisement of such merchandise or services by Defendants, in violation of the Acts.

182. Defendants concealed, omitted, and/or minimized the risk of serious and harmful side effects of SLGT2 Inhibitor, and/or provided misinformation about adverse reactions, risks, and potential harm from the use of SLGT2 Inhibitor, and succeeded in persuading physicians to prescribe it despite Defendants' knowledge that it was, and is, unreasonably dangerous and of the risk of adverse health effects connected with SLGT2 Inhibitor, as described in this Complaint.

183. Defendants' practice of promoting and marketing SLGT2 Inhibitor created and reinforced the false impression as to the safety of SLGT2 Inhibitor, thereby placing consumers at serious risk of potential lethal side effects from use of the drug.

184. Defendants violated their duty to warn, post-manufacture, of the injurious and sometimes fatal side effects that arose when Defendants knew, or with reasonable care should have known, that SLGT2 Inhibitor was injurious and sometimes fatal to consumers.

185. Defendants intended, at the time Decedent's healthcare providers prescribed SLGT2 Inhibitor, that physicians and ultimately consumers, would reasonably rely upon the concealment, suppression, or omission by Defendants' officers, directors, agents, employees, principals, and representatives of the risks connected with the use of SLGT2 Inhibitor.

186. Defendants' actions in connection with manufacturing, distributing, and marketing SLGT2 Inhibitor evidence a lack of good faith, the failure of honesty in fact, and failure of observance of fair dealing so as to constitute unconscionable commercial practices, in violation of the Acts.

187. Defendants acted willfully, knowingly, intentionally, unconscionably and with reckless indifference for the health, safety, and well-being of the consumers of SLGT2 Inhibitor when committing the above-described acts of consumer fraud. As a foreseeable, direct, and proximate result of Defendants' fraud upon the consumers of SLGT2 Inhibitor, Decedent's healthcare providers prescribed (and Plaintiff and Plaintiff's insurance company, were billed for) an unreasonably dangerous and unsafe product and incurred monetary damages and expenses.

188. As a proximate result of Defendants' acts and omissions and Decedent's ingestion of SLGT2 Inhibitor, Decedent lost his life and Plaintiff incurred substantial medical costs and expenses.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor on this Count for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further

relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT XIV
WRONGFUL DEATH

189. Plaintiff adopts by reference each and every paragraph of this Complaint as if fully copied and set forth at length herein.

190. Plaintiff is the living heir of the Decedent. Plaintiff is the proper beneficiary. Plaintiff intends to introduce evidence of economic damages and mental anguish damages at the time of trial.

COUNT XV
SURVIVOR

191. Plaintiff adopts by reference each and every paragraph of this Complaint as if fully copied and set forth at length herein.

192. Plaintiff is the living heir of the Decedent. Plaintiff is the proper beneficiary. Plaintiff intends to introduce evidence of economic damages and mental anguish damages at the time of trial.

COUNT TWELVE
UNJUST ENRICHMENT

193. Plaintiff restates the allegations set forth above as if fully rewritten herein.

194. Decedent conferred a benefit on Defendants by purchasing SLGT2 Inhibitor.

195. Decedent did not receive a safe and effective drug for which they paid.

196. It would be inequitable for the Defendants to retain this money because Decedent did not, in fact, receive a safe and efficacious drug. By virtue of

the conscious wrongdoing alleged in this Complaint, Defendants have been unjustly enriched at the expense of Plaintiff and Decedent, who hereby seeks the disgorgement and restitution of Defendants' wrongful profits, revenue, and benefits, to the extent, and in the amount, deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor on this Count for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

PRAYER FOR RELIEF

WHEREFORE, on the basis of each and all of the foregoing claims and causes of action herein asserted against Defendants, jointly and severally, Decedent pray for relief and judgment against each and all of the Defendants, individually, and jointly and severally, as follows:

1. Compensatory damages, medical expenses and other economic damages, pain and suffering, and non-economic damages;
2. Punitive damages in favor of Plaintiff in the amount of $5,000,000;
3. Pre-judgment interest at the highest lawful rate allowed by law;
4. Post-judgment interest on the judgment at the highest legal rate from the date of judgment until collected;
5. Damages for loss of care, comfort, society, and companionship;

6. Restitution, disgorgement of profits, and other equitable relief;
7. Attorneys' fees, expenses, and costs of this action; and,
8. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiff respectfully requests pursuant to the Seventh Amendment to the United States Constitution, for a jury trial on all issues of fact and law to which they are entitled. Such jury demand is timely and properly made pursuant to Fed. R. Civ. P. 38(a) and (b)(1).

Respectfully submitted,

s/Alex C. Davis
JONES WARD PLC
Alex C. Davis
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312 S. Fourth Street, 6th Floor
Louisville, Kentucky 40202
Tel. (502) 882-6000
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Counsel for Plaintiff

Jason C. Webster, Pro Hac Vice Pending
The Webster Law Firm
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Tel. (713) 581-3900
Fax (502) 581-3907
Counsel for Plaintiff

JS 44 (Rev. 08/16)

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

Donna Royse, Individually and as Representative of the Estate of Terry Royse.

(b) County of Residence of First Listed Plaintiff Montgomery County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Alex C. Davis, Jones Ward PLC, 312 S. Fourth St., 6th Floor
Louisville KY 40204. Tel. 502-882-6000

DEFENDANTS

Janssen Pharmaceuticals, Inc., Janssen Research and Development, LLC., et al

County of Residence of First Listed Defendant Mercer County
(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
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 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)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

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

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
❒ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	❒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		❒ 820 Copyrights	❒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	❒ 830 Patent	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	❒ 370 Other Fraud	❒ 710 Fair Labor Standards Act	❒ 840 Trademark	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 371 Truth in Lending	❒ 720 Labor/Management Relations	SOCIAL SECURITY	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 380 Other Personal Property Damage	❒ 740 Railway Labor Act	❒ 861 HIA (1395ff)	❒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 385 Property Damage Product Liability	❒ 751 Family and Medical Leave Act	❒ 862 Black Lung (923)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury		❒ 790 Other Labor Litigation	❒ 863 DIWC/DIWW (405(g))	❒ 490 Cable/Sat TV
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 791 Employee Retirement Income Security Act	❒ 864 SSID Title XVI	❒ 850 Securities/Commodities/ Exchange
❒ 196 Franchise				❒ 865 RSI (405(g))	❒ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	❒ 891 Agricultural Acts
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	Habeas Corpus:	❒ 462 Naturalization Application	❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 893 Environmental Matters
❒ 220 Foreclosure	❒ 441 Voting	❒ 463 Alien Detainee	❒ 465 Other Immigration Actions	❒ 871 IRS—Third Party 26 USC 7609	❒ 895 Freedom of Information Act
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 510 Motions to Vacate Sentence			❒ 896 Arbitration
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 530 General			❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	❒ 535 Death Penalty			❒ 950 Constitutionality of State Statutes
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	Other:			
	❒ 448 Education	❒ 540 Mandamus & Other			
		❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

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 U.S. § 1332

Brief description of cause:
Product liability pharmaceutical

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 _____ DOCKET NUMBER MDL 2750

DATE
11/28/2016

SIGNATURE OF ATTORNEY OF RECORD
s/ Alex C. Davis

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.