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UNITED STATES DISTRICT COURT FOR THE

NORTHERN DISTRICT OF CALIFORNIA

Diana Ford, individually and as personal representative of the estate of Bruce Ford, Plaintiff, -vs.- GLOBAL BLOOD THERAPEUTICS, INC. and PFIZER, INC. Defendants.	**CASE NO.:** 3:25-cv-4229 **COMPLAINT FOR DAMAGES FOR** **1) STRICT LIABILITY, DESIGN DEFECT;** **2) STRICT LIABILITY, FAILURE TO WARN;** **3) NEGLIGENCE;** **4) NEGLIGENT MISREPRESENTATION;** **5) BREACH OF EXPRESS WARRANTIES;** **6) BREACH OF IMPLIED WARRANTIES;** **7) UNJUST ENRICHMENT;** **8) VIOLATION OF THE TENNESSEE CONSUMER PROTECTION ACT, Tenn. Code Ann. § 47-18-101, et seq.;** **9) LOSS OF CONSORTIUM;** **10) WRONGFUL DEATH; and** **11) SURVIVAL ACTION** **DEMAND FOR JURY TRIAL**

Plaintiff Diana Ford, individually and as personal representative of the estate of Bruce Ford, by and through her undersigned counsel, bring this civil action against Defendants Global Blood Therapeutics, Inc. and Pfizer, Inc. (collectively "Defendants") for personal injuries and damages, and allege the following:

INTRODUCTION

1. This is an action for damages related to Defendants' wrongful conduct in connection with the development, design, testing, manufacturing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of Oxbryta® (generic name: voxelotor), a prescription medication used to treat sickle cell disease ("SCD") in adults and children aged 4 and older.

2. Oxbryta is a brand name prescription medication, manufactured as an oral, once-daily

therapy for patients with SCD.

3. On September 25, 2024, Defendant Pfizer, Inc. announced that it was voluntarily withdrawing all lots of Oxbryta, in all markets where it is approved (hereinafter the Recall).[1] The decision came after "data showed an imbalance in Vaso-occlusive crises ("VOCs"), a complication of the disease and "fatal events" that required further assessment."[2]

4. Defendants knew or should have known that Oxbryta, when administered and prescribed as intended, can cause or substantially contribute to VOCs and even death.

5. Numerous patient reports and scientific studies have established that Oxbryta causes increased VOCs and death. Two registry-based studies found that patients had a higher occurrence of vaso-occlusive crises during treatment with Oxbryta than they did prior to starting the medication. In addition, data from two separate clinical trials showed a higher number of deaths than with placebo and/or than anticipated.

6. Nevertheless, Defendants failed to warn, instruct, advise, educate, or otherwise inform Oxbryta users and prescribers about the risk of VOCs and/or death.

7. On September 25, 2024, Defendants withdrew Oxbryta from the market, ceased distribution, and discontinued all active clinical trials due to safety concerns and the dangers associated with the use of Oxbryta as intended and prescribed.

8. As a proximate result of Defendants' wrongful actions and inactions, Bruce Ford was seriously injured after consuming Defendants' Oxbryta product.

9. Oxbryta caused Bruce Ford to suffer multiple additional vaso-occlusive crises requiring hospitalization, a stroke, and death. Vaso-occlusive crises (VOCs) are characterized by severe pain caused by sickled red blood cells blocking blood flow and oxygen delivery to tissues. VOCs occur when

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[1] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-voluntarily-withdraws-all-lots-sickle-cell-disease

[2] https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-withdraws-sickle-cell-disease-treatment-all-markets-2024-09-25/

sickled red blood cells irritate the lining of blood vessels and cause an inflammatory response leading to vascular occlusion, tissue ischemia and pain. VOCs can lead to additional health complications, including anemia, arthritis, acute chest syndrome, kidney and other organ failure, stroke, and death.

10. Plaintiff Diana Ford was the spouse of and is the personal representative of the estate of Bruce Ford. As a result of the decedent, Bruce Ford's, injuries and death resulting from the use of Oxbryta, Plaintiff Diana Ford brings a claim on behalf of his estate and on her own behalf having suffered emotional stress and the loss of the care and companionship of her husband, as detailed below.

11. Plaintiff therefore demands judgment against Defendants and request, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

PARTIES

12. Plaintiff Diana Ford is a natural person and resident of Tennessee. Plaintiff brings this suit in her personal capacity.

13. Plaintiff Diana Ford was officially appointed as the Personal Representative of the Estate of Bruce Ford. *See* Exhibit A. The Chancery Court of Claiborne County, Tennessee has issued Letters of Administration to Diana Ford. *Id.*

14. Defendant Global Blood Therapeutics, Inc. ("Global Blood Therapeutics") is a Delaware corporation, with its principal executive offices located at 181 Oyster Point Boulevard, South San Francisco, California 94080.

15. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation, with its principal executive offices located at 66 Hudson Boulevard East, New York, New York and is licensed to do business in all states of the United States of America, including the States of California and Illinois.

16. Global Blood Therapeutics is a biopharmaceutical company that was founded in 2011 with the goal of developing treatments for patients with SCD.

17. Global Blood Therapeutics "discovered and developed" Oxbryta, which was granted

accelerated approval by the U.S. Food and Drug Administration ("FDA") in November 2019.[3]

18. Global Blood Therapeutics submitted new drug applications ("NDAs") for Oxbryta (NDA #213137 and #216157), which were approved in November 2019 and December 2021, respectively.

19. Upon information and belief, Global Blood Therapeutics is a wholly owned subsidiary of Defendant Pfizer since August 2022.

20. On October 5, 2022, Pfizer announced the acquisition of Global Blood Therapeutics, in a transaction "valued at $68.50 per Global Blood Therapeutics share in cash, for a total enterprise value of approximately $5.4 billion."[4]

21. Upon information and belief, Pfizer has effectively held Oxbryta NDA #213137 and #216157 since approximately October 2022 when it acquired Global Blood Therapeutics.

22. Upon information and belief, in or after October 2022, Pfizer assumed responsibility for communicating with physicians, patients, the FDA and other regulatory bodies regarding Oxbryta.

23. At least as early as August 2023, Pfizer's 800 number (1-800-438-1985) and website address (www.pfizer.com) are listed in Oxbryta's Label, Full Prescribing Information, Instructions for Use, and Patient Information describing where to go for more information about the drug, and Pfizer's name and logo appear with the text "Distributed by Global Blood Therapeutics, Inc., A subsidiary of Pfizer Inc." immediately underneath the logo.

24. Pfizer reported $328 million in revenues from Oxbryta in 2023, and $176 million for the first half of 2024.

25. Defendants manufactured and distributed the Oxbryta ingested by Bruce Ford.

26. At all times material herein, Defendants were, and still are, pharmaceutical companies involved in the manufacturing, research, development, marketing, distribution, sale, and release for use

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[3] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-acquisition-global-blood-therapeutics

[4] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-acquire-global-blood-therapeutics-54-billion-enhance

to the general public of pharmaceuticals, including Oxbryta, in California and Illinois, and throughout the United States.

JURISDICTION AND VENUE

27. Jurisdiction over this matter is proper in this Court pursuant to 28 U.S.C.A. § 1331 because of diversity of citizenship of the parties and because the amount in controversy is in excess of $75,000 exclusive of costs and interest.

28. This Court has jurisdiction over Defendant Global Blood Therapeutics because its principal place of business is in San Mateo County, California.

29. This Court also has jurisdiction over Defendant Pfizer because it is a business entity that does sufficient business and has minimum contacts in California or otherwise intentionally avails itself of the California market, through the sale, marketing and use of its products in California, to render the exercise of jurisdiction over it by the California courts consistent with traditional notions of fair play and substantial justice.

30. Defendants regularly conduct business in California and Illinois by, among other things, distributing, marketing, selling and/or profiting from Oxbryta in California and Illinois as well as throughout the United States.

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

32. Venue of this case is proper in California because some or all of the causes of action arose in California.

BRUCE FORD

33. Bruce Ford was a 62-year-old male who was diagnosed with SCD as a child.

34. In 2022, he began taking Oxbryta, as prescribed, for the treatment of SCD. Defendants failed to disclose the dangerous nature of Oxbryta to Bruce Ford or his prescribing physicians.. The risks and harm associated with Oxbryta consumption were not known to the medical or scientific community when Bruce Ford's prescribing physicians prescribed Oxbryta to him. Had Bruce Ford or his prescribing physicians known about the dangers caused by Oxbryta, they would have declined to prescribe Oxbryta

to him and he would not have purchased or consumed Oxbryta.

35. At all relevant times, Defendants represented Oxbryta to be appropriate, safe and suitable for such purposes.

36. Defendants intended that Bruce Ford would rely upon their representations made, *inter alia*, in advertisements and on the Oxbryta packaging that Oxbryta was a safe and effective drug indicated for treatment of SCD. Plaintiff Bruce Ford read and reasonably relied upon Defendants' statements and representations on the Oxbryta label when purchasing and consuming Oxbryta.

37. Bruce Ford's prescribing physicians reviewed and reasonably relied upon the marketing and informational materials published by Defendants, and reviewed and reasonably relied upon Defendants' statements and representations on the Oxbryta label when prescribing Oxbryta to him.

38. While being prescribed and consuming Oxbryta, Plaintiff Bruce Ford suffered a significant number of side effects, including a higher rate of VOCs than prior to starting the medication, pain, swelling, stroke and death – all caused by his consumption of Oxbryta.

39. In April 2024, while still on Oxbryta, Bruce Ford had a VOC which led to a stroke and hospitalization.

40. On May 19, 2024, Bruce Ford died. His death certificate notes the cause of death was stroke and sickle cell disease. As a result of Defendants' actions and inactions, Bruce Ford was seriously injured and died while on Oxbryta.

41. Bruce Ford was unaware that Oxbryta treatment resulted in a higher rate of VOCs. He was also unaware that there were more deaths in the Oxbryta treatment group as compared to the placebo group in post-marketing studies or that there were higher rates of vaso-occlusive crises in patients with sickle cell disease receiving Oxbryta in two real-world registry studies.

42. Defendants failed to timely and adequately warn Bruce Ford and his prescribing physicians of the adverse effects, including reduced oxygen delivery and increased VOCs, associated with Oxbryta despite Defendants' knowledge of it.

43. Defendants paused the sale of Oxbryta in two studies in May 2024 due to safety concerns, including the death of multiple patients taking Oxbryta, yet Defendants allowed Bruce Ford to continue

to take Oxbryta with no warning to him or his prescribing physicians.

44. Defendants' Oxbryta product was at all times utilized and prescribed in a manner foreseeable to Defendants, as Defendants generated the Oxbryta Label, Full Prescribing Information, Instructions For Use, and Patient Information.

45. Bruce Ford's physicians prescribed, and Bruce Ford used, Oxbryta in the manner in which it was intended and recommended to be used. Bruce Ford did not misuse or alter Oxbryta in an unforeseeable manner, making such use reasonably foreseeable to Defendants.

46. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Bruce Ford and his physicians the true and significant risks associated with Oxbryta consumption.

47. At no time did Defendants provide any warning or information to Bruce Ford's prescribing physicians, or to the medical community generally, about the dangerous nature of Oxbryta. The dangerous and defective nature of Oxbryta was not known to Bruce Ford's prescribing physicians when they prescribed Oxbryta to Bruce Ford. Had Defendants informed Bruce Ford's prescribing physicians of the risks of Oxbryta—or had the risks of Oxbryta been generally known in the medical community—Bruce Ford's prescribing physicians would have declined to prescribe Oxbryta to him. Had Defendants or Bruce Ford's prescribing physicians informed him of the dangers of Oxbryta, Bruce Ford would have refused to use Oxbryta.

48. As a result of Defendants' actions, Bruce Ford and his physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that he would be exposed to the risks identified in this Complaint and that those risks were the direct and proximate result of Defendants' conduct.

49. As a direct result of being prescribed and consuming Oxbryta, Bruce Ford suffered and died.

GENERAL ALLEGATIONS

Sickle Cell Disease

50. SCD is a group of inherited red blood cell disorders that affects more than 100,000 people

in the United States and 20 million people worldwide, most of whom are of African descent.

51. SCD is a lifelong condition.

52. Red blood cells contain hemoglobin, a protein that carries oxygen. Healthy red blood cells are round, and they move through small blood vessels to carry oxygen to all parts of the body.

53. In someone who has SCD, the hemoglobin is abnormal, which causes the red blood cells to become hard and sticky and look like a C-shaped farm tool called a sickle. The sickle cells die early, which causes a constant shortage of red blood cells. Also, when they travel through small blood vessels, sickle cells get stuck and clog the blood flow. This can cause pain and other serious health complications such as infection, acute chest syndrome, and stroke.

54. There are several types of SCD. The specific type of SCD a person has depends on the genes they inherited from their parents. People with SCD inherit genes that contain instructions, or code, for abnormal hemoglobin, including:

HbSS: People who have this form of SCD inherit two genes, one from each parent, that code for hemoglobin "S." Hemoglobin S is an abnormal form of hemoglobin that causes the red cells to become rigid, and sickle shaped. This is commonly called sickle cell anemia and is usually the most severe form of the disease.

HbSC: People who have this form of SCD inherit a hemoglobin S gene from one parent and a gene for a different type of abnormal hemoglobin called "C" from the other parent. This is usually a milder form of SCD.

HbS beta thalassemia: People who have this form of SCD inherit a hemoglobin S gene from one parent and a gene for beta thalassemia, another type of hemoglobin abnormality, from the other parent. There are two types of beta thalassemia: "zero" (HbS beta0) and "plus" (HbS beta+). Those with HbS beta0-thalassemia usually have a severe form of SCD. People with HbS beta+-thalassemia tend to have a milder form of SCD.

55. SCD is diagnosed with a simple blood test. In children born in the United States, it most often is found at birth during routine newborn screening tests at the hospital. In addition, SCD can be diagnosed while the baby is in the womb. Diagnostic tests before the baby is born, such as chorionic

villus sampling and amniocentesis, can check for chromosomal or genetic abnormalities in the baby. Chorionic villus sampling tests a tiny piece of the placenta called chorionic villus. Amniocentesis tests a small sample of amniotic fluid surrounding the baby.[5]

The Development of Oxbryta

56. Ted W. Love, a cardiologist and Global Blood Therapeutic's former President and CEO, led the development of Oxbryta. The intent of the drug is to directly inhibit sickle hemoglobin (HbS) polymerization, i.e., to prevent the sickling of red blood cells.

57. The FDA granted voxelotor Fast Track Designation on October 7, 2015, Orphan Drug Designation (#15-4997) on December 29, 2015, Rare Pediatric Disease Designation on June 5, 2017, and Breakthrough Therapy Designation on January 3, 2018.

58. Global Blood Therapeutics obtained FDA approval (NDA #213137) to market Oxbryta under an accelerated approval pathway in November 2019 for the treatment of SCD in adults and pediatric patients 12 years of age and older. In December 2021, Global Blood Therapeutics obtained FDA accelerated approval (NDA #216157) of Oxbryta for the treatment of SCD in patients 4 to 11 years of age.

59. Accelerated approval allows drugs to enter the market early based on a surrogate or intermediate clinical endpoint. FDA defines a surrogate endpoint as "a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit."[6] The surrogate endpoint for which Oxbryta received accelerated approval is an increase in hemoglobin. FDA required post-marketing studies to verify the clinical benefit of Oxbryta.

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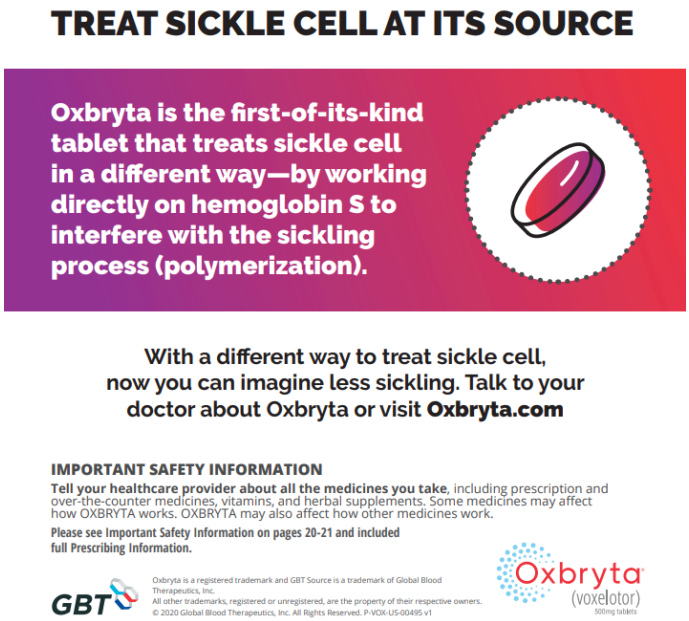
[5] https://www.cdc.gov/sickle-cell/about/index.html#:~:text=Sickle%20cell%20disease%20(SCD)%20is,some%20more%20severe%20than%20others.

[6] https://www.fda.gov/drugs/nda-and-bla-approvals/accelerated-approval-program (last accessed Dec. 5, 2024).

60. Defendants marketed Oxbryta through various forms of media and promised its purchasers would "experience less sickling."[7]

[7] https://www.mmm-online.com/home/channel/first-look-oxbryta-spot-aims-to-empower-patients-with-sickle-cell/

61. Defendant Global Blood Therapeutics called Oxbryta a "firsts-of-its-kind tablet that treats sickle cell. . ." and would lead to "less sickling" by "address[ing] sickling at its source." [8]



Id.

62. Upon information and belief, Global Blood Therapeutics downplayed the significance to the FDA of VOCs and other SCD-related adverse events suffered by individuals taking Oxbryta in its clinical trials, attributing these events to the underlying disease instead of to Oxbryta.[9]

63. Upon information and belief, at no time after receiving accelerated approval did Defendants request permission from the FDA to warn about an increase in VOCs, anemia, acute chest syndrome, stroke, organ failure or death. Nor did Defendants use the "changes being effected" ("CBE") labeling changes provision of 21 C.F.R. § 314.70(c)(6)(iii)(A), (C); 21 C.F.R § 314.3(b) to add or

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[8] https://sicklecellconsortium.org/wp-content/uploads/2020/06/Oxbryta-Core-Patient-Leave-Behind-Electronic-Version-2.pdf

[9] E.g., https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/213137Orig1s000Multidiscipline.pdf (Multi-discipline Review, Nov. 25, 2019, at 140-155 of 259 (last accessed Dec. 5, 2024).

strengthen the warning and precautions or adverse reactions sections of the Oxbryta label to alert patients and physicians of the increased dangers of Oxbryta. Defendants never asked the FDA to consider the possibility of strengthening the Oxbryta label to warn of increased dangers and the FDA never rejected any such proposed changes.

64. At all relevant times, there were other treatments and/or other FDA-approved medications for the treatment of SCD which prescribing physicians could have prescribed as an alternative treatment to Oxbryta, including but not limited to various forms of medications containing Hydroxyurea (a chemotherapeutic agent that increases fetal hemoglobin (HgF)), L-glutamine (Endari®), Crizanlizumab (Adakveo®), blood transfusions, bone marrow transplant, gene therapies, and lifestyle recommendations including hydration management, regular exercise, avoiding triggers by wearing warm clothing and avoiding sudden temperature changes.

Lack of Clinical Benefit and Dangers of Oxbryta

65. The HOPE trial was an international, randomized, double-blind, placebo-controlled, phase 3 trial funded by Global Blood Therapeutics of 274 patients with confirmed sickle cell disease who were randomly assigned to a voxelotor 1500 mg group, a voxelotor 900 mg group or a placebo group.[10] The FDA based its grant of accelerated approval primarily on the HOPE trial.

66. Despite increased hemoglobin concentrations, administration of Oxbryta (voxelotor) in the HOPE trial "did not result in improved clinical outcomes, such as a reduction in the incidence of vaso-occlusive crises, a reduction in the proportion of patients who received red blood cell transfusions, or an increase in patient-reported quality of life."[11] If oxygen delivery were improved from Oxbryta, a reduction in VOCs would be expected. The HOPE trial did not find a reduction in VOCs except in a

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[10] Howard, et al., Voxelotor in adolescents and adults with sickle cell disease (HOPE): long-term follow-up results of an international, randomized, double-blind, placebo-controlled, phase 3 trial. Lancet Haematol 2021; 8:e323-33.

[11] Inusa, et al., Will the changing therapeutic landscape meet the needs of patients with sickle cell disease? Lancet Haematol 2021; 8:e306-307.

small fraction of SCD patients with hemoglobin levels greater than 12g/dL.[12]

67. The failure of the HOPE trial to demonstrate a significant effect on the frequency or severity of VOCs has been attributed to Oxbryta's impairment of oxygen delivery.[13] "The lack of efficacy of voxelotor in ameliorating vaso-occlusion is probably caused by impaired unloading of oxygen in the microcirculation of the organs and tissues due to increased oxygen affinity."[14] Put simply, voxelotor-induced increases in hemoglobin are misleading due to voxelotor's adverse effect on oxygen delivery, which results in a reduction in functional hemoglobin and a worsening of the anemia.[15]

68. Concern that hemoglobin is not a reliable indicator of clinical benefit for Oxbryta due to a net decrease in oxygen delivery has been voiced repeatedly in the medical literature by leaders in the field, including by Global Blood Therapeutics' own consultant, Dr. H. Franklin Bunn, as early as 2017.[16] Upon information and belief, Global Blood Therapeutics did not inform the FDA of the newly-acquired, mounting evidence that, regardless of its effect on hemoglobin, use of Oxbryta would result in a net decrease of oxygen delivery and an increase in SCD-related adverse events, including VOCs.[17]

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[12] Henry, ER, et al., Treatment of sickle cell disease by increasing oxygen affinity of hemoglobin. *Blood.* 2021; 138(13):1172-1181.

[13] Bunn, H.F., Oxygen Delivery in the Treatment of Anemia. N Engl J Med 2022;387:2362-5; Ferrone, F.A., More of the same? Voxelotor spawns a successor, but on what success does it build? Br J Haematol. 2023;202:13-15.

[14] Bunn, H.F., Oxygen Delivery in the Treatment of Anemia. N Engl J Med 2022;387:2362-5.

[15] Alaimo, et al., Therapeutic potential of the latest oxygen affinity-modifying agent, GBT021601, for treating sickle cell disease is questionable. Br J Haematol. 2024;00:1-3.

[16] E.g., Eaton, WA & Bunn, HF, Treating sickle cell disease by targeting HbS polymerization. Blood. 2017; 129(20):2719-2726.

[17] Henry, ER, et al., Treatment of sickle cell disease by increasing oxygen affinity of hemoglobin. Blood. 2021; 138(13):1172-1181; Bunn, H.F., Oxygen Delivery in the Treatment of Anemia. N Engl J Med 2022;387:2362-5; Ferrone, FA. More of the same? Voxelotor spawns a successor, but on what success does it build? Br J Haematol. 2023;202(1):13-15; Alaimo, et al., Therapeutic potential of the latest oxygen affinity-modifying agent, GBT021601, for treating sickle cell disease is questionable. Br J Haematol. 2024;00:1-3.

69. The concern regarding reduced oxygen delivery was reiterated in a single-center, open-label, single-arm, longitudinal pilot study of children with SCA treated with Oxbryta (voxelotor) who had cardiopulmonary exercise testing before and after treatment.[18] The study found that voxelotor treatment did not improve peak oxygen consumption in 9 of 10 children who were on hydroxyurea and had relatively high Hgb F, which is "the singularly most effective molecule in protecting against deleterious complications of sickle hemoglobin."[19] This study raised the concern that "impairment of oxygen delivery from voxelotor-modified Hgb F counters the benefit of Hgb F in inhibiting Hgb S polymerization."[20] The authors concluded that "[i]t is possible that limitation of oxygen delivery played a role in the lack of improvement in exercise capacity in patients treated with voxelotor."[21]

70. Upon information and belief, at no time did Defendants request permission from the FDA to warn physicians and patients about the newly acquired information related to a net decrease in oxygen delivery with Oxbryta, nor did Defendants use the CBE labeling changes provision to alert physicians and patients of same.

71. In 2022, more than two years before Defendant Pfizer withdrew Oxbryta from the market on September 25, 2024, a published systematic review compared Oxbryta with other FDA-approved drugs for the treatment of VOCs in SCD patients. Oxbryta's competitor drugs, L-glutamine and Crizanlizumab, were found to be effective in reducing the frequency of VOCs. Although Oxbryta's effect on increasing hemoglobin levels (its surrogate endpoint) was significant, it was not found to be effective

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[18] Phan, V., et al., Effect of voxelotor on cardiopulmonary testing in youths with sickle cell anemia in a pilot study. Pediatr Blood Cancer. 2023;70:e30423.

[19] *Id.*

[20] *Id.*

[21] *Id.*

in reducing the frequency of VOCs.[22]

72. Although Global Blood Therapeutics publicly presented interim results of its registry studies when the results were consistent with its messaging regarding an increase in hemoglobin,[23] it did not publicly disclose the increase in VOCs and other adverse events associated with Oxbryta until it withdrew the drug from the market near the end of 2024.

73. Global Blood Therapeutic's President and CEO, Dr. Ted W. Love, defended the astronomical $125,000 per year list price of Oxbryta based on the drug's alleged "efficacy against SCD."[24]

74. On September 25, 2024, Pfizer issued a press release in which it announced that it was withdrawing all lots of Oxbryta for the treatment of SCD in all markets where it is approved, and that it was discontinuing all clinical trials of the drug worldwide. Pfizer explained that its decision was "based on the totality of clinical data that now indicates the overall benefit of Oxbryta no longer outweighs the risk in the approved sickle cell patient population. The data suggest an imbalance in vaso-occlusive crises and fatal events which require further assessment."[25]

75. On September 26, 2024, Dr. Ian Winburn, Pfizer's Chief Medical Affairs Officer of Specialty Care, sent a letter to health care providers with "Important Prescribing Information" which included the following bullet-point summary:

- Newly generated clinical data evaluated by Pfizer and shared with the FDA indicates that

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[22] Dick, et al., (May 11, 2022) Comparing the Safety and Efficacy of L-Glutamine, Voxelotor, and Crizanlizumab for Reducing the Frequency of Vaso-Occlusive Crisis in Sickle Cell Disease: A Systematic Review, Cureus 14(5): e24920. DOI 10.7759/cureus.24920.

[23] E.g., Andemariam, et al., Real-World Experience of Patients with Sickle Cell Disease Treated with Voxelotor: A Multicenter, Retrospective Study. Blood. 2021; 138(Supp. 1):3100-3102.

[24] https://www.genengnews.com/topics/drug-discovery/global-blood-therapeutics-ceo-defends-price-of-sickle-cell-drug-oxbryta/ (last accessed Dec. 6, 2024).

[25] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-voluntarily-withdraws-all-lots-sickle-cell-disease (last accessed Dec. 5, 2024).

the risk profile of Oxbryta in people living with sickle cell disease exceeds the benefits observed in previously generated global research.

- Pfizer is voluntarily suspending distribution of Oxbryta and removing the product from the market at this time.
- Pfizer is also discontinuing all ongoing Oxbryta clinical studies and early access programs.
- Patients should no longer be prescribed Oxbryta. Prescribers should inform those living with sickle cell disease currently on treatment with Oxbryta to stop treatment and discuss alternative treatment options with them.[26]

76. On September 26, 2024, the FDA alerted patients, caregivers and health care professionals of Pfizer's decision to withdraw Oxbryta from the market. The FDA explained that the clinical data reported by Pfizer that formed the basis for this decision included (1) post-marketing clinical trials of Oxbryta that found a higher rate of VOCs in SCD patients on Oxbryta compared to placebo; (2) a higher number of deaths of patients in the Oxbryta treatment group as compared to placebo in those post-marketing studies; and (3) a higher rate of VOCs in SCD patients receiving Oxbryta in two real-world registry studies.[27]

77. Although Pfizer finally announced in September 2024 that it was discontinuing its clinical research studies of voxelotor, according to the European Medicines Agency ("EMA"), Pfizer had paused dosing in two global clinical studies (GBT440-032 and GBT440-042) as of May 2024 due to safety concerns.[28] Pfizer paused and then discontinued these clinical research studies due to multiple deaths of

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[26] https://webfiles.pfizer.com/dear-hcp-letter-oxbryta-us-final-092524 (last accessed Dec. 5, 2024).

[27] https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerting-patients-and-health-care-professionals-about-voluntary-withdrawal-oxbryta-market-due (last accessed Dec. 6, 2024).

[28] European Medicines Agency, Assessment report on temporary measures, Procedure under Article 20 of Regulation (EC) No 726/2004, Oxbryta EMEA/H/A-20/1583/C/004869/0014. Sept. 26, 2024. https://www.ema.europa.eu/en/documents/referral/oxbryta-aricle-20-procedure-assessment-report-temporary-measures_en.pdf (last accessed Dec. 5, 2024).

patients receiving voxelotor.

78. Study GBT440-032 was designed to assess the effects of Oxbryta on the transcranial doppler ultrasound measurements of cerebral arterial blood flow in children from 2 to 15 years of age who have sickle cell disease and are at high risk of stroke. The study recruited 236 patients from Egypt, Ghana, Kenya, Nigeria, Oman, Saudi Arabia, the United States and the United Kingdom and had a global end date of January 11, 2023.[29] There were 8 deaths among the patients taking voxelotor as compared to 2 deaths among the patients taking placebo.[30]

79. Study GBT440-042 was designed to assess the effects of Oxbryta on leg ulcers in 88 patients aged 12 years or older recruited from Brazil, Kenya and Nigeria. Eleven deaths of patients on voxelotor have been reported.[31]

80. The two real-world registry studies for which Pfizer reported to the FDA and EMA a higher rate of VOCs in SCD patients receiving Oxbryta are: (1) "A Retrospective Data Collection and Analysis Study of Patients with Sickle Cell Disease (SCD) Who Have Been Treated with Oxbryta® (Voxelotor)") (Study GBT440-4R1, C5341018) ("RETRO"); and (2) "An Open Label, Observational, Prospective Registry of Participants with Sickle Cell Disease (SCD) Treated with Oxbryta® (Voxelotor)") (Study GBT440-4R2, C5341019) ("PROSPECT").

81. RETRO was completed on February 25, 2022.[32]

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[29] https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-000903-26/FR (last accesed Dec. 5, 2024).

[30] European Medicines Agency, Assessment report on temporary measures, Procedure under Article 20 of Regulation (EC) No 726/2004, Oxbryta EMEA/H/A-20/1583/C/004869/0014. Sept. 26, 2024. https://www.ema.europa.eu/en/documents/referral/oxbryta-article-20-procedure-assessment-report-temporary-measures_en.pdf (last accessed Dec. 5, 2024).

[31] *Id.*

[32]https://www.clinicaltrials.gov/study/NCT04930328?term=voxelotor%20or%20Oxbryta&rank=2&page=1&limit=10&tab=table (last accessed Dec. 5, 2024).

82. PROSPECT was terminated by Pfizer prior to its completion.[33]

83. At or around July 2023, Pfizer assumed responsibility and sponsorship of RETRO and PROSPECT.[34]

84. RETRO is a post-marketing, retrospective, multicenter study conducted at 9 clinical sites in the United States of patients with SCD aged 12 years or older receiving voxelotor. In RETRO, SCD complications were defined as acute chest syndrome, acute pain crisis, cerebral infarct, transient ischemic attack, leg ulcer, priapism, cardiac malfunction and pulmonary hypertension, iron overload, and retinopathy. Based on an interim analysis of SCD complications in 140 patients before and after enrollment in the study: the annualized incidence of any SCD complication pre-Oxbryta and post-Oxbryta were 45.0% and 106.7%, respectively; the annualized incidence of acute chest syndrome pre-Oxbryta and post-Oxbryta were 2.9% and 8.8%, respectively; the annualized incidence of acute pain crisis pre-Oxbryta and post-Oxbryta were 33.6% and 68.7%, respectively; and the annualized incidence of Cardiac Malfunction and Pulmonary Hypertension pre-Oxbryta and post-Oxbryta were 1.4% and 2.8%, respectively, all as set forth in the table below.[35] In short, the incidence of these SCD complications more than doubled once Oxbryta was administered in all of the endpoints as set forth below.

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[33]https://www.clinicaltrials.gov/study/NCT04930445?term=voxelotor%20or%20Oxbryta&rank=1&page=1&limit=10&tab=results&a=11 (last accessed Dec. 5, 2024).

[34]https://www.clinicaltrials.gov/search?term=voxelotor%20or%200Oxbryta&rank=1&page=1&limit=10 (last accessed Dec. 5, 2024).

[35] European Medicines Agency, Assessment report on temporary measures, Procedure under Article 20 of Regulation (EC) No 726/2004, Oxbryta EMEA/H/A-20/1583/C/004869/0014. Sept. 26, 2024. https://www.ema.europa.eu/en/documents/referral/oxbryta-article-20-procedure-assessment-report-temporary-measures_en.pdf (last accessed Dec. 5, 2024).

Annualized Incidence of SCD Complications, Enrolled Population, RETRO Study (Interim Analysis)		
Type of SCD Complication	Pre-Oxbryta (%)	Post-Oxbryta (%)
Any SCD Complications	45	106.7
Acute Chest Syndrome	2.9	8.8
Acute Pain Crisis	33.6	68.7
Cardiac Malfunction and Pulmonary Hypertension	1.4	2.8

85. PROSPECT is a prospective, open-label, multicenter, registry study of SCD patients 4 years of age or older receiving voxelotor. In PROSPECT, based on an exploratory analysis using an interim data cutoff with 161 patients: the number of VOCs pre-Oxbryta and post-Oxbryta were 67 and 1022, respectively; and the number of VOCs per patient-year pre-Oxbryta and post-Oxbryta were 0.49 and 2.71, respectively, as set forth in the table below, again showing a more than doubling of VOCs in patients who took Oxbryta.[36]

VOC Rate by Patient-Years, Subgroup Analysis – Sickle cell anaemia with crisis, Enrolled Population, PROSPECT Study					
Number of VOCs Pre-Oxbryta	Patient-Years Pre-Oxbryta	Number of VOCs Pre-Oxbryta per Patient-Year	Number of VOCs Post-Oxbryta	Patient-Years Post-Oxbryta	Number of VOCs Post-Oxbryta per Patient-Year
67	138	**0.49**	1022	377.81	**2.71**

86. In its analysis of the interim results of RETRO and PROSPECT, the Committee for Medicinal Products for Human Use (CHMP) of the EMA found that "[t]hese additional results strongly suggest an increase in VOCs in comparison to the incidence of VOCs prior to voxelotor treatment." "The CHMP is of the view that the newly submitted data indicating a disbalance in the number of VOCs before and after initiation of treatment with Oxbryta in both registry-based studies raises serious safety concerns."[37]

87. In its September 26, 2024 alert, the FDA stated that it is conducting its own safety review

[36] *Id.*

[37] *Id.*

of the post-marketing clinical trial data for Oxbryta, the real-world registry studies, and post-marketing data from the FDA's Adverse Event Reporting System (FAERS).

88. Almost immediately upon launch of Oxbryta, thousands of adverse events, including serious adverse events, were reported via the FAERS. As of September 30, 2024, 21,498 adverse events related to Oxbryta had been reported, including 8980 serious cases, of which 363 were deaths. The breakdown of adverse events reported annually since 2020 is: 2634 cases in 2020; 3479 cases in 2021; 9517 cases in 2022; 4314 cases in 2023; and 1554 cases in 2024.[38]

89. VOC adverse events reported to the FDA, which were characterized as "Sickle Cell Anemia with Crisis," are set forth in the table below:

Table of Adverse Events Claims Related to Sickle Cell Anaemia with Crisis				
Year	Claims of Crisis	Serious Crisis Claims	Unserious Crisis Claims	Claims Resulting in Deaths
2020	1253	802	451	4
2021	2002	1421	581	9
2022	4646	2282	2364	7
2023	2301	1492	809	5
2024	637	585	52	5
Total	10839	6582	4257	30

From the table it can be seen that of the 21,498 cases, more than half 10,839 (50.4% of all events) reported VOC ("Sickle Cell Anemia With Crisis"). 6,582 of those VOC claims were characterized as "Serious" (60.7%), and 30 resulted in deaths (0.28%).

90. A published analysis of the FAERS database found that adverse events were most frequently reported for voxelotor, as compared to hydroxyurea, L-glutamine and crizanlizumab.[39] Symptoms of headache and abdominal pain were most frequently reported for voxelotor. "[P]ain

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[38] https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis (last accessed Dec. 5, 2024).

[39] Chen, M., et al. Comparative pharmacovigilance assessment of adverse events associated with the use of hydroxyurea, L-glutamine, voxelotor, and crizanlizumab in sickle cell disease. *Am J Hematol.* 2024;99:E37-E41

symptoms were more strongly associated with the use of voxelotor and crizanlizumab."[40] The authors noted that the adverse events in the FAERS database for these drugs are likely underreported.[41]

Defendants' Failure to Test Oxbryta

91. Defendants knew or should have known of the potential of Oxbryta to result in a net decrease of oxygen delivery and an increase in VOCs, anemia, acute chest syndrome, stroke, organ failure and death but failed to adequately test for these adverse effects.

92. Despite the fact that peer-reviewed articles and studies emerged providing evidence of the dangers of Oxbryta, Defendants failed to adequately investigate the threat of Oxbryta resulting in an increase in SCD-related complications.

93. Defendants failed to adequately test Oxbryta to investigate the risks, including the potential of decreased delivery of oxygen and increased VOCs, and the clinical benefits, if any, of the drug. Defendants' trials have been small in size and limited in duration of follow-up. The HOPE trial was not designed or powered to assess or detect the impact of Oxbryta on VOCs.[42]

Defendants' Failure to Warn

94. Despite multiple peer-reviewed publications, Defendants' knowledge of over twenty thousand adverse events, and the interim results of ongoing clinical and registry studies, Defendants continued to manufacture, promote, and distribute Oxbryta without alerting prescribers or patients in labeling, marketing materials, product inserts or otherwise of the increased risks of serious injury, including increased VOCs, anemia, acute chest syndrome, stroke, organ failure and death, from use of Oxbryta.

95. After FDA approval, Defendants acquired new evidence that Oxbryta increased the risk

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[40] *Id.*

[41] *Id.*

[42] Howard, et al., Voxelotor in adolescents and adults with sickle cell disease (HOPE): long-term follow-up results of an international, randomized, double-blind, placebo-controlled, phase 3 trial. Lancet Haematol 2021; 8:e323-33.

of VOCs and other adverse health events and should have prompted a request for a label change for Oxbryta.

96. In their marketing materials, Defendants promoted Oxbryta as a "first-of-its-kind tablet that treats sickle cell in a different way." Defendants claimed that Oxbryta "treat[s] sickle cell at its source" and "interferes with sickle cell at its core." "Because Oxbryta impacts this very first step, it helps to prevent sickling and hemolysis (the breakdown of red blood cells)." Defendants encouraged patients with SCD to "imagine less sickling."[43] In bold font, Defendants proclaimed to patients that "**Oxbryta helps hemoglobin do its job, that is, helping red blood cells deliver oxygen throughout the body."**[44] Defendants repeated these claims, including that "It's your time to experience less sickling with Oxbryta" and that "Oxbryta works at the source to reduce sickling and help red blood cells deliver oxygen throughout your body" in their commercial "It's My Time."[45]

97. Global Blood Therapeutic Inc's President and CEO, as the public face of the company, made repeated representations that Oxbryta is safe and effective, attacks the root cause of SCD, and increases oxygen delivery in SCD patients.[46]

98. According to the Drugs@FDA website, the label for Oxbryta has been updated twice, but Defendants' labels have not contained any warning or any information whatsoever on the propensity of Oxbryta to cause a net decrease in oxygen delivery, increased VOCs, increased SCD-related adverse events, and/or death.

99. Defendants should have warned patients and prescribers, including Bruce Ford and his

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[43] https://sicklecellconsortium.org/wp-content/uploads/2020/06/Oxbryta-Core-Patient-Leave-Behind-Electronic-Version-2.pdf (last accessed Dec. 5, 2024).

[44] "Getting Started on Oxbryta: The first 30 days and beyond," at 13 (attached as Exhibit A).

[45] Oxbryta TV Spot, 'It's My Time' - iSpot.tv (last accessed Dec. 6, 2024).

[46] E.g., https://www.genengnews.com/gen-edge/love-is-on-the-air-the-march-to-cure-sickle-cell-disease/ (last accessed Dec. 6, 2024); https://www.genengnews.com/topics/drug-discovery/global-blood-therapeutics-ceo-defends-price-of-sickle-cell-drug-oxbryta/ (last accessed Dec. 6, 2024).

prescribing physicians, that Oxbryta may result in a net decrease of oxygen delivery and an increase in VOCs, anemia, other SCD-related adverse events, stroke, organ failure and death. Defendants were on notice of these risks from the peer-reviewed literature, reports of adverse events, and their own studies.

100. Defendants could have filed a CBE supplement under Section 314.70(c) of the FDCA to make "moderate changes" to Oxbryta's label without any prior FDA approval.

101. Examples of moderate label changes that can be made via a CBE supplement explicitly include changes "to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction." By definition and by regulation such changes to add a warning based on newly acquired information—such as that imparted by the litany of newly emerging literature and data discussed above—are considered a "moderate change." § 340.70(c)(6)(iii).

102. Recently, the Third Circuit reaffirmed that plain text interpretation of the CBE supplement process in a precedential decision holding that the defendant in that case, Merck, could not rely on a preemption defense based on an allegedly irreconcilable conflict between federal (FDCA) and state (civil tort) law so long as the warning could have been effected via a CBE change. *See generally In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, Case No. 22-3412, D.I. 82 at 73 on the docket (J. Jordan) (3d Cir. Sept. 20, 2024) (noting "the availability of a label change via a CBE supplement is problematic for Merck, as will very often be the case for pharmaceutical companies raising an impossibility defense").

CAUSES OF ACTION

COUNT 1

STRICT LIABILITY – DESIGN DEFECT

103. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

104. Plaintiff brings this strict liability claim against Defendants for defective design with respect to Oxbryta.

105. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting Oxbryta, which is defective and unreasonably dangerous to consumers, including Bruce Ford, thereby placing Oxbryta into the stream

of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, and/or distributed the Oxbryta used by Bruce Ford, as described herein.

106. At all relevant times, Defendants' Oxbryta was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that rendered Oxbryta dangerous for use by or exposure to the public, including Bruce Ford.

107. At all relevant times, Oxbryta reached the intended consumers, handlers, and users or other persons coming into contact with Oxbryta within this judicial district and throughout the United States, including Bruce Ford, without substantial change in its condition as designed, manufactured, sold, distributed, labeled, and/or marketed by Defendants. Defendants had complete and independent control over the testing, creation, design and development of Oxbryta before it sought FDA approval for the drug. Defendants had a duty to create, design, and develop drugs that are reasonably safe for their intended use. In the pre-approval stage, Defendants could have and should have created a safer alternative design.

108. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, packaged, and/or sold Oxbryta within this judicial district and aimed at a consumer market within this judicial district. Defendants were at all relevant times involved in the sales and promotion of Oxbryta marketed and sold in this judicial district.

109. Oxbryta, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and/or marketed by Defendants was defective in design and formulation in that, when Oxbryta left the control of Defendants' manufacturers and/or suppliers, Oxbryta was unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate.

110. Oxbryta, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and/or marketed by Defendants was defective in design and formulation in that, when Oxbryta left the hands of Defendants' manufacturers and/or suppliers, the foreseeable risks

exceeded the alleged benefits associated with its design and formulation.

111. At all relevant times, Defendants knew or had reason to know that Oxbryta was defective and inherently dangerous and unsafe when used in the manner instructed and provided by Defendant.

112. At all relevant times, Oxbryta failed to perform as safely as Bruce Ford's prescribing physicians, Bruce Ford, or any ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

113. Therefore, at all relevant times, Oxbryta, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and/or marketed by Defendants was defective in design and formulation, in one or more of the following ways:

a. When placed in the stream of commerce, Oxbryta was defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate;

b. When placed in the stream of commerce, Oxbryta was unreasonably dangerous in that Oxbryta was hazardous and posed a grave risk of VOCs and other serious illnesses when used in a reasonably anticipated manner;

c. When placed in the stream of commerce, Oxbryta contained unreasonably dangerous design defects and was not reasonably safe when used in areasonably anticipated or intended manner;

d. Defendants did not sufficiently test, investigate, or study Oxbryta;

e. Exposure to Oxbryta presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

f. Defendants knew or should have known at the time of marketing/selling Oxbryta that exposure to Oxbryta could result severe illnesses and injuries and even death;

g. Defendants did not conduct adequate post-marketing surveillance of Oxbryta;

h. Defendants could have employed safer alternative designs and formulations.

114. Bruce Ford used and was exposed to Oxbryta without knowledge of Oxbryta's dangerous characteristics.

115. At all times relevant to this litigation, Bruce Ford used and/or was exposed to the use of Oxbryta in an intended or reasonably foreseeable manner without knowledge of Oxbryta's dangerous characteristics.

116. Bruce Ford could not reasonably have discovered the defects and risks associated with Oxbryta before or at the time of exposure due to the Defendants' suppression or obfuscation of scientific information.

117. The harm caused by Oxbryta far outweighed its benefit, rendering Defendants' drug dangerous to an extent beyond that which an ordinary consumer would contemplate. Oxbryta was and is more dangerous than alternative products, medicines, and/or SCD treatments, and Defendants could have designed Oxbryta to make Oxbryta less dangerous. Indeed, at the time Defendants designed Oxbryta, the state of the industry's scientific knowledge was such that a less risky design or formulation was attainable.

118. At the time Oxbryta 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 Oxbryta.

119. Defendants' defective design of Oxbryta was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of Oxbryta, including Bruce Ford.

120. Therefore, as a result of the unreasonably dangerous condition of Oxbryta, Defendants are strictly liable.

121. The defects in Oxbryta were substantial and contributing factors in causing Bruce Ford's injuries and death, and, but for Defendants' misconduct and omissions, Bruce Ford's physicians would not have prescribed Oxbryta, Bruce Ford would not have ingested Oxbryta, and Bruce Ford would not have sustained injuries from Oxbryta, or died from Oxbryta.

122. Defendants' conduct, as described herein, was reckless. Defendants risked the lives of consumers and users of Oxbryta, including Bruce Ford, with knowledge of the safety problems associated with Oxbryta, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants

an award of punitive damages.

123. As a direct and proximate result of Defendants placing Oxbryta, a defective product, into the stream of commerce, and the resulting injuries, Bruce Ford sustained pecuniary loss including general damages in a sum which exceeds the jurisdictional minimum of this Court.

124. As a proximate result of Defendants placing their Oxbryta, a defective product, into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Bruce Ford suffered great mental anguish and other personal injury, death and damages.

125. As a proximate result of the Defendants placing their Oxbryta, a defective product, into the stream of commerce, as alleged herein, Bruce Ford sustained loss of income and/or loss of earning capacity.

126. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendants 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.

COUNT II:

STRICT LIABILITY – FAILURE TO WARN

127. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

128. Plaintiff brings this strict liability claim against Defendants for failure to warn.

129. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting Oxbryta. Oxbryta was and is defective and unreasonably dangerous to consumers, including Bruce Ford, because Oxbryta did not and does not contain adequate warnings or instructions concerning the dangerous characteristics of Oxbryta. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Oxbryta within this judicial district and aimed at a consumer market. Defendants were at all relevant times involved in the retail and promotion of Oxbryta marketed and sold in in this judicial district.

130. Defendants researched, developed, designed, tested, manufactured, inspected, labeled,

distributed, marketed, promoted, sold, and otherwise released Oxbryta into the stream of commerce, and in the course of same, directly advertised or marketed Oxbryta to consumers and end users, including Bruce Ford, and therefore had a duty to warn of the risks associated with the use of Oxbryta.

131. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure Oxbryta did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Bruce Ford and his prescribing physicians of dangers associated with reasonable and expected use of Oxbryta as prescribed. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

132. At the time of manufacture, Defendants could have provided warnings or instructions regarding the full and complete risks of Oxbryta because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to Oxbryta.

133. Defendants could have and should have submitted a stronger initial label with adequate safety warnings as part of their submission for FDA approval.

134. Defendants could and should have submitted a stronger initial label with adequate safety warnings as part of their submission for FDA approval.

135. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote safety or to minimize the dangers to users and consumers of Oxbryta and to those who would foreseeably use or be harmed by Oxbryta, including Bruce Ford.

136. Even though Defendants knew or should have known that Oxbryta posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with Oxbryta use and exposure. The dangerous propensities of Oxbryta, as described above, were known to Defendants, or were scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold Oxbryta, and were not known to end users and consumers, such as Bruce Ford.

137. Defendants knew or should have known that Oxbryta created significant risks of serious

bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn consumers, i.e., the reasonably foreseeable users, of the risks of exposure to Oxbryta. Defendants have wrongfully concealed information concerning the dangerous nature of Oxbryta, and further, have made false and/or misleading statements concerning the safety of Oxbryta.

138. At all relevant times, Oxbryta reached the intended consumers, handlers, and users or other persons coming into contact with these products within this judicial district and throughout the United States, including Bruce Ford, without substantial change in its condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

139. Bruce Ford was exposed to Oxbryta without knowledge of its dangerous characteristics.

140. At all relevant times, Bruce Ford used and/or was exposed to the use of Oxbryta while using it for its intended or reasonably foreseeable purposes, without knowledge of its dangerous characteristics.

141. Bruce Ford could not have reasonably discovered the defects and risks associated with Oxbryta prior to or at the time of Bruce Ford consuming Oxbryta. Bruce Ford relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Oxbryta.

142. Defendants knew or should have known that the minimal warnings disseminated with Oxbryta were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render Oxbryta safe for its ordinary, intended and reasonably foreseeable uses.

143. The information Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Bruce Ford to utilize Oxbryta safely and with adequate protection. Instead, Defendants 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 and/or exposure to Oxbryta; continued to aggressively promote the efficacy of Oxbryta, even after they knew or should have known of the unreasonable risks from Oxbryta use or exposure; and concealed, downplayed, or otherwise

suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Oxbryta.

144. This alleged failure to warn is not limited to the information contained on Oxbryta's labeling. Defendants should have warned the public about risks associated with Oxbryta through other non-labeling mediums, i.e., promotion, advertisements, public service announcements, and/or public information sources. But Defendants did not disclose these known risks through any medium.

145. Defendants are liable to Plainitff for injuries caused by their negligent or willful failure, as described above, to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of Oxbryta and the risks associated with the use of Oxbryta.

146. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with Oxbryta, Bruce Ford could have avoided the risk of developing injuries and death from Oxbryta, and could have obtained or used alternative medication.

147. The dangers of Oxbryta were not disclosed by Defendants to Bruce Ford's physicians and were not otherwise known by the medical community when Bruce Ford's prescribing physicians prescribed Oxbryta for use by Bruce Ford. Had Bruce Ford's prescribing physicians been informed of the risks of Oxbryta by Defendants, or had those risks been otherwise known by the medical community, they would have declined to prescribe Oxbryta to Bruce Ford. Had Bruce Ford been informed by Defendants or by his prescribing physicians about the risks of Oxbryta, Bruce Ford would have declined to purchase or ingest Oxbryta. As a direct and proximate result of Defendants placing Oxbryta, a defective product, into the stream of commerce, Bruce Ford was injured and died, and sustained pecuniary loss resulting and general damages in a sum exceeding the jurisdictional minimum of this Court.

148. As a proximate result of Defendants placing Oxbryta, a defective product, into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Bruce Ford suffered great mental anguish and other personal injuries and damages.

149. As a proximate result of Defendants placing Oxbryta, a defective product, into the stream of commerce, as alleged herein, Bruce Ford sustained loss of income and/or loss of earning capacity.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against

Defendants 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.

COUNT III:

NEGLIGENCE

150. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

151. Defendants or indirectly, caused Oxbryta to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Bruce Ford. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed and sold Oxbryta within this judicial district and aimed at a consumer market within this district.

152. At all relevant times, Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of Oxbryta, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers and users of the product.

153. At all relevant times, Defendants had a duty to exercise reasonable care in the marketing, advertisement, and sale of Oxbryta. Defendants' duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using Oxbryta and appropriate, complete, and accurate warnings concerning the potential adverse effects of Oxbryta.

154. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known of the hazards and dangers of Oxbryta.

155. Accordingly, at all relevant times, Defendants knew or, in the exercise of reasonable care, should have known that use of Oxbryta products could cause or be associated with Bruce Ford's injuries, and thus, create a dangerous and unreasonable risk of injury to the users of these products, including Bruce Ford.

156. Defendants also knew or, in the exercise of reasonable care, should have known that users and consumers of Oxbryta were unaware of the risks and the magnitude of the risks associated with use of Oxbryta.

157. As such, Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, supply, promotion, advertisement, packaging, sale, and distribution of Oxbryta, in that Defendants manufactured and produced Oxbryta, a defective product; knew or had reason to know of the defects inherent in their products; knew or had reason to know that a user's or consumer's use of the products created a significant risk of harm and unreasonably dangerous side effects; and failed to prevent or adequately warn of these risks and injuries.

158. Defendants were negligent in their promotion of Oxbryta, outside of the labeling context, by failing to disclose material risk information as part of their promotion and marketing of Oxbryta, including the internet, television, print advertisements, etc. Nothing prevented Defendants from being honest in their promotional activities, and, in fact, Defendants had a duty to disclose the truth about the risks associated with Oxbryta in their promotional efforts, outside of the context of labeling.

159. Despite their ability and means to investigate, study, and test the products and to provide adequate warnings, Defendants failed to do so. Indeed, Defendants wrongfully concealed information and further made false and/or misleading statements concerning the safety and use of Oxbryta.

160. Defendants' negligence included:

a. Manufacturing, producing, promoting, formulating, creating, developing,designing, selling, and/or distributing Oxbryta without thorough and adequate pre- and post-market testing;

b. Manufacturing, producing, promoting, formulating, creating, developing,designing, selling, and/or distributing Oxbryta while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of Oxbryta;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Oxbryta was safe for its intended consumer use;

d. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Oxbryta so as to avoid the risk of serious harm associated with the prevalent use of Oxbryta;

e. Failing to design and manufacture Oxbryta so as to ensure they were at least as safe and effective as other medications on the market intended to treat the same symptoms;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendants could reasonably foresee would use Oxbryta;

g. Failing to disclose to Bruce Ford, users/consumers, and the general public that use of Oxbryta presented severe risks of VOCs and other grave illnesses;

h. Failing to warn Bruce Ford, consumers, and the general public that Oxbryta's risk of harm was unreasonable and that there were safer and effective alternative medications and therapies available to Bruce Ford and other consumers;

i. Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of Oxbryta;

j. Representing that Oxbryta was and is safe for its intended use when, in fact, Defendants knew or should have known Oxbryta was not and is not safe for its intended purpose;

k. Declining to make or propose any changes to Oxbryta's product labeling or other promotional materials that would alert consumers and the general public of the risks of Oxbryta;

l. Advertising, marketing, and recommending the use of Oxbryta, while concealing and failing to disclose or warn of the dangers known (by Defendants) to be associated with or caused by the use of or exposure to Oxbryta;

m. Continuing to disseminate information to their consumers, which indicate or imply Oxbryta was and is not unsafe or dangerous for regularconsumer use; and

n. Continuing the manufacture and sale of Oxbryta with the knowledge thatOxbryta is unreasonably unsafe and dangerous.

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

162. Bruce Ford did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to Oxbryta.

163. Defendants' negligence was the proximate cause of Bruce Ford's injuries and death.

164. Defendants' conduct, as described above, was reckless. Defendants regularly risked the lives of consumers and users of their products, including Bruce Ford, with full knowledge of the dangers of Oxbryta. Defendants have made conscious decisions not to redesign, re-label, warn, or otherwise inform the unsuspecting public, including Bruce Ford. Defendants' reckless conduct therefore warrants an award of punitive damages.

165. As a direct and proximate result of Defendants placing Oxbryta, a defective product, into the stream of commerce, Bruce Ford was injured and has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

166. As a proximate result of Defendants placing Oxbryta, a defective product, into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Bruce Ford suffered great mental anguish and other personal injury and damages.

167. As a proximate result of Defendants placing Oxbryta, a defective product, into the stream of commerce, as alleged herein, Bruce Ford sustained a loss of income, and loss of earning capacity.

168. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendants 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.

COUNT IV:

NEGLIGENT MISREPRESENTATION

169. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

170. At all relevant times, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Oxbryta for use by consumers, such as Bruce Ford.

171. Defendants owed a duty to prescribing physicians, other healthcare providers, the medical

and scientific community generally, and to consumers of Oxbryta, including Bruce Ford, to accurately and truthfully represent the risks of Oxbryta. Defendants breached their duty by misrepresenting the safety and known risks of Oxbryta and/or by failing to adequately warn Bruce Ford's prescribing physicians, the medical community, Bruce Ford, and the public about the risks of Oxbryta, including that use of Oxbryta results in a net decrease of oxygen delivery and in increased VOCs, anemia, acute chest syndrome, stroke, organ failure and death, which Defendants knew or in the exercise of diligence should have known.

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

173. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of Oxbryta knew, or reasonably should have known, that patients using Oxbryta would suffer increased VOCs, anemia, acute chest syndrome, stroke, organ failure and death because the information disseminated by Defendants and relied upon by health care professionals and consumers, including Bruce Ford, was materially inaccurate, misleading, or otherwise false.

174. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the risks of Oxbryta was accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers, including via advertising campaigns, labeling materials, print advertisements, and commercial media, that was materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Bruce Ford.

175. Among Defendants' numerous misrepresentations and misleading omissions were Defendants' assurances that Oxbryta was safe, effective, prevents sickling, reduces sickling, increases oxygen delivery, and helps red blood cells deliver oxygen throughout the body. Defendants made these negligent misrepresentations without reasonable ground for believing them to be true.

176. Despite their knowledge of serious problems with Oxbryta, Defendants continued to

market Oxbryta, present at conferences, and distribute medical literature, studies, and other communications to the medical community in an effort to mislead the medical community and the general public about the risks associated with Oxbryta and instead create the image and impression that Oxbryta was safe.

177. Defendants made such statements even after they became aware of serious complications with Oxbryta. Defendants did not reveal (and instead concealed) their knowledge of serious complications which result from the ordinary use of Oxbryta and other bad data demonstrating Oxbryta's dangers.

178. Defendants made these representations with the intent to induce reliance thereon, and to encourage prescribing and using Oxbryta.

179. Defendants knew or should have known that Bruce Ford, Bruce Ford's prescribing physicians, and the general medical community did not have the ability to determine the true facts which were intentionally and/or negligently concealed and misrepresented by Defendants.

180. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Bruce Ford and Bruce Ford's prescribing physicians were induced to, and did, prescribe and use Oxbryta, thereby causing Bruce Ford to suffer severe personal injuries.

181. Bruce Ford and Bruce Ford's prescribing physicians would not have used or prescribed Oxbryta had the true facts not been concealed by Defendants.

182. Defendants had sole access to many of the material facts concerning the defective nature of Oxbryta and its propensity to cause serious and dangerous side effects.

183. At the time Bruce Ford was prescribed and took Oxbryta, Bruce Ford and Bruce Ford's prescribing physicians were unaware of Defendants' negligent misrepresentations and omissions.

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

185. Defendants failed to exercise ordinary care in making their representations concerning Oxbryta.

186. Bruce Ford and Bruce Ford's prescribing physicians reasonably relied upon the

misrepresentations and omissions made by Defendants about Oxbryta. The dangers of Oxbryta were not disclosed by Defendants to Bruce Ford's physicians and were not otherwise known by the medical community when Bruce Ford's prescribing physicians prescribed Oxbryta for use by Bruce Ford. Had Bruce Ford's prescribing physicians been informed of the risks of Oxbryta by Defendants, or had those risks been otherwise known by the medical community, they would have declined to prescribe Oxbryta to Bruce Ford. Had Bruce Ford been informed by Defendants or by his prescribing physicians about the risks of Oxbryta, Bruce Ford would have declined to purchase or ingest Oxbryta. Bruce Ford's and Bruce Ford's prescribing physicians' reliance on the above described misrepresentations and omissions was the direct and proximate cause of Bruce Ford's injuries and death.

187. As a direct and proximate result of reliance upon Defendants' negligent misrepresentations and omissions, Bruce Ford sustained serious bodily injury, pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, medical expenses, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions.

188. Defendants acted intentionally, recklessly, and wantonly without regard for Bruce Ford's rights beyond all standards of decency, entitling Bruce Ford to recover punitive damages.

189. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendants 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.

COUNT V:

BREACH OF EXPRESS WARRANTIES

190. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

191. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting Oxbryta, which was and is defective and unreasonably dangerous to consumers, including Bruce Ford, thereby placing Oxbryta. These actions were under the ultimate control and supervision of Defendants.

192. Defendants had a duty to exercise reasonable care in the research, development, design,

testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of Oxbryta, including a duty to:

a. ensure that Oxbryta did not cause the user unreasonably dangerous side effects;

b. warn of dangerous and potentially fatal side effects; and

c. disclose adverse material facts, such as the true risks associated with the use of and exposure to Oxbryta, when making representations to consumers and the general public, including Bruce Ford.

193. Oxbryta's label, which Plaintiff read prior to ingesting the drug, confirms that it was "indicated for the treatment of sickle cell disease in adults and pediatric patients 4 years of age and older."[47]

194. As alleged throughout this pleading, the ability of Defendants to properly disclose those risks associated with Oxbryta is not limited to representations made on the labeling.

195. Defendants marketed Oxbryta through various forms of media and promised its purchasers would "experience less sickling."[48]

196. At all relevant times, Defendants expressly represented and warranted to the purchasers of their products, by and through statements made by Defendants in labels, publications, package inserts, and other written materials intended for consumers and the general public, that Oxbryta was and is safe to human health and the environment, effective, fit, and proper for its intended use. Defendants advertised, labeled, marketed, and promoted Oxbryta products, representing the quality to consumers and the public in such a way as to induce Oxbryta's purchase or use, thereby making an express warranty that Oxbryta would conform to the representations.

197. These express representations include incomplete warnings and instructions that purport,

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[47] https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213137s006lbl.pdf

[48] https://www.mmm-online.com/home/channel/first-look-oxbryta-spot-aims-to-empower-patients-with-sickle-cell/

but fail, to include the complete array of risks associated with use of and/or exposure to Oxbryta. Defendants knew and/or should have known that the risks expressly included in Oxbryta warnings and labels did not and do not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Defendants expressly represented that Oxbryta products were safe and effective, that they were safe and effective for use by individuals such as the Bruce Ford, and/or that they were safe and effective as consumer medication.

198. The representations about Oxbryta, as set forth herein, 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 would conform to the representations.

199. Defendants placed Oxbryta products into the stream of commerce for sale and recommended its use to consumers and the public without adequately warning of the true risks of developing the injuries associated with the use of Oxbryta.

200. Defendants breached these warranties because, among other things, Oxbryta products were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with its use, and were not merchantable or safe for its intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the warranties in the following ways:

a. Defendants represented through their labeling, advertising, and marketing materials that Oxbryta products were safe, and intentionally withheldand concealed information about the risks of serious injury associated with useof Oxbryta and by expressly limiting the risks associated with use within its warnings and labels; and

b. Defendants represented that Oxbryta was safe for use and intentionally concealed information that demonstrated that Oxbryta could lead to higher risks of VOCs and death.

201. Bruce Ford detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of Oxbryta in deciding to purchase Oxbryta. Bruce Ford reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of

Oxbryta. Bruce Ford would not have purchased or used Oxbryta had Defendants properly disclosed the risks associated with Oxbryta, either through advertising, labeling, or any other form of disclosure.

202. Defendants had sole access to material facts concerning the nature of the risks associated with Oxbryta, as expressly stated within its warnings and labels, and knew that consumers and users such as Bruce Ford could not have reasonably discovered that the risks expressly included in Oxbryta warnings and labels were inadequate and inaccurate.

203. Bruce Ford had no knowledge of the falsity or incompleteness of Defendants' statements and representations concerning Oxbryta.

204. Bruce Ford used and/or was exposed to Oxbryta as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendants.

205. Had the warnings, labels, advertisements, or promotional material for Oxbryta accurately and adequately set forth the true risks associated with the use of Oxbryta, including Bruce Ford's injuries, rather than expressly excluding such information and warranting that Oxbryta was safe for its intended use, Bruce Ford could have avoided the injuries complained of herein.

206. As a direct and proximate result of Defendants' breach of express warranties, Bruce Ford has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

207. As a proximate result of Defendants' breach of express warranties, as alleged herein, there was a measurable and significant interval of time during which Bruce Ford suffered great mental anguish and other personal injury and damages.

208. As a proximate result of Defendants' breach of express warranties, as alleged herein, Bruce Ford sustained a loss of income and/or loss of earning capacity.

209. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendants 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.

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COUNT VI:

BREACH OF IMPLIED WARRANTIES

210. Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

211. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting Oxbryta, which was and is defective and unreasonably dangerous to consumers, including Bruce Ford, thereby placing Oxbryta into the stream of commerce.

212. Before Bruce Ford used Oxbryta, Defendants impliedly warranted to their consumers, including Bruce Ford, that Oxbryta was of merchantable quality and safe and fit for the use for which Oxbryta was intended; specifically, as consumer medication. It was not.

213. Defendants failed to disclose that Oxbryta has dangerous propensities when used as intended and that use of Oxbryta carries an increased risk of developing severe injuries, including Bruce Ford's injuries and death.

214. Bruce Ford was an intended beneficiary of the implied warranties made by Defendants to purchasers of Oxbryta.

215. Oxbryta was expected to reach and did in fact reach consumers and users, including Bruce Ford, without substantial change in the condition in which Oxbryta was manufactured and sold by Defendants.

216. At all relevant times, Defendants were aware that consumers and users of Oxbryta, including Bruce Ford, would use Oxbryta as marketed by Defendants, which is to say that Bruce Ford was a foreseeable user of Oxbryta.

217. Defendants intended that Oxbryta be used in the manner in which Bruce Ford, in fact, used Oxbryta and which Defendants impliedly warranted Oxbryta to be of merchantable quality, safe, and fit for this use, even though Oxbryta was not adequately tested or researched.

218. In reliance upon Defendants' implied warranty, Bruce Ford used Oxbryta as instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by

Defendants.

219. Bruce Ford could not have reasonably discovered or known of the risks of serious injury associated with Oxbryta.

220. Defendants breached their implied warranty to Bruce Ford in that Oxbryta was not of merchantable quality, safe, or fit for its intended use, or adequately tested. Oxbryta has dangerous propensities when used as intended and can cause serious injuries, including those injuries complained of herein.

221. The harm caused by Oxbryta far outweighed its benefit, rendering Oxbryta more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products, medicines, and/or SCD treatments.

222. As a direct and proximate result of Defendants' breach of implied warranty, Bruce Ford has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

223. As a proximate result of the Defendants' breach of implied warranty, as alleged herein, there was a measurable and significant interval of time during which Bruce Ford suffered great mental anguish and other personal injury and damages.

224. As a proximate result of Defendants' breach of implied warranty, as alleged herein, Bruce Ford sustained a loss of income and/or loss of earning capacity.

225. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendants 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.

COUNT VII:

UNJUST ENRICHMENT

226. Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

227. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold, or otherwise released Oxbryta products into the

stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that consumed it, including Bruce Ford.

228. Defendants were unjustly enriched as a result of their wrongful conduct, including through the false and misleading marketing, promotions, and advertisements that omitted disclosure that the products presented an unreasonable risk of substantial bodily injury resulting from its use.

229. Defendants appreciated, recognized, and chose to accept the monetary benefits Plaintiff and Bruce Ford conferred onto Defendants at their detriment. These benefits were the expected result of Defendants acting in their pecuniary interests at the expense of Plaintiff and Bruce Ford.

230. There is no justification for Defendants' enrichment. It would be inequitable, unconscionable, and unjust for Defendants to be permitted to retain these benefits because the benefits were procured as a result of their wrongful conduct.

231. Defendants wrongfully obfuscated the harm caused by their Oxbryta products. Thus, Plaintiff, who mistakenly enriched Defendants by relying on Defendants' misrepresentations of product safety, could not and did not know the effect that using Oxbryta products would have on Bruce Ford's health and life.

232. Plaintiff is entitled to restitution of the benefits Defendants unjustly retained and/or any amounts necessary to return Plaintiff to the position they occupied prior to dealing with Defendant. Plaintiff would expect compensation from Defendants' unjust enrichment stemming from their wrongful actions.

233. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendants 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.

COUNT VIII:

VIOLATION OF THE TENNESSEE CONSUMER PROTECTION ACT (TCPA), Tenn. Code Ann. § 47-18-101, et seq. (2015)

234. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

235. The Tennessee Consumer Protection Act (TCPA), Tenn. Code Ann. § 47-18-101, et seq. (2015), prohibits sellers of goods from representing that goods have sponsorship, approval, characteristics, uses, or benefits that they do not have.

236. Notwithstanding the above-described statute, and the duty imposed upon Defendants by the TCPA, Defendants engaged in an unfair method of competition and/or engaged in a deceptive act or practice. Defendants have willfully violated the TCPA by, among other things,

a. misrepresenting that Oxbryta was safe when in fact Oxbryta was and is unsafe because it has at all relevant times posed an excessively high risk of VOCs and death;

b. failing to disclose to consumers in labeling or otherwise that Oxbryta was and is unsafe for human consumption;

c. continuing to market, advertise and sell Oxbryta after they knew or should have known of Oxbryta's dangers.

237. Defendants' unfair conduct, as described herein, is intentional, and Defendants intended for consumers to rely on their unfair and misleading practices.

238. Defendants' unfair conduct, as described herein, occurred in the course of trade or commerce.

239. Defendants' conduct, as described herein, violates the TCPA because it (1) offends public policy; (2) is immoral, unethical, oppressive, or unscrupulous; and (3) causes substantial injury and death to consumers, including Bruce Ford.

240. Defendants' conduct offends the public policy of Tennessee in that it violates a standard of conduct contained in an existing statute or common law doctrine that typically applies to such a situation. Specifically, among other things, it is unfair and misleading to represent to consumers that a product like Oxbryta is safe when in fact the product is unsafe.

241. Defendants' conduct, as described herein, has caused substantial injury to Bruce Ford.

242. Defendants' deceptive statements and omissions are material because they concern the safety of the product, which is the type of information that consumers, including Bruce Ford, would be expected to rely upon in making purchasing decisions.

243. Defendants' deceptive statements and omissions had the capacity to deceive consumers, including Bruce Ford, by inducing them to purchase and ingest Oxbryta. Defendants intended for consumers, including Bruce Ford, to rely on their deceptive statements and omissions by purchasing Oxbryta.

244. Defendants made their deceptive statements and omissions in the course of conduct involving trade or commerce.

245. Bruce Ford has been injured as a direct and proximate result of Defendants' deceptive conduct in violation of the TCPA. Bruce Ford paid for Oxbryta as a result of Defendants' deceptive statements and omissions.

246. Through their deceptive practices, Defendants have improperly obtained and continues to improperly obtain and retain money from Bruce Ford.

247. The injuries caused by Defendants' conduct is not outweighed by any countervailing benefits to consumers or to competition.

248. Defendants' intentionally made the above representations knowing that they were false, and have continued to distribute material to consumers, which overstates Oxbryta's indications for use and its safety profile.

249. Defendants' conduct was intentional and reckless. Defendants risked the lived of consumers and users of Oxbryta, including Bruce Ford. Defendants knew there representations regarding the approved indications and the safety profile of Oxbryta were false, and they willfully disregarded the risk of harm there representations presented to users of Oxbryta, including Plaintiff.

250. As a foreseeable, direct, and proximate result of Defendants' violation of the TCPA, as alleged herein, Bruce Ford sustained physical injury, death and financial loss.

251. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendants 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.

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COUNT IX

LOSS OF CONSORTIUM

252. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

253. At all relevant times, Diana Ford was legally married to Bruce Ford.

254. As a foreseeable, direct, and proximate result of Defendants' unlawful conduct as described herein, Plaintiff Diana Ford has suffered and will continue to suffer from physical injuries such as emotional distress, economic losses, and other damages.

255. As a foreseeable, direct, and proximate result of Defendants' unlawful conduct Plaintiff Diana Ford has paid and has become liable to pay for medical aid, treatment and for medications for Bruce Ford.

256. As a foreseeable, direct, and proximate result of Defendants' unlawful conduct as described herein, Diana Ford has suffered and will continue to suffer the loss of Bruce Ford's care, comfort, companionship, services, society, love, and affection.

257. Plaintiff Diana martial relationship with Bruce Ford has been impaired and depreciated.

258. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in favor of Diana Ford and against Defendants 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.

COUNT X

WRONGFUL DEATH

259. Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

260. Bruce Ford died as a result of the defects in and undisclosed risks of Defendants' Oxbryta Products and is survived by his wife, Plaintiff Diana Ford.

261. As representative of Bruce Ford's estate, Plaintiff Diana Ford brings this claim on behalf of his lawful heirs.

262. Defendants' wrongful conduct, as described in this Complaint, has foreseeably, directly,

and proximately caused Plaintiff's heirs to suffer the loss of Decedent Bruce Ford's companionship, services, society, love, consortium, and/or all other damages allowed under Tennessee statutes and laws.

263. Bruce Ford's estate representatives and/or surviving heirs further plead all wrongful death damages allowed by statue.

264. Defendants' conduct with respect to their design and sale of their Oxbryta products to Plaintiff and the public was fraudulent, malicious, oppressive, willful, reckless, and/or grossly negligent, and indicates a wanton disregard of the rights of others, justifying an award of punitive or exemplary damages.

COUNT XI

SURVIVAL ACTION

265. Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

266. Bruce Ford has passed away after suffering injuries and losses as a result of Defendants' Oxbryta products and conduct described in this Complaint.

267. As a direct and proximate result of Bruce Ford's reasonably anticipated use of Defendants' Oxbryta products as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, he suffered serious physical and mental injuries, harm, damages, economic and non-economic loss, and loss of time prior to his death.

268. The representative of Bruce Ford's estate brings this claim for damages on behalf of and for the benefit of Plaintiffand Bruce Ford's beneficiaries.

269. Defendants' conduct with respect to their design and sale of their Oxbryta products to Plaintiff and the public was fraudulent, malicious, oppressive, willful, reckless, and/or grossly negligent, and indicates a wanton disregard of the rights of others, justifying an award of punitive or exemplary damages.

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IV. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for a jury trial and for judgment against Defendants, and each of them, as follows **FOR ALL CAUSES OF ACTION:**

1. For past, present and future general damages in an amount to be determined at trial;
2. For past, present and future special damages, including but not limited to past, present and future lost earnings, economic damages and others, in an amount to be determined at trial;
3. Any appropriate punitive or exemplary damages;
4. Any appropriate statutory damages;
5. For costs of suit;
6. For interest as allowed by law;
7. For attorney's fees and costs as applicable;
8. For treble damages as applicable;
9. For such other and further relief as the court may deem proper.

Respectfully submitted,

Dated: May 16, 2025

AYLSTOCK, WITKIN, KREIS & OVERHOLTZ
BRADLEY/GROMBACHER, LLP

By: /s/ *Sin-Ting Mary Liu, Esq.*
Sin-Ting Mary Liu, Esq.
Marcus J. Bradley, Esq.
Kiley L. Grombacher, Esq. .
Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial in this matter.

Dated: May 16, 2025

AYLSTOCK, WITKIN, KREIS & OVERHOLTZ
BRADLEY/GROMBACHER, LLP

By: /s/ *Sin-Ting Mary Liu, Esq.*
Sin-Ting Mary Liu, Esq.
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Attorneys for Plaintiff