AYLSTOCK, WITKIN, KREIS, & OVERHOLTZ, PLLC
Sin-Ting Mary Liu (SBN 282884)
17 East Main Street, Suite 200
Pensacola, Florida 3205
Tel: (850) 202-1010
Fax: (850) 916-7449
Email: mliu@awkolaw.com

BRADLEY/GROMBACHER, LLP
Marcus J. Bradley, Esq. (SBN 174156)
Kiley Lynn Grombacher, Esq. (SBN 245960)
31365 Oak Crest Drive., Suite 240
Westlake Village, California, 91361
Tel: (805) 270-7100
Fax: (805) 270-7589
Email: mbradley@bradleygrombacher.com
Email: kgrombacher@bradleygrombacher.com

Attorneys for Plaintiff Maurice Frazier

UNITED STATES DISTRICT COURT FOR THE

NORTHERN DISTRICT OF CALIFORNIA

MAURICE FRAZIER,

Plaintiff,

-vs.-

GLOBAL BLOOD THERAPEUTICS, INC. and PFIZER, INC.

Defendants.

CASE NO.: 3:25-cv-4027

COMPLAINT FOR DAMAGES

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; and
8) VIOLATIONS OF THE NEW JERSEY CONSUMER FRAUD ACT, 56:8-1, et seq.

DEMAND FOR JURY TRIAL

Plaintiff Maurice Frazier, by and through his undersigned counsel, bring this civil action against Defendants Global Blood Therapeutics, Inc. and Pfizer, Inc. (collectively "Defendants") for personal injuries and damages suffered by Plaintiff, 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

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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/

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 Maurice Frazier was seriously injured after consuming Defendants' Oxbryta product.

9. Oxbryta caused Plaintiff Maurice Frazier 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. Plaintiff therefore demands judgment against Defendants and request, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

PARTIES

11. Plaintiff Maurice Frazier is a natural person and resident of New Jersey.

12. 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.

13. 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 New Jersey.

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

15. 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]

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

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

18. 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]

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

20. 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 Maurice Frazier.

24. At all times material herein, Defendants were, and still are, pharmaceutical companies

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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

involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Oxbryta, in California and New Jersey, and throughout the United States.

JURISDICTION AND VENUE

25. 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.

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

27. 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.

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

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

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

PLAINTIFF MAURICE FRAZIER

31. Plaintiff Maurice Frazier is a 35-year-old male who was diagnosed with SCD as a child.

32. In approximately November 2023, he began taking Oxbryta, as prescribed, for the treatment of SCD. Defendants failed to disclose the dangerous nature of Oxbryta to Plaintiff Maurice Frazier's prescribing physicians or to Plaintiff Maurice Frazier. The risks and harm associated with Oxbryta consumption were not known to the medical or scientific community when Plaintiff Maurice

Frazier's prescribing physicians prescribed Oxbryta to him. Had Plaintiff Maurice Frazier 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.

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

34. Defendants intended that Plaintiff Maurice Frazier 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 Maurice Frazier read and reasonably relied upon Defendants' statements and representations on the Oxbryta label when purchasing and consuming Oxbryta.

35. Plaintiff'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 Plaintiff.

36. While being prescribed and consuming Oxbryta, Plaintiff Maurice Frazier 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.

37. Plaintiff Maurice Frazier was hospitalized in January 2024 with a sickle cell crisis. He was again hospitalized in May 2024, September 2024, and October 2024, each time with an acute sickle cell crisis. During his September and October 2024 hospitalizations, he was also diagnosed with pneumonia.

38. Plaintiff Maurice Frazier visited his hematologist on November 22, 2024, who noted that Plaintiff had suffered from over 10 VOCs within the year.

39. As a result of Defendants' actions and inactions, Plaintiff Maurice Frazier was seriously injured while on Oxbryta.

40. At the time of injury, Plaintiff Maurice Frazier 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.

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

42. 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 Plaintiff Maurice Frazier to continue to take Oxbryta with no warning to him or his prescribing physicians.

43. 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.

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

45. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff Maurice Frazier and his physicians the true and significant risks associated with Oxbryta consumption.

46. At no time did Defendants provide any warning or information to Plaintiff Maurice Frazier'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 Plaintiff Maurice Frazier's prescribing physicians when they prescribed Oxbryta to Plaintiff Maurice Frazier. Had Defendants informed Plaintiff Maurice Frazier's prescribing physicians of the risks of Oxbryta—or had the risks of Oxbryta been generally known in the medical community—Plaintiff Maurice Frazier's prescribing physicians would have declined to prescribe Oxbryta to Plaintiff Maurice Frazier. Had Defendants or Plaintiff Maurice Frazier's prescribing physicians informed Plaintiff Maurice Frazier of the dangers of Oxbryta, Plaintiff Maurice Frazier would have refused to use Oxbryta.

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

48. As a direct result of being prescribed and consuming Oxbryta, Plaintiff Maurice Frazier suffered and continues to suffer from severe injury and physical pain and suffering.

GENERAL ALLEGATIONS

Sickle Cell Disease

49. 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.

50. SCD is a lifelong condition.

51. 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.

52. 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.

53. 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.

54. 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

55. 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.

56. 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.

57. 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

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

of age.

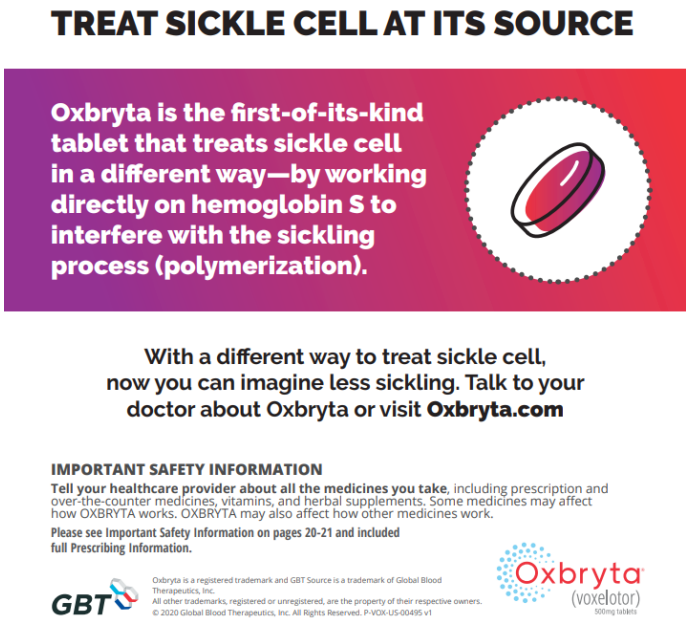
58. Accelerated approval allows drugs to enter the market early based on a surrogate or intermediate clinical endpoint. FDA defines a surrogate endpoint as "a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is 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.

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

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

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

60. 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.

61. 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]

62. 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")

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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).

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.

63. 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

64. 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.

65. 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

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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.

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.[12]

66. 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]

67. 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

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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.

decrease of oxygen delivery and an increase in SCD-related adverse events, including VOCs.[17]

68. 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]

69. 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.

70. In 2022, more than two years before Defendant Pfizer withdrew Oxbryta from the market

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[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.

[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.*

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.[22]

71. 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.

72. 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]

73. 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

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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).

and fatal events which require further assessment."[25]

74. 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.[26]

75. 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

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

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

registry studies.[27]

76. 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 patients receiving voxelotor.

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

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]

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[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).

[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.

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]

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

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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).

[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).

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.

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

[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).

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 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:

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[36] *Id.*

[37] *Id.*

[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).

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 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

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[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

[40] *Id.*

[41] *Id.*

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 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**

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[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.

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

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 Plaintiff Maurice Frazier 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.

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,

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[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).

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

104. Plaintiff Maurice Frazier 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 Plaintiff Maurice Frazier, thereby placing Oxbryta into the stream of commerce. 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.

106. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, and/or distributed the Oxbryta used by Plaintiff Maurice Frazier, as described herein.

107. 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 Maurice Frazier.

108. 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 Maurice Frazier, 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.

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 Plaintiff's prescribing physicians, Plaintiff, 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. Plaintiff Maurice Frazier used and was exposed to Oxbryta without knowledge of Oxbryta's dangerous characteristics.

115. At all times relevant to this litigation, Plaintiff Maurice Frazier 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. Plaintiff Maurice Frazier 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 Plaintiff Maurice Frazier.

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

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

122. Defendants' conduct, as described herein, was reckless. Defendants risked the lives of consumers and users of Oxbryta, including Plaintiff Maurice Frazier, 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, Plaintiff Maurice Frazier 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 Plaintiff Maurice Frazier has suffered great mental anguish and other personal injury and damages.

125. As a proximate result of the Defendants placing their Oxbryta, a defective product, into the stream of commerce, as alleged herein, Plaintiff Maurice Frazier sustained loss of income and/or loss

of earning capacity.

126. WHEREFORE, Plaintiff Maurice Frazier respectfully requests this Court to enter judgment in Plaintiff Maurice Frazier'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 Maurice Frazier incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

128. Plaintiff Maurice Frazier 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 Plaintiff Maurice Frazier, 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 Plaintiff Maurice Frazier, 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 Plaintiff Maurice Frazier

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. 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 Maurice Frazier.

134. 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 Maurice Frazier.

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

136. 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.

137. 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 Maurice Frazier, without substantial change in its condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

138. Plaintiff Maurice Frazier was exposed to Oxbryta without knowledge of its dangerous

characteristics.

139. At all relevant times, Plaintiff Maurice Frazier 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.

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

141. 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.

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

143. 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.

144. Defendants are liable to Plaintiff Maurice Frazier 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.

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

146. The dangers of Oxbryta were not disclosed by Defendants to Plaintiff Maurice Frazier's physicians and were not otherwise known by the medical community when Plaintiff Maurice Frazier's prescribing physicians prescribed Oxbryta for use by Plaintiff Maurice Frazier. Had Plaintiff Maurice Frazier'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 Maurice Frazier. Had Plaintiff Maurice Frazier been informed by Defendants or by his prescribing physicians about the risks of Oxbryta, Plaintiff Maurice Frazier 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 Maurice Frazier was injured and has sustained pecuniary loss resulting and general damages in a sum exceeding the jurisdictional minimum of this Court.

147. 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 Maurice Frazier suffered great mental anguish and other personal injuries and damages.

148. As a proximate result of Defendants placing Oxbryta, a defective product, into the stream of commerce, as alleged herein, Plaintiff Maurice Frazier sustained loss of income and/or loss of earning capacity.

149. WHEREFORE, Plaintiff Maurice Frazier respectfully requests this Court to enter judgment in Plaintiff Maurice Frazier'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 Maurice Frazier 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 Plaintiff Maurice Frazier. 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 Plaintiff Maurice Frazier's injuries, and thus, create a dangerous and unreasonable risk of injury to the users of these products, including Plaintiff Maurice Frazier.

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 Plaintiff Maurice Frazier, users/consumers, and the general

public that use of Oxbryta presented severe risks of VOCs and other grave illnesses;

h. Failing to warn Plaintiff Maurice Frazier, 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 Maurice Frazier 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 Plaintiff Maurice Frazier would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Oxbryta.

162. Plaintiff Maurice Frazier 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 Plaintiff Maurice Frazier's injuries.

164. Defendants' conduct, as described above, was reckless. Defendants regularly risked the

lives of consumers and users of their products, including Plaintiff Maurice Frazier, 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 Maurice Frazier. 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, Plaintiff Maurice Frazier 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 Plaintiff Maurice Frazier 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, Plaintiff Maurice Frazier sustained a loss of income, and loss of earning capacity.

168. WHEREFORE, Plaintiff Maurice Frazier respectfully requests this Court to enter judgment in Plaintiff Maurice Frazier'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 Maurice Frazier 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 Plaintiff Maurice Frazier.

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

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 Plaintiff Maurice Frazier, Plaintiff Maurice Frazier'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, Plaintiff Maurice Frazier and Plaintiff Maurice Frazier's prescribing physicians were induced to, and did, prescribe and use Oxbryta, thereby causing Plaintiff Maurice Frazier to suffer severe personal injuries.

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

187. As a direct and proximate result of reliance upon Defendants' negligent misrepresentations and omissions, Plaintiff Maurice Frazier 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 Plaintiff Maurice Frazier's rights beyond all standards of decency, entitling Plaintiff Maurice Frazier to recover punitive damages.

189. WHEREFORE, Plaintiff Maurice Frazier respectfully requests this Court to enter judgment in Plaintiff Maurice Frazier'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 Maurice Frazier 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 Plaintiff Maurice Frazier, 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 Plaintiff Maurice Frazier.

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

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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/

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, 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 Maurice Frazier, 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. Plaintiff Maurice Frazier 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 Maurice Frazier reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of Oxbryta. Plaintiff Maurice Frazier 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 Plaintiff Maurice Frazier could not have reasonably discovered that the risks expressly included in Oxbryta warnings and labels were inadequate and inaccurate.

203. Plaintiff Maurice Frazier had no knowledge of the falsity or incompleteness of Defendants' statements and representations concerning Oxbryta.

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

206. As a direct and proximate result of Defendants' breach of express warranties, Plaintiff Maurice Frazier 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 Plaintiff Maurice Frazier suffered great mental anguish and other personal injury and damages.

208. As a proximate result of Defendants' breach of express warranties, as alleged herein,

Plaintiff Maurice Frazier sustained a loss of income and/or loss of earning capacity.

209. WHEREFORE, Plaintiff Maurice Frazier respectfully requests this Court to enter judgment in Plaintiff Maurice Frazier'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 VI:

BREACH OF IMPLIED WARRANTIES

210. Plaintiff Maurice Frazier 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 Plaintiff Maurice Frazier, thereby placing Oxbryta into the stream of commerce.

212. Before Plaintiff Maurice Frazier used Oxbryta, Defendants impliedly warranted to their consumers, including Plaintiff Maurice Frazier, 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 Plaintiff Maurice Frazier's injuries.

214. Plaintiff Maurice Frazier 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 Plaintiff Maurice Frazier, 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 Plaintiff Maurice Frazier, would use Oxbryta as marketed by Defendants, which is to say that Plaintiff Maurice Frazier was a foreseeable user of Oxbryta.

217. Defendants intended that Oxbryta be used in the manner in which Plaintiff Maurice Frazier, 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, Plaintiff Maurice Frazier used Oxbryta as instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by Defendants.

219. Plaintiff Maurice Frazier could not have reasonably discovered or known of the risks of serious injury associated with Oxbryta.

220. Defendants breached their implied warranty to Plaintiff Maurice Frazier 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, Plaintiff Maurice Frazier 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 Plaintiff Maurice Frazier suffered great mental anguish and other personal injury and damages.

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

225. WHEREFORE, Plaintiff Maurice Frazier respectfully requests this Court to enter judgment in Plaintiff Maurice Frazier'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 Plaintiff.

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 Plaintiff conferred onto Defendants at their detriment. These benefits were the expected result of Defendants acting in their pecuniary interests at the expense of Plaintiff.

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 Plaintiff'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:

VIOLATIONS OF THE NEW JERSEY CONSUMER FRAUD ACT, 56:8-1, *et seq.*

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

235. Defendants are engaged in trade and commerce in the State of New Jersey.

236. Defendants have violated the New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-2, by engaging in unfair, fraudulent, and unconscionable conduct, including but not limited to the following:

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 N.J.S.A. § 56:8-2 because it (1) offends public policy; (2) is immoral, unethical, oppressive, or unscrupulous; and (3) causes substantial injury to consumers, including Plaintiff Maurice Frazier.

240. Defendants' conduct offends the public policy of New Jersey 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 Plaintiff Maurice Frazier.

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 Plaintiff Maurice Frazier, would be expected to rely upon in making purchasing decisions.

243. Defendants' deceptive statements and omissions had the capacity to deceive consumers, including Plaintiff Maurice Frazier, by inducing them to purchase and ingest Oxbryta. Defendants intended for consumers, including Plaintiff Maurice Frazier, 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. Plaintiff Maurice Frazier has been injured as a direct and proximate result of Defendants' deceptive conduct in violation of N.J.S.A. § 56:8-2. Plaintiff Maurice Frazier 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 Plaintiff Maurice Frazier.

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

248. As a proximate result of Defendants' violation of N.J.S.A. § 56:8-2, as alleged herein, Plaintiff Maurice Frazier sustained physical injury and financial loss.

249. WHEREFORE, Plaintiff Maurice Frazier respectfully requests this Court to enter judgment in Plaintiff Maurice Frazier's favor and against Defendants for compensatory and punitive damages, including treble damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

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.

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Respectfully submitted,

Dated: May 8, 2025

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

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

DEMAND FOR JURY TRIAL

Plaintiff Maurice Frazier demands a jury trial in this matter.

Dated: May 8, 2025

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

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

CIVIL COVER SHEET - for people without lawyers only

See Civil Local Rule 3-2 (amended April 28, 2025), which requires the filing of a civil cover sheet only by those unrepresented by counsel.

I. PLAINTIFF(S)

Maurice Fraizer

County of Residence of First Listed Plaintiff: Union County, New Jersey
Leave blank in cases where United States is plaintiff.

Attorney or Pro Se Litigant Information *(Firm Name, Address, and Telephone Number)*

Aylstock, Witkin, Kreis & Overholtz, PLLC
17 East Main Street, Suite 200
Pensacola, FL 32502

DEFENDANT(S)

Global Blood Therapeutics, Inc. and Pfizer, Inc.

County of Residence of First Listed Defendant:
Use ONLY in cases where United States is plaintiff.

Defendant's Attorney's Name and Contact Information *(if known)*

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

- ☐ U.S. Government Plaintiff
- ☐ Federal Question *(U.S. Government Not a Party)*
- ☐ U.S. Government Defendant
- ☒ Diversity

III. CAUSE OF ACTION

Cite the U.S. Statute under which you are filing: *(Use jurisdictional statutes only for diversity)*
28 U.S.C.A. § 1331

Brief description of case: Defendants knew or should have known for decades that Oxbryta, when administered and prescribed as intended, can cause substantially contribute to VOCs and even death.

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

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury -Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury – Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities–Employment
- ☐ 446 Amer. w/Disabilities–Other
- ☐ 448 Education

PRISONER PETITIONS

HABEAS CORPUS
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

OTHER
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee–Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC § 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC § 158
- ☐ 423 Withdrawal 28 USC § 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent–Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS–Third Party 26 U.S.C. § 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC § 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced & Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

- ☒ Original Proceeding
- ☐ Removed from State Court
- ☐ Remanded from Appellate Court
- ☐ Reinstated or Reopened
- ☐ Transferred from Another District
- ☐ Multidistrict Litigation–Transfer
- ☐ Multidistrict Litigation–Direct File

VI. FOR DIVERSITY CASES ONLY: CITIZENSHIP OF PRINCIPAL PARTIES

(Place an "X" in One Box for Plaintiff and One Box for Defendant)

Plaintiff	Defendant	
☐	☐	Citizen of California
☒	☐	Citizen of Another State
☐	☐	Citizen or Subject of a Foreign Country
☐	☒	Incorporated or Principal Place of Business In California
☐	☐	Incorporated and Principal Place of Business In Another State
☐	☐	Foreign Nation

VII. REQUESTED IN COMPLAINT

- ☑ Check if the complaint contains a **jury demand.**
- ☐ Check if the complaint contains a **monetary demand**. Amount:
- ☐ Check if the complaint seeks **class action** status under Fed. R. Civ. P. 23.
- ☐ Check if the complaint seeks a **nationwide injunction** or Administrative Procedure Act vacatur.

VIII. RELATED CASE(S) OR MDL CASE

Provide case name(s), number(s), and presiding judge(s).

Allen et al. vs. Global Blood Therapeutics, Inc. et al. | 3:24-cv-07786-TLT | Judge Trina L. Thompson;
Jolly et al. vs. Global Blood Therapeutics, Inc. et al | 3:24-cv-09345-TLT | Judge Trina L. Thompson

IX. DIVISIONAL ASSIGNMENT pursuant to Civil Local Rule 3-2

(Place an "X" in One Box Only)

- ☒ SAN FRANCISCO/OAKLAND
- ☐ SAN JOSE
- ☐ EUREKA-MCKINLEYVILLE

DATE 05/08/2025 **SIGNATURE OF ATTORNEY OR PRO SE LITIGANT** /s/ Sin-Ting Mary Liu

COMPLETING THE CIVIL COVER SHEET

Complete the form as follows:

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

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

Attorney/Pro Se Litigant Information. Enter the firm name, address, telephone number, and email for attorney of record or pro se litigant. If there are several individuals, list them on an attachment.

II. Jurisdiction. Under Federal Rule of Civil Procedure 8(a), pleadings must establish the basis of jurisdiction. If multiple bases for jurisdiction apply, prioritize them in the order listed:

(1) *United States plaintiff*. Jurisdiction based on 28 U.S.C. §§ 1345 and 1348 for suits filed by the United States, its agencies or officers.

(2) *United States defendant.* Applies when the United States, its agencies, or officers are defendants.

(3) *Federal question*. Select this option when jurisdiction is based on 28 U.S.C. § 1331 for cases involving the U.S. Constitution, its amendments, federal laws, or treaties (but use choices 1 or 2 if the United States is a party).

(4) *Diversity of citizenship.* Select this option when jurisdiction is based on 28 U.S.C. § 1332 for cases between citizens of different states and complete Section VI to specify the parties' citizenship. Note: Federal question jurisdiction takes precedence over diversity jurisdiction.

III. Cause of Action. Enter the statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless jurisdiction is based on diversity. Example: U.S. Civil Statute: 47 U.S.C. § 553. Brief Description: Unauthorized reception of cable service.

IV. Nature of Suit. Check one of the boxes. If the case fits more than one nature of suit, select the most definitive or predominant.

V. Origin. Check one of the boxes:

(1) *Original Proceedings*. Cases originating in the United States district courts.

(2) *Removed from State Court*. Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C. § 1441. When the petition for removal is granted, check this box.

(3) *Remanded from Appellate Court*. Check this box for cases remanded to the district court for further action, using the date of remand as the filing date.

(4) *Reinstated or Reopened*. Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

(5) *Transferred from Another District*. Check this box for cases transferred under Title 28 U.S.C. § 1404(a). Do not use this for within-district transfers or multidistrict litigation (MDL) transfers.

(6) *Multidistrict Litigation Transfer*. Check this box when a multidistrict (MDL) case is transferred into the district under authority of Title 28 U.S.C. § 1407.

(7) *Multidistrict Litigation Direct File.* Check this box when a multidistrict litigation case is filed in the same district as the Master MDL docket.

VI. Residence (citizenship) of Principal Parties. Mark for each principal party *only* if jurisdiction is based on diversity of citizenship.

VII. Requested in Complaint.

(1) *Jury demand.* Check this box if plaintiff's complaint demanded a jury trial.

(2) *Monetary demand*. For cases demanding monetary relief, check this box and enter the actual dollar amount being demanded.

(3) *Class action.* Check this box if plaintiff is filing a class action under Federal Rule of Civil Procedure 23.

(4) *Nationwide injunction.* Check this box if plaintiff is seeking a nationwide injunction or nationwide vacatur pursuant to the Administrative Procedures Act.

VIII. Related Cases. If there are related pending case(s), provide the case name(s) and number(s) and the name(s) of the presiding judge(s). If a short-form MDL complaint is being filed, furnish the MDL case name and number.

IX. Divisional Assignment. Identify the divisional venue according to Civil Local Rule 3-2: "the county in which a substantial part of the events or omissions which give rise to the claim occurred or in which a substantial part of the property that is the subject of the action is situated." Note that case assignment is made without regard for division in the following case types: Property Rights (Patent, Trademark and Copyright), Prisoner Petitions, Securities Class Actions, Anti-Trust, Bankruptcy, Social Security, and Tax.