

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

W.W., on behalf of herself and as Parent
and Natural Guardian of Minor, Z.C.,

Civil Action No.:

Plaintiffs,

vs.

GLOBAL BLOOD THERAPEUTICS, INC.
and PFIZER, INC.,

Defendants.

PLAINTIFF’S COMPLAINT

AND NOW, come the Plaintiffs, by and through their undersigned counsel, bring this civil action against Defendants Global Blood Therapeutics, Inc. and Pfizer, Inc. (collectively “Defendants”) for personal injuries and damages suffered by Plaintiffs, 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 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). 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.”

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, Plaintiff Z.C. was seriously injured after consuming Defendants' Oxbryta product.

9. Oxbryta caused Plaintiff Z.C. to suffer multiple additional vaso-occlusive crises requiring hospitalization and severe emotional distress. 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 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. Plaintiffs therefore demand judgment against Defendants and request, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

PARTIES

11. Plaintiff, Z.C., by and through his parent and natural guardian W.W., at all times relevant hereto, was and is a minor born on August 17, 2011, age thirteen (13), currently residing in New Kensington, Pennsylvania. Plaintiff is therefore a domicile and citizen of Pennsylvania.

12. Plaintiff, W.W., is the parent and natural guardian of the minor Plaintiff, currently residing in New Kensington, Pennsylvania. Plaintiff is therefore a domicile and citizen of Pennsylvania.

13. Defendant Global Blood Therapeutics, Inc. (“Global Blood Therapeutics”) is a Delaware corporation, with its principal place of business located at 181 Oyster Point Boulevard South, San Francisco, California 94080, and is a citizen of Delaware and California for the purposes of diversity under 28 U.S.C. § 1332(a).

14. Defendant, Pfizer, Inc. (“Pfizer”) is a Delaware corporation, with its principal place of business located at 66 Hudson Boulevard East, New York, New York 10001, and is a citizen of Delaware and New York for the purposes of diversity under 28 U.S.C. § 1332(a).

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

16. 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

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

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

19. 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.”

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

21. 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.

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

23. Defendants manufactured and distributed the Oxbryta ingested by Plaintiff Z.C.

24. 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 to the general public of pharmaceuticals, including Oxbryta, in Pennsylvania, and throughout the United States.

JURISDICTION AND VENUE

25. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. § 1332, as the amount in controversy exceeds \$75,000.00 and the Parties are citizens of different States.

26. All Defendants regularly conduct business in the Commonwealth of Pennsylvania.

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

28. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim, including the distribution, sale, and administration of Oxbryta to Plaintiff and Plaintiff's injuries all occurred in the Western District of Pennsylvania.

FACTS COMMON TO ALL CAUSES OF ACTION
PLAINTIFF Z.C

29. Plaintiff Z.C. is a 13-year-old boy who was diagnosed with SCD as a child.

30. Plaintiff began usage of Voxelotor, then GBT440 study medication, in April of 2021 for the treatment of SCD.

31. Plaintiff Z.C. was thereafter used either Oxbryta or Voxelotor as prescribed until November of 2024.

32. Defendants failed to disclose the dangerous nature of Oxbryta/ Voxelotor to Plaintiff or Plaintiff's prescribing physicians.

33. The risks and harm associated with Oxbryta/ Voxelotor consumption were not known to the medical or scientific community when Plaintiff Z.C.'s prescribing physicians prescribed Oxbryta/ Voxelotor to him. Had Plaintiff Z.C. or his prescribing physicians known about the dangers caused by Oxbryta/ Voxelotor, they would have declined to prescribe Oxbryta/ Voxelotor to him and he would not have purchased or consumed Oxbryta/ Voxelotor.

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

35. While being prescribed and consuming Oxbryta/ Voxelotor, Plaintiff Z.C. suffered a significant number of side effects, including a higher rate of VOCs than prior to starting the medication, pain, swelling, and other debilitating symptoms all caused by his consumption of Oxbryta/ Voxelotor.

36. Plaintiff Z.C. began experiencing intense pain related to VOC crises beginning in 2022, although it did not begin manifesting fully until October of 2023.

37. In response to Plaintiff Z.C.'s intense pain, Plaintiff Z.C.'s physicians prescribed him intense painkillers, including Oxycodone and Morphine.

38. On physicians' orders, Plaintiff Z.C. sought psychiatric help in coping with his chronic illness as a minor.

39. By 2023, Plaintiff Z.C.'s physicians described the pain related to his repeated VOC crises as chronic.

40. At the end of 2023, Plaintiff Z.C.'s physicians decided to perform monthly blood transfusions in response to his pain. It was thought by Z.C.'s physicians that these transfusions would sufficiently lower his sickle hemoglobin levels and lead to a reduction in pain.

41. After transfusions failed to reduce Plaintiff Z.C.'s pain, his physicians began to suspect they may be contributing to his pain.

42. Plaintiff Z.C. was then referred to an expert for liver care, his iron concentration had reached concerning levels.

43. In addition to Plaintiff Z.C.'s chronic pain, he has experienced fevers and acute chest pneumonia.

44. Plaintiff Z.C. was put into critical care and/ or the ICU on several occasions in response to his chronic pain. Plaintiff Z.C. almost died in critical care and/ or the ICU multiple times.

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

46. As a direct result of being prescribed and consuming Oxbryta/Voxelotor, Plaintiff Z.C. suffered and continues to suffer from severe injury and physical pain and suffering.

Sickle Cell Disease

47. 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.

48. SCD is a lifelong condition.

49. 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.

50. 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.

51. 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.

52. 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

The Development of Oxbryta

53. 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.

54. 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.

55. 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.

56. 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.

57. Defendants marketed Oxbryta through various forms of media and promised its purchasers would "experience less sickling."

58. 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.”

59. 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.

60. 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 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.

61. 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 (HbF)), 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

62. 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. The FDA based its grant of accelerated approval primarily on the HOPE trial.

63. 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.” 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 small fraction of SCD patients with hemoglobin levels greater than 12g/dL.

64. 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. “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.

65. 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. 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.

66. 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. 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.” 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.” 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.”

67. 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.

68. 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 in reducing the frequency of VOCs.

69. 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, 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.

70. 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."

71. 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."

72. 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 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.

73. 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.

74. 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. Pfizer paused and then discontinued these clinical research studies due to multiple deaths of patients receiving voxelotor.

75. As set forth herein, Plaintiff Z.C. experienced multiple vaso-occlusive crises and other health complications after the May 2024 discontinuation of the dosing in the two aforementioned clinical studies.

76. 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. There were 8 deaths among the patients taking voxelotor as compared to 2 deaths among the patients taking placebo.

77. 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.

78. 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”).

79. RETRO was completed on February 25, 2022.

80. PROSPECT was terminated by Pfizer prior to its completion.

81. At or around July 2023, Pfizer assumed responsibility and sponsorship of RETRO and PROSPECT.

82. 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 postOxbryta were 45.0% and 106.7%, respectively; the annualized incidence of acute chest syndrome preOxbryta 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. In short, the incidence of these SCD complications more than doubled once Oxbryta was administered in all of the endpoints as set forth below.

83. 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.

84. 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.”

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

86. 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.

87. Of VOC adverse events reported to the FDA, 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%).

88. 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. Symptoms of headache and abdominal pain were most frequently reported for voxelotor. "[P]ain symptoms were more strongly associated with the use of voxelotor and crizanlizumab." The authors noted that the adverse events in the FAERS database for these drugs are likely underreported.

Defendants' Failure to Test Oxbryta

89. 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.

90. 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.

91. 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.

Defendants' Failure to Warn

92. 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.

93. 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.”

94. 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.

95. 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.

96. Defendants should have warned patients and prescribers, including Plaintiff Z.C. and his 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.

97. 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.

98. 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).

99. 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 I
STRICT LIABILITY – DESIGN DEFECT

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

101. Plaintiff Z.C. brings this strict liability claim against Defendants for defective design with respect to Oxbryta/ Voxelotor.

102. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting Oxbryta/ Voxelotor, which is defective and unreasonably dangerous to consumers, including Plaintiff Z.C., thereby placing Oxbryta/ Voxelotor 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/ Voxelotor used by Plaintiff T.C, as described herein.

103. 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 Plaintiff Z.C.

104. 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 Plaintiff Z.C., without substantial change in its condition as designed, manufactured, sold, distributed, labeled, and/or marketed by Defendants. 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.

105. 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.

106. 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.

107. 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.

108. 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 a reasonably 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.

109. Plaintiff Z.C. used and was exposed to Oxbryta without knowledge of Oxbryta's dangerous characteristics.

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

111. Plaintiff Z.C. 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.

112. 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.

113. 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.

114. Defendants' defective design of Oxbryta was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of Oxbryta, including Plaintiff Z.C.

115. Therefore, as a result of the unreasonably dangerous condition of Oxbryta, Defendants are strictly liable to Plaintiff Z.C.

116. The defects in Oxbryta were substantial and contributing factors in causing Plaintiff Z.C.'s injuries, and, but for Defendants' misconduct and omissions, Plaintiff Z.C. would not have sustained injuries.

117. Defendants' conduct, as described herein, was reckless. Defendants risked the lives of consumers and users of Oxbryta, including Plaintiff Z.C., 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.

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

119. 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 Plaintiff Z.C. has suffered great mental anguish and other personal injury and damages

120. As a direct and proximate result of the Defendant's negligent design, Plaintiff Z.C. 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.

WHEREFORE, Plaintiff Z.C. respectfully requests this Court to enter judgment in his 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 (Plaintiff Z.C.)

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

122. Plaintiff Z.C. brings this strict liability claim against Defendants for failure to warn.

123. 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 Plaintiff Z.C., 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.

124. 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 Plaintiff Z.C., and therefore had a duty to warn of the risks associated with the use of Oxbryta.

125. 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 Plaintiff Z.C. 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.

126. 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.

127. 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 Plaintiff Z.C.

128. 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 Plaintiff Z.C.

129. 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.

130. 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 Plaintiff Z.C., without substantial change in its condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

131. Plaintiff Z.C. was exposed to Oxbryta without knowledge of its dangerous characteristics.

132. At all relevant times, Plaintiff Z.C. 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.

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

134. 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.

135. The information Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff Z.C. 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.

136. 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.

137. Defendants are liable to Plaintiff Z.C. 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.

138. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with Oxbryta, Plaintiff Z.C. could have avoided the risk of developing injuries and could have obtained or used alternative medication.

139. The dangers of Oxbryta were not disclosed by Defendants to Plaintiff Z.C.'s physicians and were not otherwise known by the medical community when Plaintiff Z.C.'s prescribing physicians prescribed Oxbryta for use by Plaintiff Z.C. Had Plaintiff Z.C.'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 Plaintiff Z.C.

Had Plaintiff Z.C. been informed by Defendants or by his prescribing physicians about the risks of Oxbryta, Plaintiff Z.C. 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, Plaintiff Z.C. was injured and has sustained pecuniary loss resulting and general damages in a sum exceeding the jurisdictional minimum of this Court.

140. As a direct and proximate result of the Defendant's failure to warn, Plaintiff Z.C. 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.

WHEREFORE, Plaintiff Z.C. respectfully requests this Court to enter judgment in his 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 (Plaintiff Z.C.)

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

142. Defendants, directly or indirectly, caused Oxbryta to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff Z.C. 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.

143. 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.

144. 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.

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

146. 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 Plaintiff Z.C.'s injuries, and thus, create a dangerous and unreasonable risk of injury to the users of these products, including Plaintiff Z.C.

147. 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.

148. 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.

149. 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.

150. 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.

151. 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 Plaintiff Z.C., users/consumers, and the general public that use of Oxbryta presented severe risks of VOCs and other grave illnesses;
- h. Failing to warn Plaintiff Z.C., 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 Plaintiff Z.C. 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 indicates or implies Oxbryta was and is not unsafe or dangerous for regular consumer use; and
- n. Continuing the manufacture and sale of Oxbryta with the knowledge that Oxbryta is unreasonably unsafe and dangerous.

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

153. Plaintiff Z.C. did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to Oxbryta.

154. Defendants' negligence was the proximate cause of Plaintiff Z.C.'s injuries.

155. Defendants' conduct, as described above, was reckless. Defendants regularly risked the lives of consumers and users of their products, including Plaintiff Z.C., 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 Plaintiff Z.C. Defendants' reckless conduct therefore warrants an award of punitive damages.

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

157. 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 Plaintiff Z.C. suffered great mental anguish and other personal injury and damages.

158. As a direct and proximate result of the Defendants' negligence Plaintiff Z.C. 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.

WHEREFORE, Plaintiff Z.C. respectfully requests this Court to enter judgment in his 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 (Plaintiff Z.C.)

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

160. 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 Plaintiff Z.C.

161. Defendants owed a duty to prescribing physicians, other healthcare providers, the medical and scientific community generally, and to consumers of Oxbryta, including Plaintiff Z.C., 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 Plaintiff Z.C.'s prescribing physicians, the medical community, Plaintiff Z.C., 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.

162. 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.

163. 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 Plaintiff Z.C., was materially inaccurate, misleading, or otherwise false.

164. 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 Plaintiff Z.C.

165. 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.

166. 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.

167. 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.

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

169. Defendants knew or should have known that Plaintiff Z.C., Plaintiff Z.C.'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.

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

171. Plaintiff Z.C. and Plaintiff Z.C.'s prescribing physicians would not have used or prescribed Oxbryta had the true facts not been concealed by Defendants.

172. 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.

173. At the time Plaintiff Z.C. was prescribed and took Oxbryta, Plaintiff Z.C. and Plaintiff Z.C.'s prescribing physicians were unaware of Defendants' negligent misrepresentations and omissions.

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

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

176. Plaintiff Z.C. and Plaintiff Z.C.'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 Plaintiff Z.C.'s physicians and were not otherwise known by the medical community when Plaintiff Z.C.'s prescribing physicians prescribed Oxbryta for use by Plaintiff Z.C. Had Plaintiff Z.C.'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 Plaintiff Z.C. Had Plaintiff Z.C. been informed by Defendants or by his prescribing physicians about the risks of Oxbryta, Plaintiff Z.C. would have declined to purchase or ingest Oxbryta. Plaintiff Z.C.'s and Plaintiff Z.C.'s prescribing physicians' reliance on the above-described misrepresentations and omissions was the direct and proximate cause of Plaintiff Z.C.'s injuries.

177. As a direct and proximate result of reliance upon Defendants' negligent misrepresentations and omissions, Plaintiff Z.C. 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.

178. Defendants acted intentionally, recklessly, and wantonly without regard for Plaintiff Z.C.'s rights beyond all standards of decency, entitling Plaintiff Z.C. to recover punitive damages.

WHEREFORE, Plaintiff Z.C. respectfully requests this Court to enter judgment in his 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

179. 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 Plaintiff Z.C., thereby placing Oxbryta. These actions were under the ultimate control and supervision of Defendants.

180. 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 Plaintiff Z.C.

181. 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."

182. 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.

183. Defendants marketed Oxbryta through various forms of media and promised its purchasers would "experience less sickling."

184. 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.

185. These express representations include incomplete warnings and instructions that purport, 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 Plaintiff Z.C., and/or that they were safe and effective as consumer medication.

186. 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.

187. 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.

188. Defendants breached these warranties because, among other things, Oxbryta products were defective, dangerous, and unfit for use, and 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 withheld and concealed information about the risks of serious injury associated with use of 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.

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

190. 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 Plaintiff Z.C. could not have reasonably discovered that the risks expressly included in Oxbryta warnings and labels were inadequate and inaccurate.

191. Plaintiff Z.C. had no knowledge of the falsity or incompleteness of Defendants' statements and representations concerning Oxbryta.

192. Plaintiff Z.C. 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.

193. 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 Plaintiff Z.C.'s injuries, rather than expressly excluding such information and warranting that Oxbryta was safe for its intended use, Plaintiff Z.C. could have avoided the injuries complained of herein.

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

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

196. As a proximate result of Defendants' breach of express warranties, as alleged herein, Plaintiff Z.C. sustained a loss of income and/or loss of earning capacity.

WHEREFORE, Plaintiff Z.C. respectfully requests this Court to enter judgment in his 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 VI
BREACH OF IMPLIED WARRANTIES (Plaintiff Z.C.)

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

198. 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 Plaintiff Z.C., thereby placing Oxbryta into the stream of commerce.

199. Before Plaintiff Z.C. used Oxbryta, Defendants impliedly warranted to their consumers, including Plaintiff Z.C., 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.

200. 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 Plaintiff Z.C.'s injuries.

201. Plaintiff Z.C. was an intended beneficiary of the implied warranties made by Defendants to purchasers of Oxbryta.

202. Oxbryta was expected to reach and did in fact reach consumers and users, including Plaintiff Z.C., without substantial change in the condition in which Oxbryta was manufactured and sold by Defendants.

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

204. Defendants intended that Oxbryta be used in the manner in which Plaintiff Z.C., 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.

205. In reliance upon Defendants' implied warranty, Plaintiff Z.C. used Oxbryta as instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by Defendants.

206. Plaintiff Z.C. could not have reasonably discovered or known of the risks of serious injury associated with Oxbryta.

207. Defendants breached their implied warranty to Plaintiff Z.C. 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.

208. 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.

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

210. 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 Plaintiff Z.C. suffered great mental anguish and other personal injury and damages

211. As a proximate result of Defendants' breach of implied warranty, as alleged herein, Plaintiff Z.C. sustained a loss of income and/or loss of earning capacity.

WHEREFORE, Plaintiff Z.C. respectfully requests this Court to enter judgment in his 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
QUASI-CONTRACT/ UNJUST ENRICHMENT

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

213. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold, or otherwise released Oxbryta into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that consumed Oxbryta, including Plaintiff Z.C.

214. 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 Oxbryta presented an unreasonable risk of substantial bodily injury resulting from its use.

215. Defendants appreciated, recognized, and chose to accept the monetary benefits Plaintiff Z.C. conferred onto Defendants at Plaintiff Z.C.'s detriment. These benefits were the expected result of Defendants acting in their pecuniary interests at the expense of Plaintiff Z.C.

216. 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.

217. Defendants wrongfully obfuscated the harm caused by ordinary and intended consumption of Oxbryta. Thus, Plaintiff Z.C., who mistakenly enriched Defendants by relying on Defendants' misrepresentations of product safety, could not and did not know the effect that using Oxbryta would have on Plaintiff Z.C.'s health.

218. Plaintiff may not be able to recover damages under other causes of action set forth herein, or such damages may not provide an adequate remedy. Accordingly, Plaintiff lacks an adequate remedy at law.

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

WHEREFORE, Plaintiff Z.C. respectfully requests this Court to enter judgment in his 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
CLAIM FOR PAST AND FUTURE MEDICAL EXPENSES ON BEHALF OF W.W.

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

221. Plaintiff W.W. asserts a claim for past and future medical expenses expended to treat the injuries of Plaintiff Z.C. that were proximately caused by the Defendants' harmful conduct as described herein.

A JURY TRIAL IS DEMANDED.

Dated: October 1, 2025

Respectfully submitted,

By: /s/ D. Aaron Rihn

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